Health Evidence Review Commission

October 6, 2016

1:30 PM - 4:30 PM

Clackamas Community College
Wilsonville Training Center, Room 111-112
29373 SW Town Center Loop E, Wilsonville, Oregon, 97070

Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION

Wilsonville Training Center, Rooms 111-112

October 6, 2016

1:30-4:30 pm

(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to Order	Kevin Olson	
2	1:35 PM	Approval of Minutes (August 11, 2016)	Kevin Olson	X
3	1:40 PM	Director's Report	Darren Coffman	
4	1.45 PM	Value-based Benefits Subcommittee Report • Includes biennial review topic of obesity-related treatments, including coverage guidance and potential Prioritized List changes involving metabolic and bariatric surgery	Ariel Smits Cat Livingston	X
5	2:45 PM	Process Efficiencies • Coverage guidance monitoring process	Jason Gingerich	X
6	3:00 PM	Skin Substitutes for Chronic Skin Ulcers • Next steps	Adam Obley Cat Livingston	X
7	3:15 PM	Non-Invasive Liver Fibrosis Testing in Patients with Chronic Hepatitis C • HTAS Recommended Coverage Guidance • VbBS Recommended Prioritized List Changes	Adam Obley Cat Livingston	X
8	4:20 PM	Next Steps • Schedule next meeting – November 10, 2016 Wilsonville Training Center, Rooms 111-112	Kevin Olson	
9	4:30 PM	Adjournment	Kevin Olson	

Note: Public comment will be taken on each topic per HERC policy at the time at which that topic is discussed.

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
August 11, 2016

Members Present: Som Saha, MD, MPH, Chair; Beth Westbrook, PsyD; Wiley Chan, MD; Mark Gibson; Leda Garside, RN, MBA (arrived at 1:45 pm); Susan Williams, MD; Kim Tippens, ND, MPH; Kevin Olson, MD; Derrick Sorweide, DO; Chris Labhart; Holly Jo Hodges, MD; Gary Allen, DMD.

Members Absent: Irene Croswell, RPh

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Denise Taray, RN; Jason Gingerich.

Also Attending: Jesse Little (Oregon Health Authority); Valerie King, MD, MPH, Adam Obley, MD, MPH, Craig Mosbaek (OHSU Center for Evidence Based Policy); Amara McCarthy; Amanda Kerbe; Duncan Neilson (Legacy Health).

Call to Order

Som Saha, Chair of the Health Evidence Review Commission (HERC), called the meeting to order. Role was called.

Minutes Approval
Meeting materials, pages 4-11

MOTION: To approve the minutes of the May 19, 2016 meeting as presented. CARRIES 11-0. *(Absent: Garside)*

Director's Report

Membership Update
Darren Coffman said Dr. Jim MacKay, vice-chair of the Health Technology Assessment Subcommittee (HTAS) recently retired. Also, in HTAS news, to fill the role of retired oncologist Gerald Ahmann, staff recruited and vetted a physician willing to serve on that subcommittee. Dr. Vinay Prasad is an oncologist and hematologist at OHSU specializing in lymphoma. He is nationally known for his research that seeks to improve the medical decisions doctors make, and improve the quality of evidence that doctors use to treat patients. Dr. Prasad is the author of "Ending Medical Reversal: Improving Outcomes, Saving Lives." Olson, also an oncologist, added his support for Dr. Prasad's appointment. Prasad regularly publishes papers about topics this body debates and is a perfect fit for this work.

Darren said there a dentist is interested in serving on the Oral Health Advisory Panel (OHAP). Dr. Len Barrozini, who is the Multnomah County dental director and would bring a nice perspective to the already-seated group.

MOTION: To approve the appointments of Drs. Prasad and Barrozini to HTAS and OHAP, respectively. Carries 11-0. *(Absent: Garside)*

Other Business
Dr. Livingston explained, as background, there is a statewide opioid taskforce, comprised of a diverse group of members (including medical, pharmacy and nursing boards, associations, clinics, and Federally Qualified Health Centers). Their guidelines are expected by the end of this year.

This year, guideline note 60 was approved, which allowed for an array of treatments for back pain (acupuncture, chiropractic, yoga) not previously covered. The guideline also limited use of surgical interventions and eliminated opioid use for chronic back pain.

It appears the Commission may need to revisit the guideline to see how it applies to other types of chronic pain. Staff considered forming a workgroup to look at the opioid guidelines but decided to wait for the taskforce's recommendations and until a sufficient time has elapsed (6-12 months) for stakeholders to gain experience with the new guideline so that the appropriate issues can be discussed.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials, pages 58-567

Ariel Smits reported the VbBS met earlier in the day, 8/11/2016. She summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (effective 10/1/16):

- Make various straightforward coding changes.
- Place the 2017 ICD-10-CM codes on various lines on the Prioritized List or in alternate implementation files.
- Add treatment codes and a new guideline to the covered laryngeal stenosis line to allow treatment of vocal cord dysfunction in children with dysphonia or dysphagia.
- Add placement code for implantable cardiac loop recorders to the diagnostic list with a new diagnostic guideline note.
- Add treatment codes for electronic tumor treatment fields to a covered cancer line with a new guideline limiting use to initial treatment of glioblastoma that meets certain criteria.
    - Commissioners concluded that it was discriminatory to disabled persons to include performance measure requirements such as the KPS or ECOG score over a certain level. There was concern that this provision might be in conflict with the ADA. Commissioners struck that portion of the proposed guideline (represented as red strike through wording):

      GUIDELINE NOTE 155 ELECTRIC TUMOR TREATMENT FIELDS FOR GLIOBLASTOMA
      Line 299

      Electric tumor treatment fields (codes HCPCS A4555 and E0766) are included on this line only when:

1) *Used for the initial treatment of supratentorial glioblastoma*
2) *Used in combination with temozolomide*
3) ~~*The patient has Karnofsky Performance Status score of 70 or higher or Eastern Cooperative Oncology Group (ECOG) performance status 0-1*~~

Electric tumor treatment fields are not included on this line for recurrent glioblastoma or any other indication.

RECOMMENDED GUIDELINE CHANGES (effective 10/1/16):

- Edit the preventive services guideline to remove dates for documents and add in links to the underlying government documents.
- Edit the hyperbaric oxygen guideline to correct two ICD-10-CM codes.
    - After a brief discussion about the coverage of hyperbaric oxygen therapy for radiation cystitis and radiation proctitis the Commissioners added codes for radiation cystitis (ICD-10-CM N30.4) and radiation proctitis (ICD-10-CM K62.7) on line 337 CONDITIONS REQUIRING HYPERBARIC OXYGEN THERAPY
- Delete the diagnostic guideline regarding TB testing.
- Add a new guideline specifying coverage of acute mediastinitis, but not chronic mediastinitis.
- Add a new guideline requiring that the underlying diagnosis be covered to allow for an encounter for desensitization for allergens.
- Edit the acupuncture guideline to clarify that the number of visits covered are per year or per pregnancy.
- Edit the back conditions medical guideline and opioid guideline to clarify the intent of coverage.

MOTION: To accept the VbBS recommendations on *Prioritized List changes* not related to coverage guidances, as amended. See the VbBS minutes of 8/11/2016 for a full description. Carries: 12-0.

Coverage Guidance Evidence Submission Policy Clarification
Meeting materials, pages 569-570

Coffman began by recalling the discussion started at the May 19, 2016 meeting (pages 5-6). Recently, after a coverage guidance was created and vetted though the established polices and was being presented at a meeting, new evidence was submitted. The decision was to stop discussion until it was determined if the new evidence would change the recommendation. In this case, it turned out that one of the documents didn't meet inclusion criteria and the other had been reviewed and did not meet inclusion criteria. This step significantly delayed the approval process. Staff have proposed a few changes to the previously reviewed language that would allow staff to determine if the evidence is a "game-changer" and allow staff to restrict consideration evidence submitted outside of 30-day public comment period.

Dr. Perez, a guest, testified that he was a previous late-submitter and explained there is some confusion about what was meant by "reviewed." He felt his submitted evidence, though late, would be added to the evidence directly addressed in the coverage guidance public comment disposition. Coffman clarified staff followed the policy for comments received outside the official public comment period. Though they were not included in the coverage guidance public comment disposition because they were late, they were sent to Commissioners to be reviewed seven days prior to the meeting as specified in HERC's

policy. If the proposed policy language is accepted, staff would have discretion to decide if the submitted evidence meets the threshold to stop the current process.

Gingerich and Livingston added that staff have implemented a new communications system to inform stakeholders about topics of interest.

There was some discussion centered on agreement and minor text editing of the policy document; please see Appendix A for the final language.

MOTION: To approve the Evidence Submission Policy as amended. Carries 12-0.

Coverage Guidance Topic: **Tobacco Cessation In Pregnancy**
Meeting materials, pages 571-651

Dr. Obley began the presentation. The rate of smoking at any time during pregnancy is 8.4%; in Oregon, the rate is 10.3%, slightly higher than the national average. Of women who smoke in the first or second trimester, only 1 in 5 will successfully quit smoking by the third trimester. Smoking in pregnancy increases risk of miscarriage, stillbirth, preterm birth, growth restriction, placental abnormalities and abruption, and premature rupture of membranes. Exposure to secondhand smoke can also impact low birth weight and can increase the risk of sudden infant death syndrome.

The scope of this coverage guidance looked at:

- Population: Women during pregnancy and the postpartum period
- Intervention: Screening for tobacco use, pharmacotherapy, behavioral interventions (telephonic, in person, individual, group), Internet based interventions, and multisector interventions such as policy, systems, and environmental change
- Comparator: No care, usual care, other studied interventions
- Outcomes: pregnancy complications (critical), low birth weight (critical), infant death (critical), abstinence from tobacco during pregnancy (important), long-term abstinence from tobacco (important)

Evidence sources included Cochrane and AHRQ systematic reviews.

Dr. Charles Bentz, a Professor at the Pacific University College of Health Professions and a private practice physician at Fanno Creek Clinic in Portland and **Dr. Duncan Neilson**, Clinical Vice President, Legacy Health System of Portland, served as experts for the subcommittee's review of this topic. Dr. Neilson attended the meeting to address questions and provide additional assistance, if required.

Livingstone read through the GRADE-Informed Framework (page 574):

- Coverage question: Should pharmacotherapy or electronic nicotine delivery systems be recommended for coverage for tobacco cessation in pregnancy?
- Coverage question: Should behavioral interventions be recommended for coverage for tobacco cessation in pregnancy?
- Coverage question: Should ultrasound with high feedback be recommended for coverage for tobacco cessation in pregnancy?
- Coverage question: Should financial incentives be recommended for coverage for tobacco cessation in pregnancy?

- Coverage question: Should partner support be recommended for coverage for tobacco cessation in pregnancy?
- Coverage question: Should clinical interventions to reduce secondhand smoke exposure be recommended for coverage for tobacco cessation in pregnancy?

Saha commented on the wording of some of the questions such as *partner support* and *high feedback*. He said we seemed to be using terms from studies and he would rather see more common and understandable terms used. Further, he took issue with the statement about FDA-approved pharmacotherapy for smoking cessation (blue box, last paragraph). The way it reads, the language appears to imply that pregnant women would be treated differently due to their condition and he suggested that their coverage be the same as for others in terms of pharmacotherapy for tobacco cessation .

Neilson said that nicotine replacement is routinely uses for pregnant patients. He also said that studies with pregnant women are flawed and difficult to conduct, making study results difficult to interpret.

After some discussion, Commissioners edited the contested paragraph in the draft proposal as follows:

> *Federal law requires coverage of tobacco cessation services, including FDA-approved pharmacotherapy, for pregnant women. There is insufficient evidence of effectiveness of pharmacotherapy on critical pregnancy-related outcomes.* ~~*Therefore, there is no coverage recommendation on pharmacotherapy for smoking cessation in pregnant women*~~ *Coverage should be based on evidence for the use of pharmacological smoking cessation therapies in adults and adolescents with attention to their safety profiles in pregnant women.*

Further discussion led to deleting all instances of "partner support."

Staff were advised to not make assumptions about a pregnant person's gender. Staff will make the language consistent throughout the coverage document, using "during pregnancy" where appropriate. Direct quotes from literature will be kept intact.

MOTION: To approve the proposed coverage guidance for Tobacco Cessation In Pregnancy as amended. Carries 12-0.

MOTION: To approve the proposed coding changes edits and edits to Guideline Note 4 TOBACCO DEPENDENCE, INCLUDING PREGNANT WOMEN and Guideline Note 99 ROUTINE PRENATAL ULTRASOUND for the Prioritized List as amended. Carries 12-0.

Approved Coverage Guidance

HERC Coverage Guidance

For women who use tobacco during pregnancy, the following interventions to aid in tobacco cessation are recommended for coverage:

- Behavioral interventions (*strong recommendation*)
- Financial incentives (incentives contingent upon laboratory tests confirming tobacco abstinence are the most effective) (*weak recommendation)*
- Prenatal ultrasound with feedback around smoking impacts on the fetus *(weak recommendation)*

The following interventions are not recommended for coverage:

- Electronic nicotine delivery systems *(strong recommendation)*
- Counseling-based interventions to reduce secondhand smoke exposure (*weak recommendation)*

Federal law requires coverage of tobacco cessation services, including FDA-approved pharmacotherapy, for pregnant women. There is insufficient evidence of effectiveness of pharmacotherapy on critical pregnancy-related outcomes. Coverage should be based on evidence for the use of pharmacological smoking cessation therapies in adults and adolescents with attention to their safety profiles in pregnant women.

Multisector Interventions

To reduce the use of tobacco during pregnancy and improve associated outcomes, the evidence supports the following interventions:

- Financial incentives (incentives contingent upon laboratory tests confirming tobacco abstinence are the most effective) (*weak recommendation)*
- Smoke-free legislation
- Tobacco excise taxes

No or insufficient evidence is available for the following:

- Internet or text messaging based interventions
- Mass media campaigns specific to pregnant women

Changes to the Prioritized List of Health Services

Modify Guideline Note 4 as follows:

GUIDELINE NOTE 4, TOBACCO DEPENDENCE, INCLUDING PREGNANT WOMEN

Lines 1, 5

Pharmacotherapy and behavioral counseling are included on ~~this~~ line 5, alone or in combination, for at least 2 quit attempts per year. A minimum of four counseling sessions of at least 10 minutes each (group or individual, telephonic or in person) are included for each quit attempt. More intensive interventions and group therapy are likely to be the most effective behavioral interventions. For pregnant women, additional intensive behavioral counseling is strongly encouraged and not subject to limits.

Inclusion on this line follows the minimum standard criteria as defined in the Oregon Public Health Division "Standard Tobacco Cessation Coverage" (based on the Patient Protection and Affordable Care Act), available here: https://public.health.oregon.gov/PreventionWellness/TobaccoPrevention/Pages/pubs.aspx. The USPSTF has also made "A" recommendations for screening, counseling, and treatment of pregnant and nonpregnant adults, included in Guideline Note 106.

The development of the pregnancy-related portions of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-reduce-tobacco-use-pregnancy.aspx

Modify Guideline Note 99 as follows:

GUIDELINE NOTE 99, ROUTINE PRENATAL ULTRASOUND

Lines 1,39,41,67

Routine ultrasound for the average risk pregnant woman is included on these lines for:

A) One ultrasound in the first trimester for the purpose of identifying fetal aneuploidy or anomaly (between 11 and 13 weeks of gestation) and /or dating confirmation. In some instances, if a patient's LMP is truly unknown, a dating ultrasound may be indicated prior to an aneuploidy screen
B) One ultrasound for the purpose of anatomy screening after 18 weeks gestation. For women using tobacco during pregnancy, additional counseling around smoking impacts on the fetus is included during this ultrasound.

Only one type of routine prenatal ultrasound should be covered in a single day (i.e., transvaginal or abdominal).

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-routine-ultrasound-pregnancy.aspx

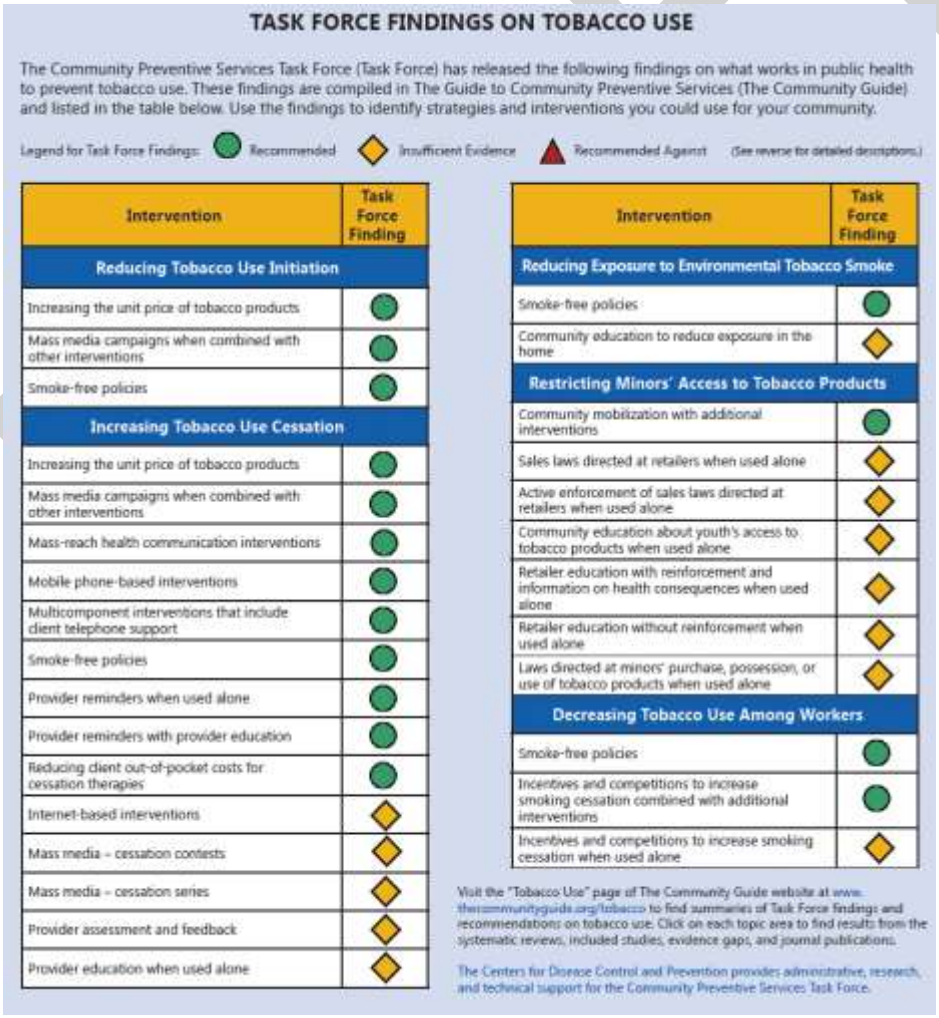
Changes to multisector interventions

MULTISECTOR INTERVENTIONS: TOBACCO PREVENTION AND CESSATION, INCLUDING PREGNANT WOMEN

Benefit coverage for smoking cessation on Line 5 and in Guideline Note 4 TOBACCO DEPENDENCE is intended to be offered with minimal barriers, in order to encourage utilization. To further prevent tobacco use and help people quit, additional evidence-based policy and programmatic interventions from a population perspective are available here:

- Oregon Public Health Division's Health Promotion and Chronic Disease Prevention Section: Evidence-Based Strategies for Reducing Tobacco Use A Guide for CCOs https://public.health.oregon.gov/PreventionWellness/TobaccoPrevention/Documents/evidence-based_strategies_reduce_tob_use_guide_cco.pdf
- Community Preventive Services Task Force (supported by the CDC) - What Works: Tobacco Use http://www.thecommunityguide.org/about/What-Works-Tobacco-factsheet-and-insert.pdf

The Community Preventive Services Task Force identified the following evidence-based strategies:



TASK FORCE FINDINGS ON TOBACCO USE

The Community Preventive Services Task Force (Task Force) has released the following findings on what works in public health to prevent tobacco use. These findings are compiled in The Guide to Community Preventive Services (The Community Guide) and listed in the table below. Use the findings to identify strategies and interventions you could use for your community.

Legend for Task Force Findings: Recommended; Insufficient Evidence; Recommended Against (See reverse for detailed descriptions.)

Intervention	Task Force Finding
Reducing Tobacco Use Initiation	
Increasing the unit price of tobacco products	Recommended
Mass media campaigns when combined with other interventions	Recommended
Smoke-free policies	Recommended
Increasing Tobacco Use Cessation	
Increasing the unit price of tobacco products	Recommended
Mass media campaigns when combined with other interventions	Recommended
Mass-reach health communication interventions	Recommended
Mobile phone-based interventions	Recommended
Multicomponent interventions that include client telephone support	Recommended
Smoke-free policies	Recommended
Provider reminders when used alone	Recommended
Provider reminders with provider education	Recommended
Reducing client out-of-pocket costs for cessation therapies	Recommended
Internet-based interventions	Insufficient Evidence
Mass media – cessation contests	Insufficient Evidence
Mass media – cessation series	Insufficient Evidence
Provider assessment and feedback	Insufficient Evidence
Provider education when used alone	Insufficient Evidence

Intervention	Task Force Finding
Reducing Exposure to Environmental Tobacco Smoke	
Smoke-free policies	Recommended
Community education to reduce exposure in the home	Insufficient Evidence
Restricting Minors' Access to Tobacco Products	
Community mobilization with additional interventions	Recommended
Sales laws directed at retailers when used alone	Insufficient Evidence
Active enforcement of sales laws directed at retailers when used alone	Insufficient Evidence
Community education about youth's access to tobacco products when used alone	Insufficient Evidence
Retailer education with reinforcement and information on health consequences when used alone	Insufficient Evidence
Retailer education without reinforcement when used alone	Insufficient Evidence
Laws directed at minors' purchase, possession, or use of tobacco products when used alone	Insufficient Evidence
Decreasing Tobacco Use Among Workers	
Smoke-free policies	Recommended
Incentives and competitions to increase smoking cessation combined with additional interventions	Recommended
Incentives and competitions to increase smoking cessation when used alone	Insufficient Evidence

Visit the "Tobacco Use" page of The Community Guide website at www.thecommunityguide.org/tobacco to find summaries of Task Force findings and recommendations on tobacco use. Click on each topic area to find results from the systematic reviews, included studies, evidence gaps, and journal publications.

The Centers for Disease Control and Prevention provides administrative, research, and technical support for the Community Preventive Services Task Force.

To reduce the use of tobacco during pregnancy and improve associated outcomes, the evidence supports the following interventions:

- Financial incentives (contingent upon laboratory tests confirming tobacco abstinence are the most effective)
- Smoke-free legislation
- Tobacco excise taxes

Coverage Guidance Topic: Skin Substitutes for Chronic Skin Ulcers
Meeting materials, pages 652-760

Saha said VbBS did not complete their discussion on this topic so it is tabled.

Public Comment

Amanda Kerbe, a former fire fighter, with no conflicts of interest offered testimony about Guideline Note 60. She said she suffers from stage 4 complex regional pain syndrome and has tried alternant therapies such as acupuncture, massage, and yoga. The only thing that helps her function and thrive are opioids, which are prescribed by her medical team. She founded "Patients Not Addicts", which advocates for chronic pain patient's right to opioids. She stated, "Pain is hard, but even harder having doctors look at us as addicts." She said doctors should fight for those who are unable to fight for themselves, including patients who, for medical reasons, need opioids to function. Amanda shared about the stigma she experiences in her daily life, including doctors and professionals in positions of power. In a recent custody battle, the state appointed custody evaluator said that chronic pain is just an excuse for an addict to get drugs. Amanda said in the absence of correctly prescribed medications, people who live in persistent pain have three options: alcohol, street drugs, and suicide

She urged the commission to find a way to restrict inappropriate use without restricting appropriate use.

Amanda shared her frustration that it is difficult for citizens to find out about meetings where topics like this are discussed. Smits and Williams said that HERC's policy is one part of the discussion; there is a multi-disciplinary taskforce who are deciding on statewide policies. They urged her to connect with that group and offered a link to the website.

Similarly, Amara McCarthy shared her struggle with chronic pain, which stemmed from a motor vehicle accident in 2001. Among other things, she stated that an addict takes drugs to *run* from life; a persistent pain sufferer takes medication to *engage* in life

Saha clarified that Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE applies to spine pain treatment so her pain condition, as well as may others such as sickle cell anemia, are unaffected. He thanked the public commenters and ended by saying the he knows the commission is avoiding collateral damage with its actions.

Items for Next Meeting

Staff will modify wording in the Tobacco Cessation in Pregnancy coverage guidance so that no assumptions are made about a pregnant person's gender.

Adjournment

Meeting adjourned at 4:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, October 6, 2016 at Clackamas Community

Appendix A

Coverage Guidance Policy on
Consideration of Evidence Discovered After Formal Public Comment Period

For coverage guidances, the Health Evidence Review Commission (HERC) generally only includes studies during its initial Coverage Guidance development (before the relevant subcommittee reviews the first draft) or when these studies are submitted during the formal written comment period. These studies are reviewed based on how well they address the pre-specified scope of the Coverage Guidance and their methodological quality.

In exceptional circumstances, however, the HERC recognizes the need to review studies submitted by stakeholders or discovered by staff outside the formal comment process. To minimize biases which may be introduced by consideration of evidence at other times in the process, HERC has approved this policy, outlining the circumstances which may justify consideration of new evidence when it is discovered outside the formal routine guidance process and public comment period.

Decisions about whether to delay the process for a new study will be made by staff, based on where a coverage guidance is in the development process and the importance of the evidence in question.

The new study or studies need to be likely to alter a recommendation in a way that would significantly impact health outcomes or cost for the population in question. Such studies are also typically:

- Randomized controlled trials or systematic reviews of randomized trials demonstrating comparative effectiveness or harm, or large registry or population-based studies demonstrating harm, AND are of
- Moderate or high quality according to HERC criteria

If staff learns of a study after the formal comment period ends, staff will make a determination of the importance of the study in question based on the criteria above. Staff would delay the process as needed in order to incorporate the study and update the existing literature search to assure that there are not any additional studies which may be appropriate to include. For studies that do not meet these criteria, they could be resubmitted at the next scheduled two-year topic rescan. New coverage guidance topics can also be nominated for consideration annually.

In the case of new evidence (that meets the criteria above) being identified after a Coverage Guidance has already been approved by the originating subcommittee, it would be referred back to that subcommittee before coming to HERC and VbBS. Less significant changes may be incorporated by the Commission during the final approval process.

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
September 1, 2016
1:30-4:00pm

Members Present: Wiley Chan, MD, Chair; Beth Westbrook, PsyD; Alison Little, MD, MPH; Kim Tippens, ND, MSAOM, MPH; Eric Stecker, MD, MPH, Vice-Chair (by phone).

Members Absent: George Waldmann, MD

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Jason Gingerich; Daphne Peck.

Also Attending: Moira Ray, MD, Val King MD, MPH, Craig Mosbaek, MPH and Rachel Hackett, MPH (OHSU Center for Evidence-based Policy); Maria Rodriguez (OHSU); Jessie Little (OHA); Joanne Rogovoy (March of Dines); Steve Sebers (The CHP Group); David Bove (Pain Consultants of Oregon).

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1. CALL TO ORDER

Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 1:30 pm.

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2. MINUTES REVIEW

No changes were made to the draft 6/2/2016 minutes.
Minutes approved 4-0 (Stecker not present).

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4. Review of public comment on Timing of Long-Acting Reversible Contraceptive (LARC) Placement

Ray reviewed the public comments presented in the meeting materials as well as some errors that were corrected in the draft coverage guidance.

There were three major concerns expressed in public comment:

- One was coverage for women covered under the Oregon Health Plan's Citizen Alien Waved Emergency Medical (CAWEM) program. Currently, contraceptive care is not covered under the CAWEM plan.

- Others expressed the need for coverage for removal or other aftercare for women who have a LARC placed. Because these devices are long-lasting, women may require aftercare even after losing the health plan coverage that paid for their LARC device.
- Some felt that this could be viewed as a form of coercion to use contraception if they can't get appropriate aftercare, especially LARC removal when fertility is desired.

These issues are not directly within HERC's purview, since its work addresses people who are covered on a health plan, not uninsured people. Staff has, however, relayed these concerns to others in the Oregon Health Authority who may be able to address them. Ray reviewed staff's recommended changes to the draft coverage guidance, which acknowledges these issues.

Livingston asked Rodriguez, who serves as ad hoc expert for this topic, if she had any additional comment. She said work is ongoing to address implementation issues. In addition she is working with others on some standardized language for use in patient counseling to address concerns about about coercion. Livington reported that Medicaid fee-for-service is moving forward with the development of a plan to address immediate LARC placement, but that some Coordinated Care Organizations may have more work to do.

A motion was made to approve the draft coverage guidance, including the changes presented in the meeting materials, then forward the draft to HERC for review. **Motion approved 4-0 (Stecker not present).**

DRAFT COVERAGE GUIDANCE

Immediate postpartum and postabortion placement of a long-acting reversible contraceptive (LARC) (implant or intrauterine device) is recommended for coverage *(strong recommendation*).

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5. Review draft scope statements for topic rescan on approved Coverage Guidances approved or rescanned in 2014

The subcommittee discussed scope statements for the following topics, with King and Livingston reviewing the key issues:

Prenatal Genetic Testing (staff recommendation is to retire this coverage guidance)

- Staff explained that with the Commission's new methodology, this coverage guidance would be impractical due to the wide variety of interventions. For the Oregon Health Plan, this topic will be left to the Prioritized List process and be handled by VbBS. There was minimal discussion.

Planned Cesarean Birth

- King reviewed the draft scope statement; there was minimal discussion.

Routine Ultrasound in Pregnancy

- The subcommittee discussed the difficulties with answering the questions related to timing. Timing of ultrasound is challenging because pregnancy dating is not always exact. After brief discussion no changes were made. Livingston said that staff discussed breaking the coverage guidance into separate parts for dating and fetal anomalies. King said some ultrasounds are for

multiple purposes. King said there is not a strong evidence base. King said that there are no new randomized trials and the additional observational trials are unlikely to change coverage policy. After discussion, the subcommittee decided to recommend retiring this coverage guidance since the existing guidance is driven more by practice guidelines than evidence.

Chronic Otitis Media with Effusion in Children

- Westbrook asked about later hearing loss, after the effusion is resolved. King said that this can happen and would be included under the outcome of persistent hearing loss. Livingston said persistent will be defined according to how the studies define it rather than specifying a specific time period. King said that the guidelines from the American Academy of Pediatrics have shifted on this and there appear to be evidence-based reasons for this. Chan clarified that the harm of antibiotic resistance would come from population-based evidence as opposed to individual outcomes.

Nonpharmacologic Interventions for Treatment Resistant Depression

- The subcommittee discussed whether to add acupuncture to scope (based on an emailed public comment) and decided against it. Livingston noted that the public commenter cited "qualitative" evidence; with such evidence, a review would likely produce a recommendation against coverage, so the subcommittee elected not to add acupuncture to scope. Acupuncture for major depression (as first line therapy) might be appropriate as a separate topic for a coverage guidance or for the Prioritized List. The subcommittee retitled the scope statement to clarify that it is only related to major depression (not milder forms of depression). At Westbrooks request, the key questions were edited to differentiate between recurrent versus single-episode major depressive disorder.

Imaging for Low Back Pain

- The subcommittee removed the word "advanced" from the entire scope statement, as scope includes plain film x-rays. At Chan's request, the subcommittee removed the word "nonspecific" and replaced it with the language in the population description regarding acute low back pain and acute excacerbations. Under key question 2, the subcommittee added response to prior treatments and known structural abnormalities as factors which may affect effectiveness. Westbrook asked how the coverage guidance would address monitoring of chronic low back pain; King explained that it would not.

Low Back Pain: Pharmacological and Herbal Therapies

- The subcommittee added oral steroids, marijuana and homeopathic therapies to the list of interventions. Under key questions, the subcommittee added the source, preparation and standardization of herbal therapies and changed the wording from "response to previous medication trials" to "response to previous interventions."
- The subcommittee then heard public comment from David Bove of Pain Consultants of Oregon. He expressed support for herbal therapies for low back pain, including California poppy and corydalis, which are used in Traditional Chinese Medicine. After discussion of the HERC's evidence standards and methodology, he suggested that these products not be called out specifically in the scope statement on Pharmacologic and Herbal therapies for low back pain.
- Tippens questioned the omission of pain from the listed outcomes. Livingston acknowledged there is some disagreement about this within OHA clinical staff, with at least one person seeing pain as important since pain is what patients complain of and seek relief for. She explained that measures of function often include pain as a component but focus on a person's ability to function in their environment. The subcommittee recognized that pain outcomes, use of pain as a fifth vital sign and treating pain to a level of zero may result in inappropriate opioid use.

Low Back Pain: Non-Pharmacologic Non-Invasive Interventions

- Under key question 2 (f) the subcommittee replaced “previous trials of non-pharmacologic, non-invasive interventions” with “any prior intervention” and deleted contextual question 2 as it was duplicative. King noted that under important outcomes, change in utilization of opioid medications would be included in scope.

Low Back Pain: Minimally Invasive and Non-corticosteroid Percutaneous Interventions

- King discussed several public comments which staff considered in the development of this scope statement. She noted that diagnostic injections are not in scope. The committee discussed that the scope statement did not need to change for the public comments, but the appointed expert may be key to discuss issues such as patient selection. The subcommittee discussed possible ad hoc experts for this topic.

Neuroimaging for Dementia

- The scope statement was changed to consistently include mild cognitive impairment as well as dementia. The subcommittee also changed “reversible causes of dementia” to “reversible causes of cognitive impairment” for precision. The subcommittee recommended retiring this topic as well.

A motion was made to approve all the scope statements as amended and retire the coverage guidances on Neuroimaging for Dementia, Prenatal Genetic Testing and Routine Ultrasound in Pregnancy. **The motion was approved 5-0.**

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6. ADJOURNMENT

The meeting was adjourned at approximately 4:30 pm. The next meeting is scheduled for November 3, 2016 from 2:00-5:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070.

MINUTES

Health Technology Assessment Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
September 15, 2016
1:00-4:00pm

Members Present: Som Saha, MD, MPH, Chair; Leda Garside, RN, MBA; Mark Bradshaw, MD; Clyde Farris, MD, Derrick Sorweide, DO.

Members Absent: Chris Labhart, Vinay Prasad, MD, MPH.

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Jason Gingerich.

Also Attending: Adam Obley, MD, Val King MD, MPH & Craig Mosbaek (OHSU Center for Evidence-based Policy); David Halmar, Abby Anderson (Bioventus); Barry Schlansky, MD (OHSU); Kari Thomas, MD (Legacy Good Samaritan); Andrea Herzka, MD (OHSU).

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1. CALL TO ORDER

Saha called the meeting to order at 1:14 p.m.

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2. MINUTES REVIEW

Minutes from the 6/16/2016 meeting were reviewed and approved 4-0 (Sorweide absent).

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3. STAFF REPORT

Coffman reported that Derrick Sorweide has agreed to serve as chair of the subcommittee, beginning at the February, 2017 meeting. In addition, Vinay Prasad has been officially appointed to the HTAS, though he could not attend today's meeting. The subcommittee voted to appoint Sorweide as chair by a vote of 4-0 (Sorweide absent).

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4. Noninvasive Testing for Liver Fibrosis in Patients with Chronic Hepatitis C

Obley reported that there were no public comments on this coverage guidance. Coffman noted that the Oregon Health Plan's fee-for-service Pharmacy and Therapeutics Committee will be discussing the appropriate treatment threshold for chronic hepatitis C, with a staff recommendation to change the treatment threshold to stage 2 fibrosis with revised prior authorization criteria which align with the draft

coverage guidance. These recommendations will be presented at their September 29th meeting, but if they are accepted the state will need to consider how to address the fiscal implication of this change.

Dr. Barry Schlansky, the appointed ad hoc expert for this topic, expressed support for the draft coverage guidance as presented. Coffman said that he had been expecting comment on FibroSure. This test has historically been included in the prior authorization criteria for the direct-acting antivirals. No comments were received, and Coffman has heard indirectly that a leading Oregon hepatologist is comfortable with the recommendations.

The subcommittee voted to refer the draft coverage guidance to the VbBS and HERC. Motion approved 4-0 (Sorweide absent).

DRAFT HERC Coverage Guidance

If a fibrosis score of ≥F2 is the threshold for antiviral treatment of Hepatitis C, the following are recommended for coverage *(weak recommendation)*:

Imaging tests:

- Transient elastography (FibroScan®)
- Acoustic radiation force impulse imaging (ARFI) (Virtual Touch™ tissue quantification, ElastPQ)
- Shear wave elastography (SWE) (Aixplorer®)

Blood tests (only if imaging tests are unavailable):

- Enhanced Liver Fibrosis (ELF™)
- Fibrometer™
- FIBROSpect® II

If a fibrosis score of ≥F3 is the threshold for antiviral treatment of Hepatitis C, one or more of the following are recommended for coverage *(strong recommendation*):

Imaging tests:

- Transient elastography (FibroScan®)
- Acoustic radiation force impulse imaging (ARFI)
- Shear wave elastography (SWE)

Magnetic resonance elastography is recommended for coverage for ≥F2 or ≥F3 only when at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminant results, a second one is similarly indeterminant, contraindicated or unavailable, and MRE is readily available *(weak recommendation).*

Noninvasive tests should be performed no more often than once per year *(weak recommendation).*

The following tests are not recommended for coverage for the detection of liver fibrosis to guide

treatment decisions with antivirals in chronic hepatitis C *(strong recommendation):*

Imaging tests

- Real time tissue elastography

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5. Scope statements for rescan of topics approved in 2014

The subcommittee discussed the draft scope statements, with Obley and Livingston presenting the key issues.

Indications for Hyperbaric Oxygen Therapy for Wounds and Burns
There was minimal discussion. Saha noted that the scope has been limited from the previous coverage guidance which covered a wide variety of indications for this therapy.

Artificial Disk Replacement
Livingston noted that the outcomes here are about function, not pain, and that this standard will be followed with all of the topics. Gingerich noted that public comments were forwarded to members of the subcommittee in their entirety. Saha stated that while pain is important, it can be hard to measure, and that the reason to treat pain is ultimately to improve function. The subcommittee changed "nonsurgical comparators" to "nonsurgical interventions (e.g. opioids)."

Hip Resurfacing
The subcommittee made the same change as made for Artificial Disk Replacement, with minimal discussion.

Knee Arthroscopy in Patients with Osteoarthritis
Farris said that he believes that this surgery has minimal benefits. Saha asked why the outcomes are not the same as for the prior two topics. After brief discussion the subcommittee agreed to standardized the outcomes to match the hip resurfacing topic, substituting the outcome of total knee arthroplasty for utilization of total hip arthroplasty.

Lumbar Discography
The subcommittee made prognostic accuracy for surgical outcomes an important outcome (rather than critical) and utilization of surgery a critical outcome.

Viscosupplementation for Osteoarthritis of the Knee
Farris expressed his doubts that this intervention improves outcomes. David Holman provided public comment, representing Bioventus, which distributes two viscosupplementation products. He presented four publications showing that viscosupplementation delays total knee replacement surgery, and asked that the scope statement include the delay in surgery. Saha said that it would under the outcome of utilization of surgery. Saha asked Obley to remove quality of life and to add utilization of nonsurgical interventions (e.g. opioids).

DXA for Screening and Monitoring of Osteoporosis
Obley explained that this topic will be split into two topics for screening and monitoring. For the

screening topic, there was no discussion. For the monitoring topic, the subcommittee discussed that in key question 2, hormones and vitamin D would be considered medications.

Femoroacetabular Impingement Syndrome
The subcommittee discussed that short-term function should be an important rather than a critical outcome, with long-term function as critical. The subcommittee agreed to make this change to all the previously discussed scope statements related to arthritis and back pain.

Saha suggested changing the outcome of quality of life to avoidance of opioids, as with the other topics. Obley said that because of the assertion that this surgery delays hip arthritis, it is different than the others. Saha asked Farris whether the candidates for this surgery are generally in chronic pain. Farris said he would hope not; generally they are young athletes. Gingerich said that in the previous coverage guidance the recommendation was to cover the surgery, despite a low level of evidence. After brief discussion the subcommittee left the quality of life outcome and removed the population restriction which required adolescents to be skeletally mature.

Dr. Andrea Herzka provided public comment on this topic, noting that several large trials are underway comparing physical therapy to surgery. She believes these trials will provide the randomized evidence the HERC is looking for. However, the studies may have had difficulties getting patients to be randomized to a physical therapy protocol. She expressed support for the scope statement as amended.

Sleep Apnea Treatment in Adults
There was minimal discussion; the subcommittee made no changes.

Upper Endoscopy for Gastroesophageal Reflux Disease (GERD)
There was no discussion.

The subcommittee voted 5-0 to approve the scope statements as revised.

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6. Coverage guidance statuses

Since the meeting was running ahead of schedule, Livingston explained some proposed upcoming changes to the coverage guidance monitoring process. Due to the increasing number of approved coverage guidances that require monitoring, it is requiring more and more staff resources. Staff is proposing a new status of “inactive” for topics where staff believes new evidence is unlikely to change conclusions. Such topics would only be rescanned if new evidence likely to change conclusions came to the attention of staff, either through their professional activities or by stakeholders. Staff would make that recommendation as a part of the rescan process and the decision would be made by the subcommittee and the Commission.

7. Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average risk Women

Dr. Kari Thomas introduced herself. She is a radiologist at Legacy Good Samaritan Hospital and OHSU. Her expertise includes breast, pelvic and fetal imaging. In her practice, she has used 3D mammography since 2012. Dr. Linda Humphrey introduced herself. She is not an expert in digital breast tomosynthesis (DBT) but knows about breast cancer screening in general. Livingston noted that she was an author of the United States Preventive Services Task Force recommendations related to mammography.

Obley reviewed the draft coverage guidance.

Humphrey asked whether, in the STORM trial, the same radiologist read each mammogram two times, with DBT on the second reading. Obley confirmed that in the Housami et. al. report, it was a single radiologist, while in the Ciatto report (based on the same data), there were two independent reviews of each mammogram. Saha asked whether Ductal Carcinoma in Situ (DCIS) counted as cancer for these studies. Obley said that it did for most studies and added that, as shown in Table 3, some studies reported on the percentage of invasive cancers detected by each imaging modality. In most trials, the proportion of cancers detected were similar. Thomas shared her clinical experience that DBT detects more invasive cancer, with the same amount of DCIS, though Obley confirmed the studies he reviewed showed mixed results. Thomas cited several more recent observational studies which which were not considered in the coverage guidance. She also noted that the studies which showed no difference in cancer detection rate were much smaller than those that did show a difference.

After extensive discussion, the subcommittee decided to request staff perform a new evidence search to pick up observational trials which would not have met inclusion criteria for the original search and include them as well as studies submitted in public comment. Staff will edit the next version of the draft coverage guidance, incorporating this evidence.

When Obley presented the data about the recall rate, the subcommittee discussed the general pattern of higher recall rates in the United States versus Europe, which accounts for the wide range in recall rates in both the DM and DBT+DM groups. Thomas noted that there are 9 studies which show a lower recall rate with DBT+DM, and the two studies showing a similar recall rate were actually conducted using the same data. She said that if you only look at the data from the United States, there are 11 studies that show lower recall rates with DBT+DM and none showing different results. Humphrey noted that the difference in specificity of 96% versus 97% shown in the table may not look large, but are actually quite significant in terms of positive predictive value when applied to a large population. Obley said that there was only one study that calculated sensitivity and specificity. Based on the differential recall rate patterns in the U.S. and Europe, Saha asked that the studies be separated to reduce confusion.

Livingston reviewed the resource allocation section as well as the values and preferences and other factors leading to the recommendation for noncoverage.

When Obley reviewed the other payer policies, Thomas noted that Cigna recently began covering DBT.

Thomas asked about the cost information and cited economic reviews suggesting lower population costs due to lower recall rate and earlier detection of invasive cancers. Gingerich explained that the cost listed in the resource allocation section of the draft coverage guidance was based on the incremental costs of mammography alone, since the quality of the evidence suggesting lower recall and earlier detection is very low.

The subcommittee requested that staff should add the cost modelling study cited by Thomas. The subcommittee added language to the resource allocation column to indicate that if recall rates and biopsies are reduced, the additional costs of 3D mammography could be offset.

Thomas commented that requiring evidence of impact on breast cancer morbidity and mortality should not be required for an improvement on digital mammograms, as these were not required for the conversion from film to digital mammography. Saha explained that the Commission knows it won't always get this data, but always looks for it in cancer-related topics.

During the discussion of values and preferences, Thomas mentioned a new study published this week which showed that many women experiencing false positive mammograms still prefer annual screening.

The subcommittee voted 5-0 to put the draft coverage guidance out for public comment. Staff will incorporate the results of an additional evidence search for newer trials together with the responses to public comments in the draft to be reviewed at the next meeting.

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8. ADJOURNMENT

The next new topic will be Breast Cancer Screening in Women at Above-Average Risk. Livingston asked whether the initial evidence search for this topic should follow the expanded approach as outlined above. The subcommittee expressed agreement with this approach.

The meeting was adjourned at 4:00 pm. The next meeting is scheduled for December 1, 2016 from 1:00-4:00pm in Room 111-112 of the Wilsonville Training Center of Clackamas Community College.

MINUTES

Health Evidence Review Commission's
Oral Health Advisory Panel (OHAP)

Clackamas Community College
Wilsonville Training Center, Room 211
September 8, 2016
8:30-10:00 AM

Members Present: Gary Allen, DMD, Chair; Bruce Austin, DMD; Deborah Loy (via phone); Mike Shirtcliff, DMD; Lori Lambright; Karen Nolan; Eli Schwarz, DDS, MPH, PhD; Len Barozzini, DDS.

Members Absent: Lynn Ironside; Patricia Parker, DMD.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH.

Also Attending: Sarah Wetherspoon, OHA (via phone); Charles Rosson, Kaiser Permanente; Cathleen Olesitse, CareOregon Dental; Laura McKeane, All Care Health; Molly Johnson and Dayna Steringer, Advantage Dental.

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 8:05 am and roll was called. The minutes from the 2015 OHAP meeting were reviewed and no corrections or concerns were raised.

Coffman reviewed the charge of OHAP and the organizational structure within HERC. Loy requested that the extracted list of dental lines be reviewed for the current biennial review for possible line reprioritization, and also review of the procedure code placement. HERC staff will send out the extracted dental lines to the OHAP group via email for review prior to the next OHAP meeting.

- **Topic: 2017 CDT code placements**

  Discussion:
  1) D0414: the suggested placement is identical to similar code D0415 and was felt to be appropriate
  2) D0600: agreed that this procedure is experimental
  3) D1575: no discussion
  4) D4346: no discussion
  5) D6081: There was robust discussion regarding this at the August DCO meeting. Allen stated that interventions necessary to save the current dental situation (implant or

not) should be covered. Austin stated that this procedure would affect the health of surrounding teeth and bones. Loy stated that providers were concerned about provider liability for treatment of an implant when they did not place the implant initially. The group response was that it is not always possible to get the patient back to the original provider and the responsibility of the current provider is to the patient and their health. Shirtcliff stated that he agreed with Allen to try to improve overall mouth health. The group felt that there was a need to discuss overall coverage of implant codes, and determine what should be covered -- cleaning, maintenance, removal, and/or other procedures. HERC staff was directed to pull implant-related CDT codes to review as a whole set to determine what should be covered. Included in this discussion should be coverage of placement of implants, as these are now becoming standard of care in dentistry and may be more cost effective than a partial denture. The next OHAP meeting should also consider implant line reprioritization. The question arose as to whether removal of an implant should be considered medical (i.e. extraction of a foreign body) or dental. HERC staff indicated that bridges are also not currently covered. If implant placement and/or repair is considered for coverage, then bridge repair codes and possibly creation codes should also be considered. Coffman indicated that partial or complete coverage of implants and/or bridges raised the concern for cost increase. The group decided that D6081 should be placed on line 622 with other implant codes for now, and an OHAP meeting should be convened later this year to discuss implants and bridges as a biennial review item. The October DCO meeting will discuss this, then the next OHAP meeting will be planned for late November or early December 2016. Any changes to implant and/or bridge coverage will be discussed at the January HERC meeting and have implementation planned for January 2018.

6) D6085: this code is similar to D6081 above. Will place on line 622 for now and will include at next meeting for biennial review discussion of dental implant coverage.
7) D9311: There was discussion about how this code and D9991-D9994 (below) could be implemented, as dental does not use ICD-10 codes and therefore the Ancillary File would be difficult for dental use. HSD staff indicated that MMIS would have to demonstrate that other covered CDT codes were billed with the visit. Schwartz was concerned that these ancillary services are not included in the DCO capitation rate, but feels that this would be very useful and should be supported. Shirtcliff asked who should be responsible for these types of services: dental, behavioral health, medical, public health? Loy stated that the system needs to get away from paying solely for dental procedures, needs additional/other payment system to fund these case management services. Smits indicated that case management services were rarely paid as an individual service in the medical world.
8) D9991-D9994: Decision was made to put in the Ancillary File. HSD will work on who can use them, how they can be billed, and other operational rules. These codes will be made open for encounter purposes but unlikely to be reimbursed for now.

Actions:

1) See Appendix A for spreadsheet of code placements

- **Topic: GN17 Preventive Dental Care**

  Discussion: Tabled until November OHAP meeting

- **Topic: GN43 Oral Surgery – Extraction of Third Molars**

  Discussion: Smits introduced the summary of the issue. Allen was concerned about the vagueness of the current guideline note. Others agreed that the current guideline is too vague and the rules based on this guideline were hard to interpret. Loy indicated that the proposed guideline was much improved.

  Allen addressed the proposed wording about requiring two or more episodes of pericoronitis. He indicated that there are other interventions other than extraction for pericoronitis.

  Austin asked about inclusion of unrestorable caries as an indication for extraction. Allen replied that the wording that the tooth can't be maintained would cover that situation. Shirtcliff inquired about the case of a painful erupted third molar, when the pain was excruciating or unmanageable. Schwartz replied that the correct path to take is to follow the evidence. The problem this guideline is attempting to solve is when the teeth are taken out preventively without pain or other pathology. Shirtcliff requested that intractable pain be added to the guideline as an indication for extraction. Allen was concerned about how to define intractable pain. Allen thought that Health Partners Minnesota had a guideline about third molar extraction that addressed pain. He will look for that guideline and see if there is language in it that could be adopted regarding when painful third molars should be extracted. . There was also a question about what to do in the situation when an orthodontist requested extraction as part of braces—the answer was not to cover this.

  Allen will get the Minnesota guideline he mentioned, and staff will rework the guideline and send around for email approval of OHAP group, and will tentatively bring to the October VBBS meeting for approval.

  Actions:

  1) HERC staff with work with Dr. Allen to revise guideline and will send to OHAP group with tentative plan to get email approval prior to the October, 2016 VBBS meeting. Otherwise discussion will continue at the November/December OHAP meeting.

- **Topic: Removal of tori and excision of hyperplastic tissue**

  Discussion: OHAP felt that the proposed changes were an excellent idea. There was some discussion about the increase in cost associated with covering removal of this type of tissue. The counterargument was that there is increased cost in the preparation of dentures when this type of tissue is not removed. HSD will look into the cost of adding these services; if significant, then these changes may have implementation delayed.

  Actions:

  1) Remove D7970 (Excision of hyperplastic tissue-per arch) from line 349 DENTAL CONDITIONS (EG. SEVERE CARIES, INFECTION) Treatment: ORAL SURGERY (I.E. EXTRACTIONS AND OTHER INTRAORAL SURGICAL PROCEDURES and add to line 457 DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS (E.G. FULL AND PARTIAL DENTURES, RELINES)
  2) Add D7472 (Removal of torus palatinus) and D7473 (Removal of torus mandibularis) to line 457 and remove from the Services Recommended for Non-Coverage table
  3) Adopt a new guideline regarding D7970, D7472 and D7473 as shown below:

     GUIDELINE NOTE XXX REMOVAL OF TORI AND EXCISION OF HYPERPLASTIC TISSUE

     Line 457

     D7472 and D7473, and D7970 are included on this line only when used in conjunction with making a prosthesis.

- **Topic: Implant removal and debridement**

  Discussion: Delayed until November/December OHAP discussion regarding implants

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**
  1) Preventive dental guideline
  2) Biennial review of implants and dental bridges

- **Next meeting:**
  - TBD, plan a late November or early December 2016 meeting

- **Adjournment**

  The meeting was adjourned at 10:12 AM.

CDT Code	Nomenclature	Suggested Code Placement	Comments
D0414	laboratory processing of microbial specimen to include culture and sensitivity studies, preparation and transmission of written report	Diagnostic	HSD will not open for payment
D0600	non-ionizing diagnostic procedure capable of quantifying, monitoring and recording changes in structure of enamel, dentin, and cementum	Services Recommended for Non-Coverage	Experimental
D1575	distal shoe space maintainer - fixed - unilateral	57 PREVENTIVE DENTAL SERVICES	HSD recommends making either/or with D1510 (SPACE MAINTAINER-FIXED UNILATERAL) and use the same limitations as apply to D1510. Rules to be devised by HSD.
D4346	scaling in presence of generalized moderate or severe gingival inflammation – full mouth, after oral evaluation	57 PREVENTIVE DENTAL SERVICES	Make either/or with D4355 (FULL MOUTH DEBRIDEMENT TO ENABLE COMPREHENSIVE EVALUATION AND DIAGNOSIS)and use the same limitations as apply to D4355. Rules to be devised by HSD.
D6081	scaling and debridement in the presence of inflammation or mucositis of a single implant, including cleaning of the implant surfaces, without flap entry and closure	622 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment IMPLANTS (I.E. IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)	Further discussion on implants at next OHAP meeting
D6085	provisional implant crown	622 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment IMPLANTS (I.E. IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)	Further discussion on implants at next OHAP meeting
D9311	consultation with medical health care professional	Ancillary	HSD will need to make rules; will not open for payment until rules are finalized.
D9991	dental case management – addressing appointment compliance barriers.	Ancillary	See D9311
D9992	dental case management – care coordination	Ancillary	See D9311
D9993	dental case management – motivational interviewing	Ancillary	See D9311
D9994	dental case management – patient education to improve oral health literacy	Ancillary	See D9311

Section 2.0

VbBS Report

Consent Agenda Issues—October, 2016

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
13100 13101 13102 13153	Repair, complex, trunk; 1.1 cm to 2.5 cm 2.6 cm to 7.5 cm each additional 5 cm or less Repair, complex, eyelids, nose, ears and/or lips; each additional 5 cm or less	**195** CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	The CPT codes used in breast reconstruction are incorrect on the breast cancer line. 13100-13102 are commonly used for breast reconstruction; 13153 appears to be on this line in error	Add 13100-13102 to line 195 Remove 13153 from line 195
27635 27637 27638	Excision or curettage of bone cyst or benign tumor, tibia or fibula with autograft (includes obtaining graft) with allograft	**205** CANCER OF BONES	OHA Hearings Division requested that 27635 be considered for pairing with D48.0 (Neoplasm of uncertain behavior of bone and articular cartilage) found only on line 205. Several similar cyst/benign lesion CPT codes are found on line 205.	Add 27635-27638 to line 205
99195	Phlebotomy, therapeutic (separate procedure)	**198** HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN **403** MYELOID DISORDERS	HSD requested that 99195 be added to line 198 to pair with D75.1 (Secondary polycythemia) and to line 403 to pair with D45 (Polycythemia vera). CPT 99195 is currently on lines 64, 119, 155, 225, 424.	Add 99195 to lines 198 and 403
D18.09	Hemangioma of other sites	**100** DIABETIC AND OTHER RETINOPATHY **298** ANOMALIES OF GALLBLADDER, BILE DUCTS, AND LIVER	HSD requested that 92235 (Fluorescein angiography) pair with D18.09, which is currently on lines 406,561,631. D18.09 has retinal, orbital, and liver hemangiomas as subdiagnoses. Retinal hemagiomas are treated with laser coagulation.	Add D18.09 to lines 100 and 298

Consent Agenda Issues—October, 2016

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
92002-92014	Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program	428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT	There are multiple complications of eye surgery ICD-10 codes on line 428 but no ophthalmologic treatment codes on that line.	Add 92002-92014 to line 428
38747	Abdominal lymphadenectomy, regional, including celiac, gastric, portal, peripancreatic, with or without para-aortic and vena caval nodes (List separately in addition to code for primary procedure)	161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS	HSD requested that 38747 be added to line 161. 38747 is on a similar line for cancer of the stomach.	Add 38747 to line 161
15574	Formation of direct or tubed pedicle, with or without transfer; forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands or feet	292 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX	HSD requested 15574 be added to line 292 to pair with C05.0 (Malignant neoplasm of hard palate). 15574 is on 11 other lines.	Add 15574 to line 292
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	292 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX	HSD requested 20962 be added to line 292 to pair with C05.0 (Malignant neoplasm of hard palate). 20962 is on lines 188,205,259,406,447,561.	Add 20962 to line 292
44015	Tube or needle catheter jejunostomy for enteral alimentation, intraoperative, any method	84 INJURY TO INTERNAL ORGANS 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION	HSD requested that 44015 be added to the stomach cancer line; however, other ostomy codes are Ancillary.	Remove 44015 from lines 84 and 105 Advise HSD to add 44015 to Ancillary File

Consent Agenda Issues—October, 2016

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
43260 43261 43262 43263 43264 43265	Endoscopic retrograde cholangiopancreatography (ERCP); diagnostic, including collection of specimen(s) by brushing or washing, when performed with biopsy, single or multiple with sphincterotomy/ papillotomy with pressure measurement of sphincter of Oddi with removal of calculi/debris from biliary/pancreatic duct(s) with destruction of calculi, any method (eg, mechanical, electrohydraulic, lithotripsy)	320 CANCER OF LIVER	HSD requested that 43260 be added to line 320. ERCP was reviewed in 2007 and the HOSC/HSC determined that ERCP should be on lines as these procedures are generally not purely diagnostic. Some ERCP codes (43275-43277) already appear on line 320	Add 43260-43265 to line 320
96155	Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)		96155 is currently Ancillary, while the rest of the health and behavior intervention CPT codes are on approximately 200 lines on the Prioritized List. Per HSD, movement onto lines is acceptable.	Add 96155 to any line with other health and behavior assessment codes (96150, etc.) Advise HSD to remove 96155 from the Ancillary File
C26.0	Malignant neoplasm of intestinal tract, part unspecified	595 SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS,	ICD-10 C26.0 is currently on the Undefined Diagnosis File at HSD. A more appropriate placement is line 595.	Add C26.0 to line 595 Advise DMAP to remove C26.0 from the Undefined Diagnosis File

Straightforward Guideline Changes
October, 2016

1) Modify GN116 as shown below and delete GN 117. Both guidelines reference intraocular steroid treatments and the same CPT codes.

GUIDELINE NOTE 116, INTRAOCULAR STEROID TREATMENTS

Lines 100,365,445

Intraocular steroid treatments (CPT 67027, 67028) are included on Line 365 for pairing with uveitis (ICD-10-CM H30.0, H30.1, H30.89, H30.9, H44.11) when the following conditions are met: uveitis is chronic, non-infectious, and there has been appropriate trial and failure, or intolerance of therapy, with local and systemic corticosteroids and/or immunosuppressive agents.

Intraocular steroid treatments (CPT 67027, 67028) are included on Line 100 for treating chronic diabetic macular edema (ICD-10-CM E11.311) only when there has been insufficient response to anti-VEGF therapies, and only when FDA approved treatments are utilized.

Intraocular steroid treatments (CPT 67027, 67028) are only included on Line 445 for treatment of macular edema due to:

1. central retinal vein occlusion (ICD-10-CM H34.81) in those individuals who have failed anti-VEGF therapy.
2. Branch retinal vein occlusion (ICD-10-CM H34.83) when treatment with laser photocoagulation has not been beneficial, or treatment with laser photocoagulation is not considered suitable because of the extent of macular hemorrhage in those individuals who have failed anti-VEGF therapy.

~~**GUIDELINE NOTE 117, INTRAOCULAR STEROID IMPLANTS FOR RETINAL VEIN OCCLUSION**~~

~~*Line 445*~~

~~Intraocular steroid treatments (CPT 67027, 67028) are only included on Line 445 for treatment of macular edema due to:~~

3. ~~central retinal vein occlusion (ICD-10-CM H34.81) in those individuals who have failed anti-VEGF therapy.~~
4. ~~Branch retinal vein occlusion (ICD-10-CM H34.83) when treatment with laser photocoagulation has not been beneficial, or treatment with laser photocoagulation is not considered suitable because of the extent of macular hemorrhage in those individuals who have failed anti-VEGF therapy~~.

2. Modify GN 104 to clarify that viscosuplementation is not included on these lines for osteoarthritis of the knee and remove language about "covered." Remove line 361 as CPT 20610 is not on that line. CPT 20610 is a generic code (Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance) that could be used for other procedures.

GUIDELINE NOTE 104, VISCOSUPPLEMENTATION OF THE KNEE

Lines ~~361,~~436,467

~~Viscosupplementation of the knee (CPT 20610) is not covered for treatment of osteoarthritis of the knee.~~

CPT 20610 is included on these lines only for interventions other than viscosupplementation for osteoarthritis of the knee.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-viscosupplementation-knee.aspx

CDT Code	Nomenclature	Suggested Code Placement	Comments
D0414	laboratory processing of microbial specimen to include culture and sensitivity studies, preparation and transmission of written report	Diagnostic Procedures File	HSD will not open for payment
D0600	non-ionizing diagnostic procedure capable of quantifying, monitoring and recording changes in structure of enamel, dentin, and cementum	Services Recommended for Non-Coverage	Experimental
D1575	distal shoe space maintainer - fixed - unilateral	57 PREVENTIVE DENTAL SERVICES	HSD recommends making either/or with D1510 (SPACE MAINTAINER-FIXED UNILATERAL) and use the same limitations as apply to D1510. Rules to be devised by HSD.
D4346	scaling in presence of generalized moderate or severe gingival inflammation – full mouth, after oral evaluation	57 PREVENTIVE DENTAL SERVICES	Make either/or with D4355 (FULL MOUTH DEBRIDEMENT TO ENABLE COMPREHENSIVE EVALUATION AND DIAGNOSIS) and use the same limitations as apply to D4355. Rules to be devised by HSD.
D6081	scaling and debridement in the presence of inflammation or mucositis of a single implant, including cleaning of the implant surfaces, without flap entry and closure	622 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment IMPLANTS (I.E. IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)	Further discussion on implants at next OHAP meeting
D6085	provisional implant crown	622 DENTAL CONDITIONS (EG. MISSING TEETH) Treatment IMPLANTS (I.E. IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)	Further discussion on implants at next OHAP meeting
D9311	consultation with medical health care professional	Ancillary File	HSD will need to make rules; will not open for payment until rules are finalized.
D9991	dental case management – addressing appointment compliance barriers.	Ancillary File	See D9311
D9992	dental case management – care coordination	Ancillary File	See D9311
D9993	dental case management – motivational interviewing	Ancillary File	See D9311
D9994	dental case management – patient education to improve oral health literacy	Ancillary File	See D9311

1) GN34 Oral Surgery

OHAP is working on substantial revisions to GN34; however, these revisions will not be completed until the next OHAP meeting. In the interim, GN34 needs the second sentence deleted so that it is not in direct conflict with the new dental guideline proposed in section #2 below.

HERC staff recommendation:

1) Modify GN34 as shown below
    a. D7970 addressed in issue #2 below

GUIDELINE NOTE 34, ORAL SURGERY

Line 349

Treatment only for symptomatic dental pain, infection, bleeding or swelling (D7220, D7230, D7240, D7241, D7250). ~~To be used in conjunction with making a prosthesis (D7970).~~

2) Removal of tori for dentures

1) Remove D7970 (EXCISION OF HYPERPLASTIC TISSUE-PER ARCH) from line 349 DENTAL CONDITIONS (EG. SEVERE CARIES, INFECTION) Treatment: ORAL SURGERY (I.E. EXTRACTIONS AND OTHER INTRAORAL SURGICAL PROCEDURES and add to line 457 DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS (E.G. FULL AND PARTIAL DENTURES, RELINES)
2) Add D7472 (Removal of torus palatinus) and D7473 (Removal of torus mandibularis) to line 457 and remove from the Services Recommended for Non-Coverage table
3) Adopt a new guideline regarding D7970, D7472 and D7473 as shown below

GUIDELINE NOTE XXX REMOVAL OF TORI AND EXCISION OF HYPERPLASTIC TISSUE

Line 457

D7472 and D7473, and D7970 are included on this line only when used in conjunction with making a prosthesis.

Question: Where should oculopathy diagnoses be placed on the Prioritized List?

Question source: HERC staff, HSD

Issue: ICD10 includes multiple codes for oculopathy. ICD-9 only included diabetic oculopathy. The ICD-10 codes were placed on lines containing the underlying disease (syphilis, toxoplasmosis, etc.). However, these lines do not contain the CPT codes required for treatment of the oculopathy. Diabetic oculopathy is listed as a subdiagnosis of ICD-9 250.50 (Diabetes with ophthalmic manifestations, type II or unspecified type) and similar codes. Oculopathy is no longer listed as a subdiagnosis for diabetic eye disease in ICD-10. The diabetic codes would appear on line 100 DIABETIC AND OTHER RETINOPATHY if they continued to be included as a subdiagnosis of diabetic eye disease.

Oculopathy is an eye disease which can present as an interstitial keratitis, scleritis, iritis, chorioretinitis, or exudative retinal detachment. It can be caused by a variety of conditions. The current placement of these codes allows treatment of the underlying disease but not the eye manifestations.

ICD-10 Code	**Code description**	**Current placement**
A50.01	Early congenital syphilitic oculopathy	16 CONGENITAL SYPHILIS
A50.30	Late congenital syphilitic oculopathy, unspecified	16 CONGENITAL SYPHILIS
A50.39	Other late congenital syphilitic oculopathy	16 CONGENITAL SYPHILIS
A51.43	Secondary syphilitic oculopathy	42 PRIMARY AND SECONDARY SYPHILIS
A52.71_	Late syphilitic oculopathy	387 LATE SYPHILIS
B58.00	Toxoplasma oculopathy, unspecified	236 MYCOBACTERIA, FUNGAL INFECTIONS, TOXOPLASMOSIS, AND OTHER OPPORTUNISTIC INFECTIONS
B58.09	Other toxoplasma oculopathy	236

HERC staff recommendations:

1) Add A50.01, A50.30, A50.39, A51.43, A52.71, B58.00 and B58.09 to lines 270 ACUTE, SUBACUTE, CHRONIC AND OTHER TYPES OF IRIDOCYCLITIS, 340 SCLERITIS and 365 CHORIORETINAL INFLAMMATION
    a. Will allow treatment of eye manifestation of the disease
    b. Keep codes on their underlying disease lines

Question: how should the Prioritized List be modified to indicate coverage for wigs for patients with hair loss due to chemotherapy and/or radiation treatment?

Question source: HERC staff, HSD staff

Issue: Under the Affordable Care Act, the Medicaid expansion population has to receive a benefit which includes the Essential Health Benefits as defined by law. Oregon is selecting the PacificSource Codeduct Plan as its base benchmark, and that plan includes coverage for wigs of up to $150 per year for people who have undergone radiation or chemotherapy treatment. In order to meet other regulatory requirements in an efficient way, Oregon has chosen to provide a single benefit package for the expansion population and the categorically eligible populations. The most expedient way to meet this requirement is to add this coverage for wigs.

Procedure code:
HCPCS A9282 (Wig, any type, each) is on the Ancillary List

Possible ICD-10 diagnostic codes:
L58.0 (Acute radiodermatitis) is on line 536 CONTACT DERMATITIS AND OTHER ECZEMA
L64.0 (Drug-induced androgenic alopecia) is on line 588 DISEASE OF NAILS, HAIR AND HAIR FOLLICLES
L65.8 (Other specified nonscarring hair loss) is on line 588 DISEASE OF NAILS, HAIR AND HAIR FOLLICLES. Radiation induced hair loss is indicated as a subdiagnosis
T45.1X5 (Adverse effect of antineoplastic and immunosuppressive drugs) in on line 107 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T66.XXX (Radiation sickness, unspecified) which has adverse effects of radiation therapy as a subdiagnosis is on lines 337 CONDITIONS REQUIRING HYPERBARIC OXYGEN THERAPY, 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
Y84.2 (Radiological procedure and radiotherapy as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure) is on the Informational List
Z92.21 (Personal history of antineoplastic chemotherapy) is on the Informational List
Z92.3 (Personal history of irradiation) is on the Informational List

HERC staff recommendations:

1) Add HCPCS A9282 (Wig, any type, each) to line 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
    a. Advise HSD to remove HCPCS A9282 from the Ancillary List
2) Add ICD-10 L58.0 (Acute radiodermatitis), L64.0 (Drug-induced androgenic alopecia) and L65.8 (Other specified nonscarring hair loss) to line 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
3) Adopt the following coding specification for line 428
    a. "ICD-10 L58.0, L64.0 and L65.8 are only included on this line for pairing with HCPCS A9282."
4) Adopt the new guideline below for line 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT

GUIDELINE NOTE XXX WIGS

Line 428

Wigs (HCPCS A9282) are covered only for hair loss due to chemotherapy or radiation therapy.

Issues:

1) GN6 was discussed at the May, 2016 VBBS meeting and the VBBS directed staff to remove vascular and cardiac rehabilitation from the guideline, as these are very different type of services with different indications for frequency and use compared to other rehabilitative services. HERC staff was directed to create a new guideline for cardiac and pulmonary rehabilitation. After reviewing many private insurance policies regarding these services, staff determined that any such guideline would need to be extremely long and detailed. OHP medical directors were queried about their need for such a guideline and the unanimous reply was that such a guideline was not useful: these services are not abused and a detailed guideline would not assist the CCOs. Therefore, staff is proposing removing vascular and cardiac rehabilitation from this guideline with no new guideline.
2) GN 6 Rehabilitative Therapies requires several edits to bring it into compliance with federal rules regarding habilitative services. Excerpts from federal rule regarding habilitative services are shown below:
    a. Separate coverage limits must also be established for rehabilitative and habilitative services and devices (see 45 CFR 156.115(a)(5)(iii)) for plan years beginning on or after January 1, 2017. A combined limit that cannot be exceeded based on medical necessity is not permissible. States will need to assess any existing limits on this coverage to determine if an amendment to the ABP SPA is required.
    b. Text of 45 CFR 156.115(a)(5)(iii)
        i. (iii) For plan years beginning on or after January 1, 2017, do not impose combined limits on habilitative and rehabilitative services and devices.
    c. Federal definition of habilitative services:
        i. 45 CFR 156.115
            1. (5) With respect to habilitative services and devices -
            2. (i) Cover health care services and devices that help a person keep, learn, or improve skills and functioning for daily living (habilitative services). Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings;

HERC staff recommendation:

1) Modify GN6 as shown below
    a. Brings guideline into alignment with federal regulations
    b. Removes cardiac and vascular rehabilitation from GN6 limits with no new guideline about these types of rehabilitation

GUIDELINE NOTE 6, REHABILITATIVE AND HABILITATIVE THERAPIES

Lines 34,50,61,72,75,76,78,85,95,96,135,136,140,154,157,164,182,187,188,200,201,205, 206,212,259,261,276,290,292,297,305,306,314,322,346,350,351,353,360,361,364,366,381, 382,392,406,407,413,421,423,427,428,436,447,459,467,470,471,482,490,501,512,532,558, 561,574,592,611,666

The quantitative limits in this guideline note do not apply to mental health or substance abuse conditions.

A total of 30 visits per year of rehabilitative therapy and a total of 30 visits per year of ~~or~~ habilitative therapy (physical, occupational and speech therapy~~, and cardiac and vascular rehabilitation~~) are included on these lines when medically appropriate. Additional visits, not to exceed 30 visits per year of rehabilitative therapy and 30 visits per year of habilitative therapy, may be authorized in cases of a new acute injury, surgery, or other significant change in functional status. Children under age 21 may have additional visits authorized beyond these limits if medically appropriate.

Physical, occupational and speech therapy~~, and cardiac and vascular rehabilitation~~ are only included on these lines when the following criteria are met:

1. therapy is provided by a licensed physical therapist, occupational therapist, speech language pathologist, physician, or other practitioner licensed to provide the therapy,
2. there is objective, measurable documentation of clinically significant progress toward the therapy plan of care goals and objectives,
3. the therapy plan of care requires the skills of a medical provider, and
4. the client and/or caregiver cannot be taught to carry out the therapy regimen independently.

No limits apply while in a skilled nursing facility for the primary purpose of rehabilitation, an inpatient hospital or an inpatient rehabilitation unit.

Spinal cord injuries, traumatic brain injuries, or cerebral vascular accidents are not subject to the visit limitations during the first year after an acute injury.

Line:	All Lines	Current and Recommended Lines w/ description	Current Lines	Recommendations	
Condition:	All Conditions			Add Lines	Remove Lines
Treatment:	All Treatments				
Z00.00	Encounter for general adult medical examination without abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z00.01	Encounter for general adult medical examination with abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z00.110	Health examination for newborn under 8 days old	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z00.111	Health examination for newborn 8 to 28 days old	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z00.121	Encounter for routine child health examination with abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z00.129	Encounter for routine child health examination without abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z00.2	Encounter for examination for period of rapid growth in childhood	Informational Diagnoses	Informational Diagnoses	3	Informational Diagnoses
Z00.3	Encounter for examination for adolescent development state	Informational Diagnoses	Informational Diagnoses	3	Informational Diagnoses
Z00.5	Encounter for examination of potential donor of organ and tissue	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z00.6	Encounter for examination for normal comparison and control in clinical research program	Conditions not covered file	Conditions not covered file		
Z00.70	Encounter for examination for period of delayed growth in childhood without abnormal findings	Informational Diagnoses	Informational Diagnoses	3	Informational Diagnoses
Z00.71	Encounter for examination for period of delayed growth in childhood with abnormal findings	Informational Diagnoses	Informational Diagnoses	3	Informational Diagnoses
Z00.8	Encounter for other general examination	Informational Diagnoses	Informational Diagnoses	3	Informational Diagnoses
Z01.00	Encounter for examination of eyes and vision without abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z01.01	Encounter for examination of eyes and vision with abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z01.10	Encounter for examination of ears and hearing without abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z01.110	Encounter for hearing examination following failed hearing screening	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		

Line:	All Lines			Recommendations	
Z01.118	Encounter for examination of ears and hearing with other abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z01.12	Encounter for hearing conservation and treatment	331: SENSORINEURAL HEARING LOSS 316: HEARING LOSS - AGE 5 OR UNDER 411: BILATERAL ANOMALIES OF EXTERNAL EAR WITH IMPAIRMENT OF HEARING 450: HEARING LOSS - OVER AGE OF FIVE 605: CONGENITAL ANOMALIES OF THE EAR WITHOUT IMPAIRMENT OF HEARING; UNILATERAL ANOMALIES OF THE EAR	331,316,411,450,605		
Z01.20	Encounter for dental examination and cleaning without abnormal findings	57: PREVENTIVE DENTAL SERVICES	57		
Z01.21	Encounter for dental examination and cleaning with abnormal findings	57: PREVENTIVE DENTAL SERVICES	57		
Z01.30	Encounter for examination of blood pressure without abnormal findings	DWF file	DWF file		
Z01.31	Encounter for examination of blood pressure with abnormal findings	DWF file	DWF file		
Z01.411	Encounter for gynecological examination (general) (routine) with abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z01.419	Encounter for gynecological examination (general) (routine) without abnormal findings	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z01.42	Encounter for cervical smear to confirm findings of recent normal smear following initial abnormal smear	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z01.810	Encounter for preprocedural cardiovascular examination	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z01.811	Encounter for preprocedural respiratory examination	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z01.812	Encounter for preprocedural laboratory examination	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z01.818	Encounter for other preprocedural examination	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z01.82	Encounter for allergy testing	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z01.83	Encounter for blood typing	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z01.84	Encounter for antibody response examination	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z01.89	Encounter for other specified special examinations	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z02.0	Encounter for examination for admission to educational institution	Conditions not covered file	Conditions not covered file		
Z02.1	Encounter for pre-employment examination	Conditions not covered file	Conditions not covered file		

Line:	All Lines			Recommendations	
Z02.2	Encounter for examination for admission to residential institution	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z02.3	Encounter for examination for recruitment to armed forces	Conditions not covered file	Conditions not covered file		
Z02.4	Encounter for examination for driving license	Conditions not covered file	Conditions not covered file		
Z02.5	Encounter for examination for participation in sport	Conditions not covered file	Conditions not covered file		
Z02.6	Encounter for examination for insurance purposes	Conditions not covered file	Conditions not covered file		
Z02.71	Encounter for disability determination	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z02.79	Encounter for issue of other medical certificate	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z02.81	Encounter for paternity testing	Conditions not covered file	Conditions not covered file		
Z02.82	Encounter for adoption services	Conditions not covered file	Conditions not covered file		
Z02.83	Encounter for blood-alcohol and blood-drug test	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z02.89	Encounter for other administrative examinations	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z02.9	Encounter for administrative examinations, unspecified	Informational Diagnoses	Informational Diagnoses		
Z03.6	Encounter for observation for suspected toxic effect from ingested substance ruled out	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z03.71	Encounter for suspected problem with amniotic cavity and membrane ruled out	1: PREGNANCY	1		
Z03.72	Encounter for suspected placental problem ruled out	1: PREGNANCY	1		
Z03.73	Encounter for suspected fetal anomaly ruled out	1: PREGNANCY	1		
Z03.74	Encounter for suspected problem with fetal growth ruled out	1: PREGNANCY	1		
Z03.75	Encounter for suspected cervical shortening ruled out	1: PREGNANCY	1		
Z03.79	Encounter for other suspected maternal and fetal conditions ruled out	1: PREGNANCY	1		
Z03.810	Encounter for observation for suspected exposure to anthrax ruled out	211: ZOONOTIC BACTERIAL DISEASES	211		
Z03.818	Encounter for observation for suspected exposure to other biological agents ruled out	211: ZOONOTIC BACTERIAL DISEASES	211		
Z03.89	Encounter for observation for other suspected diseases and conditions ruled out	DIAGNOSTIC PROCEDURES FILE	DIAGNOSTIC PROCEDURES FILE	DWF	DIAGNOSTIC PROCEDURES FILE
Z04.1	Encounter for examination and observation following transport accident	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z04.2	Encounter for examination and observation following work accident	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z04.3	Encounter for examination and observation following other accident	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z04.41	Encounter for examination and observation following alleged adult rape	125: ABUSE AND NEGLECT	125		
Z04.42	Encounter for examination and observation following alleged child rape	125: ABUSE AND NEGLECT	125		
Z04.6	Encounter for general psychiatric examination, requested by authority	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z04.71	Encounter for examination and observation following alleged adult physical abuse	125: ABUSE AND NEGLECT	125		
Z04.72	Encounter for examination and observation following alleged child physical abuse	125: ABUSE AND NEGLECT	125		
Z04.8	Encounter for examination and observation for other specified reasons	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z04.9	Encounter for examination and observation for unspecified reason	Informational Diagnoses	Informational Diagnoses	Undefined	Informational Diagnoses
Z08	Encounter for follow-up examination after completed treatment for malignant neoplasm	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z09	Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z11.0	Encounter for screening for intestinal infectious diseases	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z11.1	Encounter for screening for respiratory tuberculosis	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z11.2	Encounter for screening for other bacterial diseases	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z11.4	Encounter for screening for human immunodeficiency virus [HIV]	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z11.51	Encounter for screening for human papillomavirus (HPV)	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z11.59	Encounter for screening for other viral diseases	Informational Diagnoses	Informational Diagnoses		
Z11.6	Encounter for screening for other protozoal diseases and helminthiases	Informational Diagnoses	Informational Diagnoses		
Z11.8	Encounter for screening for other infectious and parasitic diseases	Informational Diagnoses	Informational Diagnoses		
Z11.9	Encounter for screening for infectious and parasitic diseases, unspecified	Informational Diagnoses	Informational Diagnoses		
Z12.0	Encounter for screening for malignant neoplasm of stomach	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z12.10	Encounter for screening for malignant neoplasm of intestinal tract, unspecified	Informational Diagnoses	Informational Diagnoses		
Z12.11	Encounter for screening for malignant neoplasm of colon	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z12.12	Encounter for screening for malignant neoplasm of rectum	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z12.13	Encounter for screening for malignant neoplasm of small intestine	Informational Diagnoses	Informational Diagnoses		
Z12.2	Encounter for screening for malignant neoplasm of respiratory organs	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z12.39	Encounter for other screening for malignant neoplasm of breast	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z12.4	Encounter for screening for malignant neoplasm of cervix	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z12.5	Encounter for screening for malignant neoplasm of prostate	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z12.6	Encounter for screening for malignant neoplasm of bladder	Informational Diagnoses	Informational Diagnoses		
Z12.71	Encounter for screening for malignant neoplasm of testis	Informational Diagnoses	Informational Diagnoses		
Z12.72	Encounter for screening for malignant neoplasm of vagina	Informational Diagnoses	Informational Diagnoses		
Z12.73	Encounter for screening for malignant neoplasm of ovary	Informational Diagnoses	Informational Diagnoses		
Z12.79	Encounter for screening for malignant neoplasm of other genitourinary organs	Informational Diagnoses	Informational Diagnoses		
Z12.81	Encounter for screening for malignant neoplasm of oral cavity	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z12.82	Encounter for screening for malignant neoplasm of nervous system	Informational Diagnoses	Informational Diagnoses		
Z12.83	Encounter for screening for malignant neoplasm of skin	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z12.89	Encounter for screening for malignant neoplasm of other sites	Informational Diagnoses	Informational Diagnoses		
Z12.9	Encounter for screening for malignant neoplasm, site unspecified	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z13.0	Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	Informational Diagnoses	Informational Diagnoses		
Z13.1	Encounter for screening for diabetes mellitus	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z13.21	Encounter for screening for nutritional disorder	Informational Diagnoses	Informational Diagnoses		
Z13.220	Encounter for screening for lipoid disorders	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z13.228	Encounter for screening for other metabolic disorders	Informational Diagnoses	Informational Diagnoses		
Z13.29	Encounter for screening for other suspected endocrine disorder	Informational Diagnoses	Informational Diagnoses		
Z13.4	Encounter for screening for certain developmental disorders in childhood	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z13.5	Encounter for screening for eye and ear disorders	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z13.6	Encounter for screening for cardiovascular disorders	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z13.71	Encounter for nonprocreative screening for genetic disease carrier status	DWF file	DWF file		
Z13.79	Encounter for other screening for genetic and chromosomal anomalies	DWF file	DWF file		
Z13.810	Encounter for screening for upper gastrointestinal disorder	Informational Diagnoses	Informational Diagnoses		
Z13.811	Encounter for screening for lower gastrointestinal disorder	Informational Diagnoses	Informational Diagnoses		
Z13.818	Encounter for screening for other digestive system disorders	Informational Diagnoses	Informational Diagnoses		
Z13.820	Encounter for screening for osteoporosis	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z13.828	Encounter for screening for other musculoskeletal disorder	Informational Diagnoses	Informational Diagnoses		
Z13.83	Encounter for screening for respiratory disorder NEC	Informational Diagnoses	Informational Diagnoses		
Z13.84	Encounter for screening for dental disorders	Informational Diagnoses	Informational Diagnoses		
Z13.850	Encounter for screening for traumatic brain injury	Informational Diagnoses	Informational Diagnoses		
Z13.858	Encounter for screening for other nervous system disorders	Informational Diagnoses	Informational Diagnoses		
Z13.88	Encounter for screening for disorder due to exposure to contaminants	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		

Line:	All Lines			Recommendations	
Z13.89	Encounter for screening for other disorder	Informational Diagnoses	Informational Diagnoses		
Z13.9	Encounter for screening, unspecified	Informational Diagnoses	Informational Diagnoses		
Z14.01	Asymptomatic hemophilia A carrier	DWF file	DWF file		
Z14.02	Symptomatic hemophilia A carrier	114: COAGULATION DEFECTS	114		
Z14.1	Cystic fibrosis carrier	Informational Diagnoses	Informational Diagnoses		
Z14.8	Genetic carrier of other disease	Informational Diagnoses	Informational Diagnoses		
Z15.01	Genetic susceptibility to malignant neoplasm of breast	Informational Diagnoses	Informational Diagnoses		
Z15.02	Genetic susceptibility to malignant neoplasm of ovary	Informational Diagnoses	Informational Diagnoses		
Z15.03	Genetic susceptibility to malignant neoplasm of prostate	Informational Diagnoses	Informational Diagnoses		
Z15.04	Genetic susceptibility to malignant neoplasm of endometrium	Informational Diagnoses	Informational Diagnoses		
Z15.09	Genetic susceptibility to other malignant neoplasm	Informational Diagnoses	Informational Diagnoses		
Z15.81	Genetic susceptibility to multiple endocrine neoplasia [MEN]	Informational Diagnoses	Informational Diagnoses		
Z15.89	Genetic susceptibility to other disease	Informational Diagnoses	Informational Diagnoses		
Z16.10	Resistance to unspecified beta lactam antibiotics	Informational Diagnoses	Informational Diagnoses		
Z16.11	Resistance to penicillins	Informational Diagnoses	Informational Diagnoses		
Z16.12	Extended spectrum beta lactamase (ESBL) resistance	Informational Diagnoses	Informational Diagnoses		
Z16.19	Resistance to other specified beta lactam antibiotics	Informational Diagnoses	Informational Diagnoses		
Z16.20	Resistance to unspecified antibiotic	Informational Diagnoses	Informational Diagnoses		
Z16.21	Resistance to vancomycin	Informational Diagnoses	Informational Diagnoses		
Z16.22	Resistance to vancomycin related antibiotics	Informational Diagnoses	Informational Diagnoses		
Z16.23	Resistance to quinolones and fluoroquinolones	Informational Diagnoses	Informational Diagnoses		
Z16.24	Resistance to multiple antibiotics	Informational Diagnoses	Informational Diagnoses		
Z16.29	Resistance to other single specified antibiotic	Informational Diagnoses	Informational Diagnoses		
Z16.30	Resistance to unspecified antimicrobial drugs	Informational Diagnoses	Informational Diagnoses		
Z16.31	Resistance to antiparasitic drug(s)	Informational Diagnoses	Informational Diagnoses		
Z16.32	Resistance to antifungal drug(s)	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z16.33	Resistance to antiviral drug(s)	Informational Diagnoses	Informational Diagnoses		
Z16.341	Resistance to single antimycobacterial drug	Informational Diagnoses	Informational Diagnoses		
Z16.342	Resistance to multiple antimycobacterial drugs	Informational Diagnoses	Informational Diagnoses		
Z16.35	Resistance to multiple antimicrobial drugs	Informational Diagnoses	Informational Diagnoses		
Z16.39	Resistance to other specified antimicrobial drug	Informational Diagnoses	Informational Diagnoses		
Z17.0	Estrogen receptor positive status [ER+]	Informational Diagnoses	Informational Diagnoses		
Z17.1	Estrogen receptor negative status [ER-]	Informational Diagnoses	Informational Diagnoses		
Z18.01	Retained depleted uranium fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.09	Other retained radioactive fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.10	Retained metal fragments, unspecified	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.11	Retained magnetic metal fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.12	Retained nonmagnetic metal fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.2	Retained plastic fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.31	Retained animal quills or spines	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.32	Retained tooth	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.33	Retained wood fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.39	Other retained organic fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.81	Retained glass fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.83	Retained stone or crystalline fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		

Line:	All Lines			Recommendations	
Z18.89	Other specified retained foreign body fragments	444: RESIDUAL FOREIGN BODY IN SOFT TISSUE	444		
Z18.9	Retained foreign body fragments, unspecified material	Undefined conditions	Undefined conditions		
Z20.01	Contact with and (suspected) exposure to intestinal infectious diseases due to Escherichia coli (E. coli)	Informational Diagnoses	Informational Diagnoses		
Z20.09	Contact with and (suspected) exposure to other intestinal infectious diseases	Informational Diagnoses	Informational Diagnoses		
Z20.1	Contact with and (suspected) exposure to tuberculosis	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.3	Contact with and (suspected) exposure to rabies	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.4	Contact with and (suspected) exposure to rubella	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.5	Contact with and (suspected) exposure to viral hepatitis	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.7	Contact with and (suspected) exposure to pediculosis, acariasis and other infestations	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.810	Contact with and (suspected) exposure to anthrax	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.811	Contact with and (suspected) exposure to meningococcus	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.818	Contact with and (suspected) exposure to other bacterial communicable diseases	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.820	Contact with and (suspected) exposure to varicella	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z20.89	Contact with and (suspected) exposure to other communicable diseases	Informational Diagnoses	Informational Diagnoses	3	Informational Diagnoses
Z20.9	Contact with and (suspected) exposure to unspecified communicable disease	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status	12: HIV DISEASE (INCLUDING ACQUIRED IMMUNODEFICIENCY SYNDROME) AND RELATED OPPORTUNISTIC INFECTIONS	12		
Z22.0	Carrier of typhoid	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.1	Carrier of other intestinal infectious diseases	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.2	Carrier of diphtheria	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.31	Carrier of bacterial disease due to meningococci	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.321	Carrier or suspected carrier of Methicillin susceptible Staphylococcus aureus	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.322	Carrier or suspected carrier of Methicillin resistant Staphylococcus aureus	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.330	Carrier of Group B streptococcus	1: PREGNANCY	1		
Z22.338	Carrier of other streptococcus	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.39	Carrier of other specified bacterial diseases	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.4	Carrier of infections with a predominantly sexual mode of transmission	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.50	Carrier of unspecified viral hepatitis	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.51	Carrier of viral hepatitis B	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		

Line:	All Lines			Recommendations	
Z22.52	Carrier of viral hepatitis C	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.59	Carrier of other viral hepatitis	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.6	Carrier of human T-lymphotropic virus type-1 [HTLV-1] infection	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.8	Carrier of other infectious diseases	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z22.9	Carrier of infectious disease, unspecified	Informational Diagnoses	Informational Diagnoses	625	Informational Diagnoses
Z23	Encounter for immunization	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z28.01	Immunization not carried out because of acute illness of patient	Informational Diagnoses	Informational Diagnoses		
Z28.02	Immunization not carried out because of chronic illness or condition of patient	Informational Diagnoses	Informational Diagnoses		
Z28.03	Immunization not carried out because of immune compromised state of patient	Informational Diagnoses	Informational Diagnoses		
Z28.04	Immunization not carried out because of patient allergy to vaccine or component	Informational Diagnoses	Informational Diagnoses		
Z28.09	Immunization not carried out because of other contraindication	Informational Diagnoses	Informational Diagnoses		
Z28.1	Immunization not carried out because of patient decision for reasons of belief or group pressure	Informational Diagnoses	Informational Diagnoses		
Z28.20	Immunization not carried out because of patient decision for unspecified reason	Informational Diagnoses	Informational Diagnoses		
Z28.21	Immunization not carried out because of patient refusal	Informational Diagnoses	Informational Diagnoses		
Z28.29	Immunization not carried out because of patient decision for other reason	Informational Diagnoses	Informational Diagnoses		
Z28.3	Underimmunization status	Informational Diagnoses	Informational Diagnoses		
Z28.81	Immunization not carried out due to patient having had the disease	Informational Diagnoses	Informational Diagnoses		
Z28.82	Immunization not carried out because of caregiver refusal	Informational Diagnoses	Informational Diagnoses		
Z28.89	Immunization not carried out for other reason	Informational Diagnoses	Informational Diagnoses		
Z28.9	Immunization not carried out for unspecified reason	Informational Diagnoses	Informational Diagnoses		
Z30.011	Encounter for initial prescription of contraceptive pills	6: REPRODUCTIVE SERVICES	6		

Line:	All Lines			Recommendations	
Z30.012	Encounter for prescription of emergency contraception	6: REPRODUCTIVE SERVICES	6		
Z30.013	Encounter for initial prescription of injectable contraceptive	6: REPRODUCTIVE SERVICES	6		
Z30.014	Encounter for initial prescription of intrauterine contraceptive device	6: REPRODUCTIVE SERVICES	6		
Z30.018	Encounter for initial prescription of other contraceptives	6: REPRODUCTIVE SERVICES	6		
Z30.019	Encounter for initial prescription of contraceptives, unspecified	6: REPRODUCTIVE SERVICES	6		
Z30.02	Counseling and instruction in natural family planning to avoid pregnancy	6: REPRODUCTIVE SERVICES	6		
Z30.09	Encounter for other general counseling and advice on contraception	6: REPRODUCTIVE SERVICES	6		
Z30.2	Encounter for sterilization	6: REPRODUCTIVE SERVICES	6		
Z30.40	Encounter for surveillance of contraceptives, unspecified	6: REPRODUCTIVE SERVICES	6		
Z30.41	Encounter for surveillance of contraceptive pills	6: REPRODUCTIVE SERVICES	6		
Z30.42	Encounter for surveillance of injectable contraceptive	6: REPRODUCTIVE SERVICES	6		
Z30.430	Encounter for insertion of intrauterine contraceptive device	6: REPRODUCTIVE SERVICES	6		
Z30.431	Encounter for routine checking of intrauterine contraceptive device	6: REPRODUCTIVE SERVICES	6		
Z30.432	Encounter for removal of intrauterine contraceptive device	6: REPRODUCTIVE SERVICES	6		
Z30.433	Encounter for removal and reinsertion of intrauterine contraceptive device	6: REPRODUCTIVE SERVICES	6		
Z30.49	Encounter for surveillance of other contraceptives	6: REPRODUCTIVE SERVICES	6		
Z30.8	Encounter for other contraceptive management	6: REPRODUCTIVE SERVICES 39: TERMINATION OF PREGNANCY	6,39		
Z30.9	Encounter for contraceptive management, unspecified	6: REPRODUCTIVE SERVICES	6		
Z31.0	Encounter for reversal of previous sterilization	Conditions not covered file	Conditions not covered file		
Z31.41	Encounter for fertility testing	Conditions not covered file	Conditions not covered file		
Z31.42	Aftercare following sterilization reversal	Conditions not covered file	Conditions not covered file		
Z31.430	Encounter of female for testing for genetic disease carrier status for procreative management	DWF file	DWF file		
Z31.438	Encounter for other genetic testing of female for procreative management	DWF file	DWF file		
Z31.440	Encounter of male for testing for genetic disease carrier status for procreative management	DWF file	DWF file		

Line:	All Lines			Recommendations	
Z31.441	Encounter for testing of male partner of patient with recurrent pregnancy loss	Undefined conditions	Undefined conditions	Conditions Not Covered	Undefined conditions
Z31.448	Encounter for other genetic testing of male for procreative management	DWF file	DWF file		
Z31.49	Encounter for other procreative investigation and testing	Informational Diagnoses	Informational Diagnoses	Conditions Not Covered	Informational Diagnoses
Z31.5	Encounter for genetic counseling	DWF file	DWF file		
Z31.61	Procreative counseling and advice using natural family planning	6: REPRODUCTIVE SERVICES	6		
Z31.62	Encounter for fertility preservation counseling	6: REPRODUCTIVE SERVICES	6		
Z31.69	Encounter for other general counseling and advice on procreation	6: REPRODUCTIVE SERVICES	6		
Z31.81	Encounter for male factor infertility in female patient	Conditions not covered file	Conditions not covered file		
Z31.82	Encounter for Rh incompatibility status	1: PREGNANCY 67: SPONTANEOUS ABORTION; MISSED ABORTION	1,67		
Z31.83	Encounter for assisted reproductive fertility procedure cycle	Conditions not covered file	Conditions not covered file		
Z31.84	Encounter for fertility preservation procedure	Conditions not covered file	Conditions not covered file		
Z31.89	Encounter for other procreative management	Conditions not covered file	Conditions not covered file		
Z31.9	Encounter for procreative management, unspecified	Conditions not covered file	Conditions not covered file		
Z32.00	Encounter for pregnancy test, result unknown	1: PREGNANCY	1		
Z32.01	Encounter for pregnancy test, result positive	1: PREGNANCY	1		
Z32.02	Encounter for pregnancy test, result negative	1: PREGNANCY	1		
Z32.2	Encounter for childbirth instruction	Conditions not covered file	Conditions not covered file		
Z38.68	Other multiple liveborn infant, delivered vaginally	2: BIRTH OF INFANT	2		
Z38.69	Other multiple liveborn infant, delivered by cesarean	2: BIRTH OF INFANT	2		
Z38.7	Other multiple liveborn infant, born outside hospital	2: BIRTH OF INFANT	2		
Z38.8	Other multiple liveborn infant, unspecified as to place of birth	2: BIRTH OF INFANT	2		
Z39.0	Encounter for care and examination of mother immediately after delivery	1: PREGNANCY	1		
Z39.1	Encounter for care and examination of lactating mother	1: PREGNANCY 3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	1,3		

Line:	All Lines			Recommendations	
Z39.2	Encounter for routine postpartum follow-up	1: PREGNANCY 6: REPRODUCTIVE SERVICES	1,6		
Z40.00	Encounter for prophylactic removal of unspecified organ	Informational Diagnoses	Informational Diagnoses		
Z40.01	Encounter for prophylactic removal of breast	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z40.02	Encounter for prophylactic removal of ovary	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z40.09	Encounter for prophylactic removal of other organ	Informational Diagnoses	Informational Diagnoses		
Z40.8	Encounter for other prophylactic surgery	Informational Diagnoses	Informational Diagnoses		
Z40.9	Encounter for prophylactic surgery, unspecified	Informational Diagnoses	Informational Diagnoses		
Z41.1	Encounter for cosmetic surgery	Conditions not covered file	Conditions not covered file		
Z41.2	Encounter for routine and ritual male circumcision	629: REDUNDANT PREPUCE	629		
Z41.3	Encounter for ear piercing	Conditions not covered file	Conditions not covered file		
Z41.8	Encounter for other procedures for purposes other than remedying health state	Conditions not covered file	Conditions not covered file		
Z41.9	Encounter for procedure for purposes other than remedying health state, unspecified	Conditions not covered file	Conditions not covered file		
Z42.1	Encounter for breast reconstruction following mastectomy	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z42.8	Encounter for other plastic and reconstructive surgery following medical procedure or healed injury	Informational Diagnoses	Informational Diagnoses		
Z43.0	Encounter for attention to tracheostomy	75: NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES	75		
Z43.1	Encounter for attention to gastrostomy	75: NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES	75		

Line:	All Lines			Recommendations	
Z43.2	Encounter for attention to ileostomy	75: NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES	75		
Z43.3	Encounter for attention to colostomy	75: NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES	75		
Z43.4	Encounter for attention to other artificial openings of digestive tract	75: NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES	75		
Z43.5	Encounter for attention to cystostomy	332: FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION	332		
Z43.6	Encounter for attention to other artificial openings of urinary tract	332: FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION	332		
Z43.7	Encounter for attention to artificial vagina	358: STRUCTURAL CAUSES OF AMENORRHEA	358		
Z43.8	Encounter for attention to other artificial openings	75: NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES	75		
Z43.9	Encounter for attention to unspecified artificial opening	Undefined conditions	Undefined conditions		
Z44.001	Encounter for fitting and adjustment of unspecified right artificial arm	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z44.002	Encounter for fitting and adjustment of unspecified left artificial arm	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.009	Encounter for fitting and adjustment of unspecified artificial arm, unspecified arm	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.011	Encounter for fitting and adjustment of complete right artificial arm	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.012	Encounter for fitting and adjustment of complete left artificial arm	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.019	Encounter for fitting and adjustment of complete artificial arm, unspecified arm	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.021	Encounter for fitting and adjustment of partial artificial right arm	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.022	Encounter for fitting and adjustment of partial artificial left arm	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z44.029	Encounter for fitting and adjustment of partial artificial arm, unspecified arm	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.101	Encounter for fitting and adjustment of unspecified right artificial leg	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.102	Encounter for fitting and adjustment of unspecified left artificial leg	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.109	Encounter for fitting and adjustment of unspecified artificial leg, unspecified leg	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.111	Encounter for fitting and adjustment of complete right artificial leg	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.112	Encounter for fitting and adjustment of complete left artificial leg	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.119	Encounter for fitting and adjustment of complete artificial leg, unspecified leg	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z44.121	Encounter for fitting and adjustment of partial artificial right leg	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.122	Encounter for fitting and adjustment of partial artificial left leg	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.129	Encounter for fitting and adjustment of partial artificial leg, unspecified leg	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.20	Encounter for fitting and adjustment of artificial eye, unspecified	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.21	Encounter for fitting and adjustment of artificial right eye	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.22	Encounter for fitting and adjustment of artificial left eye	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.30	Encounter for fitting and adjustment of external breast prosthesis, unspecified breast	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z44.31	Encounter for fitting and adjustment of external right breast prosthesis	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z44.32	Encounter for fitting and adjustment of external left breast prosthesis	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		

Line:	All Lines			Recommendations	
Z44.8	Encounter for fitting and adjustment of other external prosthetic devices	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z44.9	Encounter for fitting and adjustment of unspecified external prosthetic device	Informational Diagnoses	Informational Diagnoses		
Z45.010	Encounter for checking and testing of cardiac pacemaker pulse generator [battery]	73: ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 103: CARDIOMYOPATHY 115: CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 193: CHRONIC ISCHEMIC HEART DISEASE 286: LIFE-THREATENING CARDIAC ARRHYTHMIAS 290: COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 352: CARDIAC ARRHYTHMIAS	73,103,115,193,286,290,352		
Z45.018	Encounter for adjustment and management of other part of cardiac pacemaker	73: ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 103: CARDIOMYOPATHY 115: CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 193: CHRONIC ISCHEMIC HEART DISEASE 286: LIFE-THREATENING CARDIAC ARRHYTHMIAS 290: COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 352: CARDIAC ARRHYTHMIAS	73,103,115,193,286,290,352		

Line:	All Lines			Recommendations	
Z45.02	Encounter for adjustment and management of automatic implantable cardiac defibrillator	73: ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 103: CARDIOMYOPATHY 115: CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 193: CHRONIC ISCHEMIC HEART DISEASE 286: LIFE-THREATENING CARDIAC ARRHYTHMIAS 290: COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 352: CARDIAC ARRHYTHMIAS	73,103,115,193,286,290,352		
Z45.09	Encounter for adjustment and management of other cardiac device	73: ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 86 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 102 HEART FAILURE 103: CARDIOMYOPATHY 115: CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 193: CHRONIC ISCHEMIC HEART DISEASE 268 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE 286: LIFE-THREATENING CARDIAC ARRHYTHMIAS 290: COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 352: CARDIAC ARRHYTHMIAS	73,103,115,193,286,290,352	86, 102, 268	
Z45.1	Encounter for adjustment and management of infusion pump	DWF file	DWF file	Ancillary	DWF
Z45.2	Encounter for adjustment and management of vascular access device	DWF file	DWF file	Ancillary	DWF

Line:	All Lines			Recommendations	
Z45.31	Encounter for adjustment and management of implanted visual substitution device	178: GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 256: MULTIPLE SCLEROSIS AND OTHER DEMYELINATING DISEASES OF CENTRAL NERVOUS SYSTEM 367: DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM AND STENOSIS	178,256,367	Informational	178, 256, 367
Z45.320	Encounter for adjustment and management of bone conduction device	331: SENSORINEURAL HEARING LOSS	331		
Z45.321	Encounter for adjustment and management of cochlear device	331: SENSORINEURAL HEARING LOSS	331		
Z45.328	Encounter for adjustment and management of other implanted hearing device	331: SENSORINEURAL HEARING LOSS	331		
Z45.41	Encounter for adjustment and management of cerebrospinal fluid drainage device	20: HYDROCEPHALUS AND BENIGN INTRACRANIAL HYPERTENSION	20		
Z45.42	Encounter for adjustment and management of neuropacemaker (brain) (peripheral nerve) (spinal cord)	178: GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 428: COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT 446: TRIGEMINAL AND OTHER NERVE DISORDERS 490: PERIPHERAL ENTHESOPATHIES 607: DISORDERS OF SOFT TISSUE	428,446,490,607	178	
Z45.49	Encounter for adjustment and management of other implanted nervous system device	178: GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 256: MULTIPLE SCLEROSIS AND OTHER DEMYELINATING DISEASES OF CENTRAL NERVOUS SYSTEM 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 367: DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM AND STENOSIS	178,256,367	297	367
Z45.811	Encounter for adjustment or removal of right breast implant	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z45.812	Encounter for adjustment or removal of left breast implant	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		

Line:	All Lines			Recommendations	
Z45.819	Encounter for adjustment or removal of unspecified breast implant	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z45.82	Encounter for adjustment or removal of myringotomy device (stent) (tube)	Informational Diagnoses 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT	Informational Diagnoses	428	Informational Diagnoses
Z45.89	Encounter for adjustment and management of other implanted devices	DWF file	DWF file		
Z45.9	Encounter for adjustment and management of unspecified implanted device	Informational Diagnoses	Informational Diagnoses		
Z46.0	Encounter for fitting and adjustment of spectacles and contact lenses	455: DISORDERS OF REFRACTION AND ACCOMMODATION	455		
Z46.1	Encounter for fitting and adjustment of hearing aid	316: HEARING LOSS - AGE 5 OR UNDER 450: HEARING LOSS - OVER AGE OF FIVE	316,450		
Z46.2	Encounter for fitting and adjustment of other devices related to nervous system and special senses	178: GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 256: MULTIPLE SCLEROSIS AND OTHER DEMYELINATING DISEASES OF CENTRAL NERVOUS SYSTEM 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 367: DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM AND STENOSIS	178,256,367	297	367
Z46.3	Encounter for fitting and adjustment of dental prosthetic device	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z46.4	Encounter for fitting and adjustment of orthodontic device	621: DENTAL CONDITIONS (EG. MALOCCLUSION)	621		
Z46.51	Encounter for fitting and adjustment of gastric lap band	30: TYPE 2 DIABETES MELLITUS	30		

Line:	All Lines			Recommendations	
Z46.59	Encounter for fitting and adjustment of other gastrointestinal appliance and device	32: REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 46: INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION 75: NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 92: NECROTIZING ENTEROCOLITIS IN FETUS OR NEWBORN 105: CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 158: VASCULAR INSUFFICIENCY OF INTESTINE 161: CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 383: ESOPHAGEAL STRICTURE; ACHALASIA	32,46,75,92,105,158,161,383		
Z46.6	Encounter for fitting and adjustment of urinary device	332: FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION	332		
Z46.81	Encounter for fitting and adjustment of insulin pump	8: TYPE 1 DIABETES MELLITUS	8		
Z46.82	Encounter for fitting and adjustment of non-vascular catheter	DWF file	DWF file		
Z46.89	Encounter for fitting and adjustment of other specified devices	Informational Diagnoses 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	Informational Diagnoses	297,382	Informational Diagnoses
Z46.9	Encounter for fitting and adjustment of unspecified device	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z47.1	Aftercare following joint replacement surgery	85: FRACTURE OF HIP 364: DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS 297: NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 447: MALUNION AND NONUNION OF FRACTURE	85,364,297,447		
Z47.2	Encounter for removal of internal fixation device	85: FRACTURE OF HIP 136: OPEN FRACTURE/DISLOCATION OF EXTREMITIES 154: CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR UNSTABLE; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY 187: FRACTURE OF PELVIS, OPEN AND CLOSED 360: CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES) 482: CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY	85,136,154,187,360,482		
Z47.31	Aftercare following explantation of shoulder joint prosthesis	423: DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6	423		
Z47.32	Aftercare following explantation of hip joint prosthesis	85: FRACTURE OF HIP 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 314: CONGENITAL DISLOCATION OF HIP; COXA VARA AND VALGA 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT	85,314	290, 428	85,314

Line:	All Lines			Recommendations	
Z47.33	Aftercare following explantation of knee joint prosthesis	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 364: DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT	364	290, 428	364
Z47.81	Encounter for orthopedic aftercare following surgical amputation	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z47.82	Encounter for orthopedic aftercare following scoliosis surgery	366: SCOLIOSIS	366		
Z47.89	Encounter for other orthopedic aftercare	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.00	Encounter for change or removal of nonsurgical wound dressing	DWF file	DWF file		
Z48.01	Encounter for change or removal of surgical wound dressing	DWF file	DWF file		
Z48.02	Encounter for removal of sutures	DWF file	DWF file		
Z48.03	Encounter for change or removal of drains	DWF file	DWF file		
Z48.1	Encounter for planned postprocedural wound closure	DWF file	DWF file		
Z48.21	Encounter for aftercare following heart transplant	245: CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION 268: CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE	245,268		
Z48.22	Encounter for aftercare following kidney transplant	88: DIABETES MELLITUS WITH END STAGE RENAL DISEASE 104: END STAGE RENAL DISEASE 312: CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE	88,104,312		

Line:	All Lines			Recommendations	
Z48.23	Encounter for aftercare following liver transplant	166: BILIARY ATRESIA 244: SHORT BOWEL SYNDROME - AGE 5 OR UNDER 246: ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM (EG. MAPLE SYRUP URINE DISEASE, TYROSINEMIA) 312: CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE 565: CANCER OF LIVER AND INTRAHEPATIC BILE DUCTS	166,244,246,312,565		
Z48.24	Encounter for aftercare following lung transplant	245: CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION	245		
Z48.280	Encounter for aftercare following heart-lung transplant	245: CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION 268: CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE	245,268		
Z48.288	Encounter for aftercare following multiple organ transplant	88: DIABETES MELLITUS WITH END STAGE RENAL DISEASE 244: SHORT BOWEL SYNDROME - AGE 5 OR UNDER 268: CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE 312: CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE	88,244,268,312		

Line:	All Lines			Recommendations	
Z48.290	Encounter for aftercare following bone marrow transplant	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 118: APLASTIC ANEMIAS; AGRANULOCYTOSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,118,402,336,405		
Z48.298	Encounter for aftercare following other organ transplant	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.3	Aftercare following surgery for neoplasm	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.810	Encounter for surgical aftercare following surgery on the sense organs	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.811	Encounter for surgical aftercare following surgery on the nervous system	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.812	Encounter for surgical aftercare following surgery on the circulatory system	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.813	Encounter for surgical aftercare following surgery on the respiratory system	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.814	Encounter for surgical aftercare following surgery on the teeth or oral cavity	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.815	Encounter for surgical aftercare following surgery on the digestive system	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.816	Encounter for surgical aftercare following surgery on the genitourinary system	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.817	Encounter for surgical aftercare following surgery on the skin and subcutaneous tissue	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z48.89	Encounter for other specified surgical aftercare	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter	131: ACUTE KIDNEY INJURY 226: DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 344: CHRONIC KIDNEY DISEASE	131,226,344		

Line:	All Lines			Recommendations	
Z49.02	Encounter for fitting and adjustment of peritoneal dialysis catheter	131: ACUTE KIDNEY INJURY 226: DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 344: CHRONIC KIDNEY DISEASE	131,226,344		
Z49.31	Encounter for adequacy testing for hemodialysis	131: ACUTE KIDNEY INJURY 226: DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 344: CHRONIC KIDNEY DISEASE	131,226,344		
Z49.32	Encounter for adequacy testing for peritoneal dialysis	131: ACUTE KIDNEY INJURY 226: DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 344: CHRONIC KIDNEY DISEASE	131,226,344		
Z51.0	Encounter for antineoplastic radiation therapy	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER 280: CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA 446: TRIGEMINAL AND OTHER NERVE DISORDERS 239: ACUTE LYMPHOCYTIC LEUKEMIAS (ADULT) AND MULTIPLE MYELOMA 243: CANCER OF OVARY 213: CANCER OF UTERUS 215: CANCER OF THYROID 162: NON-HODGKIN'S LYMPHOMAS 263: CANCER OF PENIS AND OTHER MALE GENITAL ORGANS 264: CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME 266: CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY 267: CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS 97: CHILDHOOD LEUKEMIAS 116: CANCER OF TESTIS 117: CANCER OF EYE AND ORBIT 129: THYROTOXICOSIS WITH OR WITHOUT GOITER, ENDOCRINE EXOPHTHALMOS; CHRONIC THYROIDITIS 130: BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD 133: GRANULOMATOSIS WITH	195,280,446,239,243,213,215,162,263,264,266,267,97,116,117,129,130,133,137,139,161,204,205,219,220,234,275,291,292,299,319,320,321,347,377,439,464,561,403,119,242,402,424,406,334,606		

Line:	All Lines			Recommendations	
Z51.11	Encounter for antineoplastic chemotherapy	116: CANCER OF TESTIS 117: CANCER OF EYE AND ORBIT 137: CANCER OF CERVIX 161: CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER 204: CANCER OF SOFT TISSUE 205: CANCER OF BONES 213: CANCER OF UTERUS 215: CANCER OF THYROID 219: CANCER OF KIDNEY AND OTHER URINARY ORGANS 220: CANCER OF STOMACH 222: TESTICULAR CANCER 243: CANCER OF OVARY 263: CANCER OF PENIS AND OTHER MALE GENITAL ORGANS 264: CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME 266: CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY 267: CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS 275: CANCER OF BLADDER AND URETER 280: CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA 284: RETINAL DETACHMENT AND OTHER RETINAL DISORDERS	116,117,137,161,195,204,205,213,215,219,220,222,243,263,264,266,267,275,280,284,291,292,299,319,320,321,334,439,565		

Line:	All Lines			Recommendations	
Z51.12	Encounter for antineoplastic immunotherapy	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER 239: ACUTE LYMPHOCYTIC LEUKEMIAS (ADULT) AND MULTIPLE MYELOMA 243: CANCER OF OVARY 280: CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA 213: CANCER OF UTERUS 215: CANCER OF THYROID 162: NON-HODGKIN'S LYMPHOMAS 263: CANCER OF PENIS AND OTHER MALE GENITAL ORGANS 264: CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME 266: CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY 267: CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS 97: CHILDHOOD LEUKEMIAS 116: CANCER OF TESTIS 117: CANCER OF EYE AND ORBIT 130: BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD 137: CANCER OF CERVIX 139: HODGKIN'S DISEASE 161: CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 204: CANCER OF SOFT TISSUE 205: CANCER OF BONES	195,239,243,280,213,215,162,263,264,266,267,97,116,117,130,137,139,161,204,205,219,220,234,275,291,292,299,319,320,321,439,561,403,119,242,402,424,406,334		
Z51.5	Encounter for palliative care	DWF file	DWF file		
Z51.81	Encounter for therapeutic drug level monitoring	DWF file	DWF file		
Z51.89	Encounter for other specified aftercare	138: INTERRUPTED AORTIC ARCH	138	Informational	138

Line:	All Lines			Recommendations	
Z52.000	Unspecified donor, whole blood	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 118: APLASTIC ANEMIAS; AGRANULOCYTOSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,118,402,336,405		
Z52.001	Unspecified donor, stem cells	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 118: APLASTIC ANEMIAS; AGRANULOCYTOSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,118,402,336,405		
Z32.3	Encounter for childcare instruction	Conditions not covered file	Conditions not covered file		
Z33.1	Pregnant state, incidental	Informational Diagnoses	Informational Diagnoses		
Z33.2	Encounter for elective termination of pregnancy	39: TERMINATION OF PREGNANCY	39		
Z34.00	Encounter for supervision of normal first pregnancy, unspecified trimester	1: PREGNANCY	1		
Z34.01	Encounter for supervision of normal first pregnancy, first trimester	1: PREGNANCY	1		
Z34.02	Encounter for supervision of normal first pregnancy, second trimester	1: PREGNANCY	1		
Z34.03	Encounter for supervision of normal first pregnancy, third trimester	1: PREGNANCY	1		
Z34.80	Encounter for supervision of other normal pregnancy, unspecified trimester	1: PREGNANCY	1		
Z34.81	Encounter for supervision of other normal pregnancy, first trimester	1: PREGNANCY	1		
Z34.82	Encounter for supervision of other normal pregnancy, second trimester	1: PREGNANCY	1		

Line:	All Lines			Recommendations	
Z34.83	Encounter for supervision of other normal pregnancy, third trimester	1: PREGNANCY	1		
Z34.90	Encounter for supervision of normal pregnancy, unspecified, unspecified trimester	1: PREGNANCY	1		
Z34.91	Encounter for supervision of normal pregnancy, unspecified, first trimester	1: PREGNANCY	1		
Z34.92	Encounter for supervision of normal pregnancy, unspecified, second trimester	1: PREGNANCY	1		
Z34.93	Encounter for supervision of normal pregnancy, unspecified, third trimester	1: PREGNANCY	1		
Z36	Encounter for antenatal screening of mother	1: PREGNANCY	1		
Z3A.00	Weeks of gestation of pregnancy not specified	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.01	Less than 8 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.08	8 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.09	9 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.10	10 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.11	11 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.12	12 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.13	13 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.14	14 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.15	15 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.16	16 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.17	17 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		

Line:	All Lines			Recommendations	
Z3A.18	18 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.19	19 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.20	20 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.21	21 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.22	22 weeks gestation of pregnancy	1: PREGNANCY 39: TERMINATION OF PREGNANCY	1,39		
Z3A.23	23 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.24	24 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.25	25 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.26	26 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.27	27 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.28	28 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.29	29 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.30	30 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.31	31 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.32	32 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.33	33 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.34	34 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.35	35 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.36	36 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.37	37 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.38	38 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.39	39 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.40	40 weeks gestation of pregnancy	1: PREGNANCY	1		

Line:	All Lines			Recommendations	
Z3A.41	41 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.42	42 weeks gestation of pregnancy	1: PREGNANCY	1		
Z3A.49	Greater than 42 weeks gestation of pregnancy	1: PREGNANCY	1		
Z37.0	Single live birth	Informational Diagnoses	Informational Diagnoses		
Z37.1	Single stillbirth	Informational Diagnoses	Informational Diagnoses		
Z37.2	Twins, both liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.3	Twins, one liveborn and one stillborn	Informational Diagnoses	Informational Diagnoses		
Z37.4	Twins, both stillborn	Informational Diagnoses	Informational Diagnoses		
Z37.50	Multiple births, unspecified, all liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.51	Triplets, all liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.52	Quadruplets, all liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.53	Quintuplets, all liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.54	Sextuplets, all liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.59	Other multiple births, all liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.60	Multiple births, unspecified, some liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.61	Triplets, some liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.62	Quadruplets, some liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.63	Quintuplets, some liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.64	Sextuplets, some liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.69	Other multiple births, some liveborn	Informational Diagnoses	Informational Diagnoses		
Z37.7	Other multiple births, all stillborn	Informational Diagnoses	Informational Diagnoses		
Z37.9	Outcome of delivery, unspecified	Informational Diagnoses	Informational Diagnoses		
Z38.00	Single liveborn infant, delivered vaginally	2: BIRTH OF INFANT	2		
Z38.01	Single liveborn infant, delivered by cesarean	2: BIRTH OF INFANT	2		
Z38.1	Single liveborn infant, born outside hospital	2: BIRTH OF INFANT	2		
Z38.2	Single liveborn infant, unspecified as to place of birth	2: BIRTH OF INFANT	2		

Line:	All Lines			Recommendations	
Z38.30	Twin liveborn infant, delivered vaginally	2: BIRTH OF INFANT	2		
Z38.31	Twin liveborn infant, delivered by cesarean	2: BIRTH OF INFANT	2		
Z38.4	Twin liveborn infant, born outside hospital	2: BIRTH OF INFANT	2		
Z38.5	Twin liveborn infant, unspecified as to place of birth	2: BIRTH OF INFANT	2		
Z38.61	Triplet liveborn infant, delivered vaginally	2: BIRTH OF INFANT	2		
Z38.62	Triplet liveborn infant, delivered by cesarean	2: BIRTH OF INFANT	2		
Z38.63	Quadruplet liveborn infant, delivered vaginally	2: BIRTH OF INFANT	2		
Z38.64	Quadruplet liveborn infant, delivered by cesarean	2: BIRTH OF INFANT	2		
Z38.65	Quintuplet liveborn infant, delivered vaginally	2: BIRTH OF INFANT	2		
Z38.66	Quintuplet liveborn infant, delivered by cesarean	2: BIRTH OF INFANT	2		
Z53.29	Procedure and treatment not carried out because of patient's decision for other reasons	Informational Diagnoses	Informational Diagnoses		
Z53.8	Procedure and treatment not carried out for other reasons	Informational Diagnoses	Informational Diagnoses		
Z53.9	Procedure and treatment not carried out, unspecified reason	Informational Diagnoses	Informational Diagnoses		
Z55.0	Illiteracy and low-level literacy	Informational Diagnoses	Informational Diagnoses		
Z55.1	Schooling unavailable and unattainable	Informational Diagnoses	Informational Diagnoses		
Z55.2	Failed school examinations	Informational Diagnoses	Informational Diagnoses		
Z55.3	Underachievement in school	Informational Diagnoses	Informational Diagnoses		
Z55.4	Educational maladjustment and discord with teachers and classmates	Informational Diagnoses	Informational Diagnoses		
Z55.8	Other problems related to education and literacy	Informational Diagnoses	Informational Diagnoses		
Z55.9	Problems related to education and literacy, unspecified	Informational Diagnoses	Informational Diagnoses		
Z56.0	Unemployment, unspecified	Informational Diagnoses	Informational Diagnoses		
Z56.1	Change of job	Informational Diagnoses	Informational Diagnoses		
Z56.2	Threat of job loss	Informational Diagnoses	Informational Diagnoses		
Z56.3	Stressful work schedule	Informational Diagnoses	Informational Diagnoses		
Z56.4	Discord with boss and workmates	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z56.5	Uncongenial work environment	Informational Diagnoses	Informational Diagnoses		
Z56.6	Other physical and mental strain related to work	Informational Diagnoses	Informational Diagnoses		
Z56.81	Sexual harassment on the job	Informational Diagnoses	Informational Diagnoses		
Z56.82	Military deployment status	Informational Diagnoses	Informational Diagnoses		
Z56.89	Other problems related to employment	Informational Diagnoses	Informational Diagnoses		
Z56.9	Unspecified problems related to employment	Informational Diagnoses	Informational Diagnoses		
Z57.0	Occupational exposure to noise	Informational Diagnoses	Informational Diagnoses		
Z57.1	Occupational exposure to radiation	Informational Diagnoses	Informational Diagnoses		
Z57.2	Occupational exposure to dust	Informational Diagnoses	Informational Diagnoses		
Z57.31	Occupational exposure to environmental tobacco smoke	Informational Diagnoses	Informational Diagnoses		
Z57.39	Occupational exposure to other air contaminants	Informational Diagnoses	Informational Diagnoses		
Z57.4	Occupational exposure to toxic agents in agriculture	Informational Diagnoses	Informational Diagnoses		
Z57.5	Occupational exposure to toxic agents in other industries	Informational Diagnoses	Informational Diagnoses		
Z57.6	Occupational exposure to extreme temperature	Informational Diagnoses	Informational Diagnoses		
Z57.7	Occupational exposure to vibration	Informational Diagnoses	Informational Diagnoses		
Z57.8	Occupational exposure to other risk factors	Informational Diagnoses	Informational Diagnoses		
Z86.61	Personal history of infections of the central nervous system	Informational Diagnoses	Informational Diagnoses		
Z86.69	Personal history of other diseases of the nervous system and sense organs	Informational Diagnoses	Informational Diagnoses		
Z86.711	Personal history of pulmonary embolism	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z86.718	Personal history of other venous thrombosis and embolism	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z86.72	Personal history of thrombophlebitis	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits	420: TRANSIENT CEREBRAL ISCHEMIA; OCCLUSION/STENOSIS OF PRECEREBRAL ARTERIES WITHOUT OCCLUSION	420		
Z86.74	Personal history of sudden cardiac arrest	286: LIFE-THREATENING CARDIAC ARRHYTHMIAS	286		
Z86.79	Personal history of other diseases of the circulatory system	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z87.01	Personal history of pneumonia (recurrent)	Informational Diagnoses	Informational Diagnoses		
Z87.09	Personal history of other diseases of the respiratory system	Informational Diagnoses	Informational Diagnoses		
Z87.11	Personal history of peptic ulcer disease	Informational Diagnoses	Informational Diagnoses		
Z87.19	Personal history of other diseases of the digestive system	Informational Diagnoses	Informational Diagnoses		
Z87.2	Personal history of diseases of the skin and subcutaneous tissue	Informational Diagnoses	Informational Diagnoses		
Z87.310	Personal history of (healed) osteoporosis fracture	Informational Diagnoses	Informational Diagnoses		
Z87.311	Personal history of (healed) other pathological fracture	Informational Diagnoses	Informational Diagnoses		
Z87.312	Personal history of (healed) stress fracture	Informational Diagnoses	Informational Diagnoses		
Z87.39	Personal history of other diseases of the musculoskeletal system and connective tissue	Informational Diagnoses	Informational Diagnoses		
Z87.410	Personal history of cervical dysplasia	28: DYSPLASIA OF CERVIX AND CERVICAL CARCINOMA IN SITU, CERVICAL CONDYLOMA	28		
Z87.411	Personal history of vaginal dysplasia	Informational Diagnoses	Informational Diagnoses		
Z87.412	Personal history of vulvar dysplasia	Informational Diagnoses	Informational Diagnoses		
Z87.42	Personal history of other diseases of the female genital tract	Informational Diagnoses	Informational Diagnoses		
Z87.430	Personal history of prostatic dysplasia	Informational Diagnoses	Informational Diagnoses		
Z87.438	Personal history of other diseases of male genital organs	Informational Diagnoses	Informational Diagnoses		
Z87.440	Personal history of urinary (tract) infections	Informational Diagnoses	Informational Diagnoses		
Z87.441	Personal history of nephrotic syndrome	Informational Diagnoses	Informational Diagnoses		
Z87.442	Personal history of urinary calculi	Informational Diagnoses	Informational Diagnoses		
Z87.448	Personal history of other diseases of urinary system	Informational Diagnoses	Informational Diagnoses		
Z87.51	Personal history of pre-term labor	Informational Diagnoses	Informational Diagnoses	1	Informational Diagnoses
Z87.59	Personal history of other complications of pregnancy, childbirth and the puerperium	41: ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA	41	1	
Z87.710	Personal history of (corrected) hypospadias	Informational Diagnoses	Informational Diagnoses		
Z87.718	Personal history of other specified (corrected) congenital malformations of genitourinary system	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z87.720	Personal history of (corrected) congenital malformations of eye	Informational Diagnoses	Informational Diagnoses		
Z87.721	Personal history of (corrected) congenital malformations of ear	Informational Diagnoses	Informational Diagnoses		
Z98.86	Personal history of breast implant removal	Informational Diagnoses	Informational Diagnoses		
Z98.870	Personal history of in utero procedure during pregnancy	Informational Diagnoses	Informational Diagnoses		
Z98.871	Personal history of in utero procedure while a fetus	Informational Diagnoses	Informational Diagnoses		
Z98.89	Other specified postprocedural states	Informational Diagnoses	Informational Diagnoses		
Z99.0	Dependence on aspirator	Informational Diagnoses	Informational Diagnoses		
Z99.11	Dependence on respirator [ventilator] status	Informational Diagnoses	Informational Diagnoses		
Z99.12	Encounter for respirator [ventilator] dependence during power failure	DWF file	DWF file		
Z99.2	Dependence on renal dialysis	131: ACUTE KIDNEY INJURY	131	Informational	131
Z99.3	Dependence on wheelchair	Informational Diagnoses	Informational Diagnoses		
Z99.81	Dependence on supplemental oxygen	Informational Diagnoses	Informational Diagnoses		
Z99.89	Dependence on other enabling machines and devices	Informational Diagnoses	Informational Diagnoses		
Z52.008	Unspecified donor, other blood	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 118: APLASTIC ANEMIAS; AGRANULOCYTOSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,118,402,336,405		

Line:	All Lines			Recommendations	
Z52.010	Autologous donor, whole blood	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,402,336,405		
Z52.011	Autologous donor, stem cells	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,402,336,405		
Z52.018	Autologous donor, other blood	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,402,336,405		

Line:	All Lines			Recommendations	
Z52.090	Other blood donor, whole blood	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 118: APLASTIC ANEMIAS; AGRANULOCYTOSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,118,402,336,405		
Z52.091	Other blood donor, stem cells	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 118: APLASTIC ANEMIAS; AGRANULOCYTOSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,118,402,336,405		
Z52.098	Other blood donor, other blood	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 118: APLASTIC ANEMIAS; AGRANULOCYTOSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,118,402,336,405		
Z52.10	Skin donor, unspecified	Informational Diagnoses	Informational Diagnoses		
Z52.11	Skin donor, autologous	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z52.19	Skin donor, other	Informational Diagnoses	Informational Diagnoses		
Z52.20	Bone donor, unspecified	Informational Diagnoses	Informational Diagnoses		
Z52.21	Bone donor, autologous	Informational Diagnoses	Informational Diagnoses		
Z52.29	Bone donor, other	Informational Diagnoses	Informational Diagnoses		
Z52.3	Bone marrow donor	183: ACUTE LEUKEMIA, MYELODYSPLASTIC SYNDROME 99: HEREDITARY IMMUNE DEFICIENCIES 120: HODGKIN'S DISEASE 167: NON-HODGKIN'S LYMPHOMAS 265: MULTIPLE MYELOMA 222: TESTICULAR CANCER 293: OSTEOPETROSIS 118: APLASTIC ANEMIAS; AGRANULOCYTOSIS 402: ACUTE MYELOID LEUKEMIA 336: ACUTE PROMYELOCYTIC LEUKEMIA 405: CHRONIC MYELOID LEUKEMIA	183,99,120,167,265,222,293,118,402,336,405		
Z52.4	Kidney donor	104: END STAGE RENAL DISEASE	104		
Z52.5	Cornea donor	Informational Diagnoses	Informational Diagnoses		
Z52.6	Liver donor	166: BILIARY ATRESIA 246: ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM (EG. MAPLE SYRUP URINE DISEASE, TYROSINEMIA) 312: CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE 565: CANCER OF LIVER AND INTRAHEPATIC BILE DUCTS	166,246,312,565		
Z52.810	Egg (Oocyte) donor under age 35, anonymous recipient	Conditions not covered file	Conditions not covered file		
Z52.811	Egg (Oocyte) donor under age 35, designated recipient	Conditions not covered file	Conditions not covered file		
Z52.812	Egg (Oocyte) donor age 35 and over, anonymous recipient	Conditions not covered file	Conditions not covered file		
Z52.813	Egg (Oocyte) donor age 35 and over, designated recipient	Conditions not covered file	Conditions not covered file		
Z52.819	Egg (Oocyte) donor, unspecified	Conditions not covered file	Conditions not covered file		

Line:	All Lines			Recommendations	
Z52.89	Donor of other specified organs or tissues	Informational Diagnoses	Informational Diagnoses		
Z52.9	Donor of unspecified organ or tissue	Informational Diagnoses	Informational Diagnoses		
Z53.01	Procedure and treatment not carried out due to patient smoking	Informational Diagnoses	Informational Diagnoses		
Z53.09	Procedure and treatment not carried out because of other contraindication	Informational Diagnoses	Informational Diagnoses		
Z53.1	Procedure and treatment not carried out because of patient's decision for reasons of belief and group pressure	Informational Diagnoses	Informational Diagnoses		
Z53.20	Procedure and treatment not carried out because of patient's decision for unspecified reasons	Informational Diagnoses	Informational Diagnoses		
Z53.21	Procedure and treatment not carried out due to patient leaving prior to being seen by health care provider	Informational Diagnoses	Informational Diagnoses		
Z57.9	Occupational exposure to unspecified risk factor	Informational Diagnoses	Informational Diagnoses		
Z59.0	Homelessness	Informational Diagnoses	Informational Diagnoses		
Z59.1	Inadequate housing	Informational Diagnoses	Informational Diagnoses		
Z59.2	Discord with neighbors, lodgers and landlord	Informational Diagnoses	Informational Diagnoses		
Z59.3	Problems related to living in residential institution	Informational Diagnoses	Informational Diagnoses		
Z59.4	Lack of adequate food and safe drinking water	Informational Diagnoses	Informational Diagnoses		
Z59.5	Extreme poverty	Informational Diagnoses	Informational Diagnoses		
Z59.6	Low income	Informational Diagnoses	Informational Diagnoses		
Z59.7	Insufficient social insurance and welfare support	Informational Diagnoses	Informational Diagnoses		
Z59.8	Other problems related to housing and economic circumstances	Informational Diagnoses	Informational Diagnoses		
Z59.9	Problem related to housing and economic circumstances, unspecified	Informational Diagnoses	Informational Diagnoses		
Z60.0	Problems of adjustment to life-cycle transitions	Informational Diagnoses	Informational Diagnoses		
Z60.2	Problems related to living alone	Informational Diagnoses	Informational Diagnoses		
Z60.3	Acculturation difficulty	Informational Diagnoses	Informational Diagnoses		
Z60.4	Social exclusion and rejection	Informational Diagnoses	Informational Diagnoses		
Z60.5	Target of (perceived) adverse discrimination and persecution	Informational Diagnoses	Informational Diagnoses		
Z60.8	Other problems related to social environment	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z60.9	Problem related to social environment, unspecified	Informational Diagnoses	Informational Diagnoses		
Z62.0	Inadequate parental supervision and control	Informational Diagnoses	Informational Diagnoses		
Z62.1	Parental overprotection	Informational Diagnoses	Informational Diagnoses		
Z62.21	Child in welfare custody	Informational Diagnoses	Informational Diagnoses		
Z62.22	Institutional upbringing	Informational Diagnoses	Informational Diagnoses		
Z62.29	Other upbringing away from parents	Informational Diagnoses	Informational Diagnoses		
Z62.3	Hostility towards and scapegoating of child	Informational Diagnoses	Informational Diagnoses		
Z62.6	Inappropriate (excessive) parental pressure	Informational Diagnoses	Informational Diagnoses		
Z62.810	Personal history of physical and sexual abuse in childhood	449: ADJUSTMENT DISORDERS	449		
Z62.811	Personal history of psychological abuse in childhood	449: ADJUSTMENT DISORDERS	449		
Z62.812	Personal history of neglect in childhood	449: ADJUSTMENT DISORDERS	449		
Z62.819	Personal history of unspecified abuse in childhood	449: ADJUSTMENT DISORDERS	449		
Z62.820	Parent-biological child conflict	449: ADJUSTMENT DISORDERS	449		
Z62.821	Parent-adopted child conflict	449: ADJUSTMENT DISORDERS	449		
Z62.822	Parent-foster child conflict	449: ADJUSTMENT DISORDERS	449		
Z62.890	Parent-child estrangement NEC	449: ADJUSTMENT DISORDERS	449		
Z62.891	Sibling rivalry	449: ADJUSTMENT DISORDERS	449		
Z62.898	Other specified problems related to upbringing	449: ADJUSTMENT DISORDERS	449		
Z62.9	Problem related to upbringing, unspecified	Informational Diagnoses	Informational Diagnoses		
Z63.0	Problems in relationship with spouse or partner	Informational Diagnoses	Informational Diagnoses		
Z63.1	Problems in relationship with in-laws	Informational Diagnoses	Informational Diagnoses		
Z63.31	Absence of family member due to military deployment	Informational Diagnoses	Informational Diagnoses		
Z63.32	Other absence of family member	Informational Diagnoses	Informational Diagnoses		
Z63.4	Disappearance and death of family member	449: ADJUSTMENT DISORDERS	449		
Z63.5	Disruption of family by separation and divorce	Informational Diagnoses	Informational Diagnoses		
Z63.6	Dependent relative needing care at home	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z63.71	Stress on family due to return of family member from military deployment	Informational Diagnoses	Informational Diagnoses		
Z63.72	Alcoholism and drug addiction in family	Informational Diagnoses	Informational Diagnoses		
Z63.79	Other stressful life events affecting family and household	Informational Diagnoses	Informational Diagnoses		
Z63.8	Other specified problems related to primary support group	449: ADJUSTMENT DISORDERS	449		
Z63.9	Problem related to primary support group, unspecified	Informational Diagnoses	Informational Diagnoses		
Z64.0	Problems related to unwanted pregnancy	Informational Diagnoses	Informational Diagnoses		
Z64.1	Problems related to multiparity	Informational Diagnoses	Informational Diagnoses		
Z64.4	Discord with counselors	Informational Diagnoses	Informational Diagnoses		
Z65.0	Conviction in civil and criminal proceedings without imprisonment	Informational Diagnoses	Informational Diagnoses		
Z65.1	Imprisonment and other incarceration	Informational Diagnoses	Informational Diagnoses		
Z65.2	Problems related to release from prison	Informational Diagnoses	Informational Diagnoses		
Z65.3	Problems related to other legal circumstances	Informational Diagnoses	Informational Diagnoses		
Z65.4	Victim of crime and terrorism	Informational Diagnoses	Informational Diagnoses		
Z65.5	Exposure to disaster, war and other hostilities	Informational Diagnoses	Informational Diagnoses		
Z65.8	Other specified problems related to psychosocial circumstances	Informational Diagnoses	Informational Diagnoses		
Z65.9	Problem related to unspecified psychosocial circumstances	Informational Diagnoses	Informational Diagnoses		
Z66	Do not resuscitate	Informational Diagnoses	Informational Diagnoses		
Z67.10	Type A blood, Rh positive	Informational Diagnoses	Informational Diagnoses		
Z67.11	Type A blood, Rh negative	Informational Diagnoses	Informational Diagnoses		
Z67.20	Type B blood, Rh positive	Informational Diagnoses	Informational Diagnoses		
Z67.21	Type B blood, Rh negative	Informational Diagnoses	Informational Diagnoses		
Z67.30	Type AB blood, Rh positive	Informational Diagnoses	Informational Diagnoses		
Z67.31	Type AB blood, Rh negative	Informational Diagnoses	Informational Diagnoses		
Z67.40	Type O blood, Rh positive	Informational Diagnoses	Informational Diagnoses		
Z67.41	Type O blood, Rh negative	Informational Diagnoses	Informational Diagnoses		
Z67.90	Unspecified blood type, Rh positive	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z67.91	Unspecified blood type, Rh negative	Informational Diagnoses	Informational Diagnoses		
Z68.1	Body mass index (BMI) 19 or less, adult	Informational Diagnoses	Informational Diagnoses		
Z68.20	Body mass index (BMI) 20.0-20.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.21	Body mass index (BMI) 21.0-21.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.22	Body mass index (BMI) 22.0-22.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.23	Body mass index (BMI) 23.0-23.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.24	Body mass index (BMI) 24.0-24.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.25	Body mass index (BMI) 25.0-25.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.26	Body mass index (BMI) 26.0-26.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.27	Body mass index (BMI) 27.0-27.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.28	Body mass index (BMI) 28.0-28.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.29	Body mass index (BMI) 29.0-29.9, adult	Informational Diagnoses	Informational Diagnoses		
Z68.30	Body mass index (BMI) 30.0-30.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.31	Body mass index (BMI) 31.0-31.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.32	Body mass index (BMI) 32.0-32.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.33	Body mass index (BMI) 33.0-33.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.34	Body mass index (BMI) 34.0-34.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		

Line:	All Lines			Recommendations	
Z68.35	Body mass index (BMI) 35.0-35.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.36	Body mass index (BMI) 36.0-36.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.37	Body mass index (BMI) 37.0-37.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.38	Body mass index (BMI) 38.0-38.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.39	Body mass index (BMI) 39.0-39.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.41	Body mass index (BMI) 40.0-44.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.42	Body mass index (BMI) 45.0-49.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.43	Body mass index (BMI) 50-59.9 , adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.44	Body mass index (BMI) 60.0-69.9, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.45	Body mass index (BMI) 70 or greater, adult	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z68.51	Body mass index (BMI) pediatric, less than 5th percentile for age	Informational Diagnoses	Informational Diagnoses	DWF	

Line:	All Lines			Recommendations	
Z68.52	Body mass index (BMI) pediatric, 5th percentile to less than 85th percentile for age	Informational Diagnoses	Informational Diagnoses		
Z68.53	Body mass index (BMI) pediatric, 85th percentile to less than 95th percentile for age	Informational Diagnoses	Informational Diagnoses	DWF	
Z68.54	Body mass index (BMI) pediatric, greater than or equal to 95th percentile for age	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 325: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE)	589,325		
Z69.010	Encounter for mental health services for victim of parental child abuse	125: ABUSE AND NEGLECT	125		
Z69.011	Encounter for mental health services for perpetrator of parental child abuse	Informational Diagnoses	Informational Diagnoses	125	Informational Diagnoses
Z69.020	Encounter for mental health services for victim of non-parental child abuse	125: ABUSE AND NEGLECT	125		
Z69.021	Encounter for mental health services for perpetrator of non-parental child abuse	Informational Diagnoses	Informational Diagnoses		
Z69.11	Encounter for mental health services for victim of spousal or partner abuse	125: ABUSE AND NEGLECT	125		
Z69.12	Encounter for mental health services for perpetrator of spousal or partner abuse	Informational Diagnoses	Informational Diagnoses		
Z69.81	Encounter for mental health services for victim of other abuse	Informational Diagnoses	Informational Diagnoses	125	Informational Diagnoses
Z69.82	Encounter for mental health services for perpetrator of other abuse	Informational Diagnoses	Informational Diagnoses		
Z70.0	Counseling related to sexual attitude	Informational Diagnoses	Informational Diagnoses		
Z70.1	Counseling related to patient's sexual behavior and orientation	Informational Diagnoses	Informational Diagnoses		
Z70.2	Counseling related to sexual behavior and orientation of third party	Informational Diagnoses	Informational Diagnoses		
Z70.3	Counseling related to combined concerns regarding sexual attitude, behavior and orientation	Informational Diagnoses	Informational Diagnoses		
Z70.8	Other sex counseling	Informational Diagnoses	Informational Diagnoses		
Z70.9	Sex counseling, unspecified	Informational Diagnoses	Informational Diagnoses		
Z71.0	Person encountering health services to consult on behalf of another person	Informational Diagnoses	Informational Diagnoses		
Z71.1	Person with feared health complaint in whom no diagnosis is made	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z71.2	Person consulting for explanation of examination or test findings	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z71.3	Dietary counseling and surveillance	589: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) 625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	589,625		
Z71.41	Alcohol abuse counseling and surveillance of alcoholic	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z71.42	Counseling for family member of alcoholic	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z71.51	Drug abuse counseling and surveillance of drug abuser	4 SUBSTANCE USE DISORDER 625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625	4	625
Z71.52	Counseling for family member of drug abuser	625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	625		
Z71.6	Tobacco abuse counseling	5: TOBACCO DEPENDENCE	5		
Z71.7	Human immunodeficiency virus [HIV] counseling	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z71.81	Spiritual or religious counseling	Informational Diagnoses	Informational Diagnoses		
Z71.89	Other specified counseling	449: ADJUSTMENT DISORDERS	449		
Z71.9	Counseling, unspecified	Informational Diagnoses	Informational Diagnoses		
Z72.0	Tobacco use	Informational Diagnoses	Informational Diagnoses		
Z72.3	Lack of physical exercise	Informational Diagnoses	Informational Diagnoses		
Z72.4	Inappropriate diet and eating habits	Informational Diagnoses	Informational Diagnoses		
Z72.51	High risk heterosexual behavior	Informational Diagnoses	Informational Diagnoses		
Z72.52	High risk homosexual behavior	Informational Diagnoses	Informational Diagnoses		
Z72.53	High risk bisexual behavior	Informational Diagnoses	Informational Diagnoses		
Z72.6	Gambling and betting	Informational Diagnoses	Informational Diagnoses		
Z72.810	Child and adolescent antisocial behavior	Informational Diagnoses	Informational Diagnoses		
Z72.811	Adult antisocial behavior	Informational Diagnoses	Informational Diagnoses		
Z72.820	Sleep deprivation	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z72.821	Inadequate sleep hygiene	Informational Diagnoses	Informational Diagnoses		
Z72.89	Other problems related to lifestyle	Informational Diagnoses	Informational Diagnoses		
Z72.9	Problem related to lifestyle, unspecified	Informational Diagnoses	Informational Diagnoses		
Z73.0	Burn-out	Informational Diagnoses	Informational Diagnoses		
Z73.1	Type A behavior pattern	Informational Diagnoses	Informational Diagnoses		
Z73.2	Lack of relaxation and leisure	Informational Diagnoses	Informational Diagnoses		
Z73.3	Stress, not elsewhere classified	Informational Diagnoses	Informational Diagnoses		
Z73.4	Inadequate social skills, not elsewhere classified	Informational Diagnoses	Informational Diagnoses		
Z73.5	Social role conflict, not elsewhere classified	Informational Diagnoses	Informational Diagnoses		
Z73.6	Limitation of activities due to disability	Informational Diagnoses	Informational Diagnoses		
Z73.810	Behavioral insomnia of childhood, sleep-onset association type	Informational Diagnoses	Informational Diagnoses		
Z73.811	Behavioral insomnia of childhood, limit setting type	Informational Diagnoses	Informational Diagnoses		
Z73.812	Behavioral insomnia of childhood, combined type	Informational Diagnoses	Informational Diagnoses		
Z73.819	Behavioral insomnia of childhood, unspecified type	Informational Diagnoses	Informational Diagnoses		
Z73.82	Dual sensory impairment	Informational Diagnoses	Informational Diagnoses		
Z73.89	Other problems related to life management difficulty	Informational Diagnoses	Informational Diagnoses		
Z73.9	Problem related to life management difficulty, unspecified	Informational Diagnoses	Informational Diagnoses		
Z74.01	Bed confinement status	Informational Diagnoses	Informational Diagnoses		
Z74.09	Other reduced mobility	Informational Diagnoses	Informational Diagnoses		
Z74.1	Need for assistance with personal care	Informational Diagnoses	Informational Diagnoses		
Z74.2	Need for assistance at home and no other household member able to render care	Informational Diagnoses	Informational Diagnoses		
Z74.3	Need for continuous supervision	Informational Diagnoses	Informational Diagnoses		
Z74.8	Other problems related to care provider dependency	Informational Diagnoses	Informational Diagnoses		
Z74.9	Problem related to care provider dependency, unspecified	Informational Diagnoses	Informational Diagnoses		
Z75.0	Medical services not available in home	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z75.1	Person awaiting admission to adequate facility elsewhere	Informational Diagnoses	Informational Diagnoses		
Z75.2	Other waiting period for investigation and treatment	Informational Diagnoses	Informational Diagnoses		
Z75.3	Unavailability and inaccessibility of health-care facilities	Informational Diagnoses	Informational Diagnoses		
Z75.4	Unavailability and inaccessibility of other helping agencies	Informational Diagnoses	Informational Diagnoses		
Z75.5	Holiday relief care	Informational Diagnoses	Informational Diagnoses		
Z75.8	Other problems related to medical facilities and other health care	Informational Diagnoses	Informational Diagnoses		
Z75.9	Unspecified problem related to medical facilities and other health care	Informational Diagnoses	Informational Diagnoses		
Z76.0	Encounter for issue of repeat prescription	Informational Diagnoses	Informational Diagnoses		
Z76.1	Encounter for health supervision and care of foundling	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z76.2	Encounter for health supervision and care of other healthy infant and child	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z76.3	Healthy person accompanying sick person	Informational Diagnoses	Informational Diagnoses		
Z76.4	Other boarder to healthcare facility	Informational Diagnoses	Informational Diagnoses		
Z76.5	Malingerer [conscious simulation]	Informational Diagnoses	Informational Diagnoses		
Z76.81	Expectant parent(s) prebirth pediatrician visit	Informational Diagnoses	Informational Diagnoses		
Z76.82	Awaiting organ transplant status	Informational Diagnoses	Informational Diagnoses		
Z76.89	Persons encountering health services in other specified circumstances	Informational Diagnoses	Informational Diagnoses		
Z77.010	Contact with and (suspected) exposure to arsenic	DWF file	DWF file		
Z77.011	Contact with and (suspected) exposure to lead	DWF file	DWF file		
Z77.012	Contact with and (suspected) exposure to uranium	DWF file	DWF file		
Z77.018	Contact with and (suspected) exposure to other hazardous metals	DWF file	DWF file		
Z77.020	Contact with and (suspected) exposure to aromatic amines	DWF file	DWF file		
Z77.021	Contact with and (suspected) exposure to benzene	DWF file	DWF file		
Z77.028	Contact with and (suspected) exposure to other hazardous aromatic compounds	DWF file	DWF file		
Z77.090	Contact with and (suspected) exposure to asbestos	DWF file	DWF file		

Line:	All Lines			Recommendations	
Z77.098	Contact with and (suspected) exposure to other hazardous, chiefly nonmedicinal, chemicals	DWF file	DWF file		
Z77.110	Contact with and (suspected) exposure to air pollution	Informational Diagnoses	Informational Diagnoses		
Z77.111	Contact with and (suspected) exposure to water pollution	Informational Diagnoses	Informational Diagnoses		
Z77.112	Contact with and (suspected) exposure to soil pollution	Informational Diagnoses	Informational Diagnoses		
Z77.118	Contact with and (suspected) exposure to other environmental pollution	Informational Diagnoses	Informational Diagnoses		
Z77.120	Contact with and (suspected) exposure to mold (toxic)	DWF file	DWF file		
Z77.121	Contact with and (suspected) exposure to harmful algae and algae toxins	DWF file	DWF file		
Z77.122	Contact with and (suspected) exposure to noise	Informational Diagnoses	Informational Diagnoses		
Z77.123	Contact with and (suspected) exposure to radon and other naturally occuring radiation	Informational Diagnoses	Informational Diagnoses		
Z77.128	Contact with and (suspected) exposure to other hazards in the physical environment	Informational Diagnoses	Informational Diagnoses		
Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z77.22	Contact with and (suspected) exposure to environmental tobacco smoke (acute) (chronic)	Informational Diagnoses	Informational Diagnoses		
Z77.29	Contact with and (suspected) exposure to other hazardous substances	DWF file	DWF file		
Z77.9	Other contact with and (suspected) exposures hazardous to health	Informational Diagnoses	Informational Diagnoses	DWF	Informational Diagnoses
Z78.0	Asymptomatic menopausal state	Informational Diagnoses	Informational Diagnoses		
Z78.1	Physical restraint status	Informational Diagnoses	Informational Diagnoses		
Z78.9	Other specified health status	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z79.01	Long term (current) use of anticoagulants	71: VENTRICULAR SEPTAL DEFECT 83: PHLEBITIS AND THROMBOPHLEBITIS, DEEP 94: CONGENITAL MITRAL VALVE STENOSIS/INSUFFICIENCY 102: HEART FAILURE 103: CARDIOMYOPATHY 109: TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 115: CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 285: BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS 190: RHEUMATIC MULTIPLE VALVULAR DISEASE 193: CHRONIC ISCHEMIC HEART DISEASE 228: DISEASES AND DISORDERS OF AORTIC VALVE 262: DISEASES OF MITRAL, TRICUSPID, AND PULMONARY VALVES 322: STROKE 352: CARDIAC ARRHYTHMIAS 519: PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL	71,83,94,102,103,109,115,285,190,193,228,262,322,352,519		
Z79.02	Long term (current) use of antithrombotics/antiplatelets	DWF file	DWF file		
Z79.1	Long term (current) use of non-steroidal anti-inflammatories (NSAID)	DWF file	DWF file		
Z79.2	Long term (current) use of antibiotics	DWF file	DWF file		
Z79.3	Long term (current) use of hormonal contraceptives	DWF file	DWF file		
Z79.4	Long term (current) use of insulin	DWF file	DWF file		
Z79.51	Long term (current) use of inhaled steroids	DWF file	DWF file		
Z79.52	Long term (current) use of systemic steroids	DWF file	DWF file		
Z79.810	Long term (current) use of selective estrogen receptor modulators (SERMs)	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER 625: PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS	195,625		
Z79.811	Long term (current) use of aromatase inhibitors	DWF file	DWF file		

Line:	All Lines			Recommendations	
Z79.818	Long term (current) use of other agents affecting estrogen receptors and estrogen levels	DWF file	DWF file		
Z79.82	Long term (current) use of aspirin	DWF file	DWF file		
Z79.83	Long term (current) use of bisphosphonates	DWF file	DWF file		
Z79.890	Hormone replacement therapy (postmenopausal)	473: GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT	473		
Z79.891	Long term (current) use of opiate analgesic	DWF file	DWF file		
Z79.899	Other long term (current) drug therapy	DWF file	DWF file		
Z80.0	Family history of malignant neoplasm of digestive organs	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z80.1	Family history of malignant neoplasm of trachea, bronchus and lung	Informational Diagnoses	Informational Diagnoses		
Z80.2	Family history of malignant neoplasm of other respiratory and intrathoracic organs	Informational Diagnoses	Informational Diagnoses		
Z80.3	Family history of malignant neoplasm of breast	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z80.41	Family history of malignant neoplasm of ovary	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z80.42	Family history of malignant neoplasm of prostate	Informational Diagnoses	Informational Diagnoses		
Z80.43	Family history of malignant neoplasm of testis	Informational Diagnoses	Informational Diagnoses		
Z80.49	Family history of malignant neoplasm of other genital organs	Informational Diagnoses	Informational Diagnoses		
Z80.51	Family history of malignant neoplasm of kidney	Informational Diagnoses	Informational Diagnoses		
Z80.52	Family history of malignant neoplasm of bladder	Informational Diagnoses	Informational Diagnoses		
Z80.59	Family history of malignant neoplasm of other urinary tract organ	Informational Diagnoses	Informational Diagnoses		
Z80.6	Family history of leukemia	Informational Diagnoses	Informational Diagnoses		
Z80.7	Family history of other malignant neoplasms of lymphoid, hematopoietic and related tissues	Informational Diagnoses	Informational Diagnoses		
Z80.8	Family history of malignant neoplasm of other organs or systems	Informational Diagnoses	Informational Diagnoses		
Z80.9	Family history of malignant neoplasm, unspecified	Informational Diagnoses	Informational Diagnoses		
Z81.0	Family history of intellectual disabilities	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z81.1	Family history of alcohol abuse and dependence	Informational Diagnoses	Informational Diagnoses		
Z81.2	Family history of tobacco abuse and dependence	Informational Diagnoses	Informational Diagnoses		
Z81.3	Family history of other psychoactive substance abuse and dependence	Informational Diagnoses	Informational Diagnoses		
Z81.4	Family history of other substance abuse and dependence	Informational Diagnoses	Informational Diagnoses		
Z81.8	Family history of other mental and behavioral disorders	Informational Diagnoses	Informational Diagnoses		
Z82.0	Family history of epilepsy and other diseases of the nervous system	Informational Diagnoses	Informational Diagnoses		
Z82.1	Family history of blindness and visual loss	Informational Diagnoses	Informational Diagnoses		
Z82.2	Family history of deafness and hearing loss	Informational Diagnoses	Informational Diagnoses		
Z82.3	Family history of stroke	Informational Diagnoses	Informational Diagnoses		
Z82.41	Family history of sudden cardiac death	Informational Diagnoses	Informational Diagnoses		
Z82.49	Family history of ischemic heart disease and other diseases of the circulatory system	Informational Diagnoses	Informational Diagnoses		
Z82.5	Family history of asthma and other chronic lower respiratory diseases	Informational Diagnoses	Informational Diagnoses		
Z82.61	Family history of arthritis	Informational Diagnoses	Informational Diagnoses		
Z82.62	Family history of osteoporosis	Informational Diagnoses	Informational Diagnoses		
Z82.69	Family history of other diseases of the musculoskeletal system and connective tissue	Informational Diagnoses	Informational Diagnoses		
Z82.71	Family history of polycystic kidney	Informational Diagnoses	Informational Diagnoses		
Z82.79	Family history of other congenital malformations, deformations and chromosomal abnormalities	Informational Diagnoses	Informational Diagnoses		
Z82.8	Family history of other disabilities and chronic diseases leading to disablement, not elsewhere classified	Informational Diagnoses	Informational Diagnoses		
Z83.0	Family history of human immunodeficiency virus [HIV] disease	Informational Diagnoses	Informational Diagnoses		
Z83.1	Family history of other infectious and parasitic diseases	Informational Diagnoses	Informational Diagnoses		
Z83.2	Family history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	Informational Diagnoses	Informational Diagnoses		
Z83.3	Family history of diabetes mellitus	Informational Diagnoses	Informational Diagnoses		
Z83.41	Family history of multiple endocrine neoplasia [MEN] syndrome	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z83.49	Family history of other endocrine, nutritional and metabolic diseases	Informational Diagnoses	Informational Diagnoses		
Z83.511	Family history of glaucoma	Informational Diagnoses	Informational Diagnoses		
Z83.518	Family history of other specified eye disorder	Informational Diagnoses	Informational Diagnoses		
Z83.52	Family history of ear disorders	Informational Diagnoses	Informational Diagnoses		
Z83.6	Family history of other diseases of the respiratory system	Informational Diagnoses	Informational Diagnoses		
Z83.71	Family history of colonic polyps	Informational Diagnoses	Informational Diagnoses		
Z83.79	Family history of other diseases of the digestive system	Informational Diagnoses	Informational Diagnoses		
Z84.0	Family history of diseases of the skin and subcutaneous tissue	Informational Diagnoses	Informational Diagnoses		
Z84.1	Family history of disorders of kidney and ureter	Informational Diagnoses	Informational Diagnoses		
Z84.2	Family history of other diseases of the genitourinary system	Informational Diagnoses	Informational Diagnoses		
Z84.3	Family history of consanguinity	Informational Diagnoses	Informational Diagnoses		
Z84.81	Family history of carrier of genetic disease	Informational Diagnoses	Informational Diagnoses		
Z84.89	Family history of other specified conditions	Informational Diagnoses	Informational Diagnoses		
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ	Informational Diagnoses	Informational Diagnoses		
Z85.01	Personal history of malignant neoplasm of esophagus	319: CANCER OF ESOPHAGUS; BARRETT'S ESOPHAGUS WITH DYSPLASIA	319		
Z85.020	Personal history of malignant carcinoid tumor of stomach	595: SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	595		
Z85.028	Personal history of other malignant neoplasm of stomach	220: CANCER OF STOMACH	220		
Z85.030	Personal history of malignant carcinoid tumor of large intestine	595: SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	595		
Z85.038	Personal history of other malignant neoplasm of large intestine	161: CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS	161		
Z85.040	Personal history of malignant carcinoid tumor of rectum	595: SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	595		
Z85.048	Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus	161: CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS	161		
Z85.05	Personal history of malignant neoplasm of liver	320: CANCER OF LIVER	320		

Line:	All Lines			Recommendations	
Z85.060	Personal history of malignant carcinoid tumor of small intestine	595: SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	595		
Z85.068	Personal history of other malignant neoplasm of small intestine	Informational Diagnoses	Informational Diagnoses		
Z85.07	Personal history of malignant neoplasm of pancreas	Informational Diagnoses	Informational Diagnoses		
Z85.09	Personal history of malignant neoplasm of other digestive organs	Informational Diagnoses	Informational Diagnoses		
Z85.110	Personal history of malignant carcinoid tumor of bronchus and lung	595: SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	595		
Z85.118	Personal history of other malignant neoplasm of bronchus and lung	267: CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS	267		
Z85.12	Personal history of malignant neoplasm of trachea	267: CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS	267		
Z85.20	Personal history of malignant neoplasm of unspecified respiratory organ	267: CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS	267		
Z85.21	Personal history of malignant neoplasm of larynx	292: CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX	292		
Z85.22	Personal history of malignant neoplasm of nasal cavities, middle ear, and accessory sinuses	292: CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX	292		
Z85.230	Personal history of malignant carcinoid tumor of thymus	595: SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	595		
Z85.238	Personal history of other malignant neoplasm of thymus	Informational Diagnoses	Informational Diagnoses		
Z85.29	Personal history of malignant neoplasm of other respiratory and intrathoracic organs	Informational Diagnoses	Informational Diagnoses		
Z85.3	Personal history of malignant neoplasm of breast	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z85.40	Personal history of malignant neoplasm of unspecified female genital organ	Informational Diagnoses	Informational Diagnoses		
Z85.41	Personal history of malignant neoplasm of cervix uteri	137: CANCER OF CERVIX	137		
Z85.42	Personal history of malignant neoplasm of other parts of uterus	213: CANCER OF UTERUS	213		
Z85.43	Personal history of malignant neoplasm of ovary	243: CANCER OF OVARY	243		
Z85.44	Personal history of malignant neoplasm of other female genital organs	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z85.45	Personal history of malignant neoplasm of unspecified male genital organ	263: CANCER OF PENIS AND OTHER MALE GENITAL ORGANS	263		
Z85.46	Personal history of malignant neoplasm of prostate	334: CANCER OF PROSTATE GLAND	334		
Z85.47	Personal history of malignant neoplasm of testis	116: CANCER OF TESTIS	116		
Z85.48	Personal history of malignant neoplasm of epididymis	263: CANCER OF PENIS AND OTHER MALE GENITAL ORGANS	263		
Z85.49	Personal history of malignant neoplasm of other male genital organs	263: CANCER OF PENIS AND OTHER MALE GENITAL ORGANS	263		
Z85.50	Personal history of malignant neoplasm of unspecified urinary tract organ	219: CANCER OF KIDNEY AND OTHER URINARY ORGANS	219		
Z85.51	Personal history of malignant neoplasm of bladder	275: CANCER OF BLADDER AND URETER	275		
Z85.520	Personal history of malignant carcinoid tumor of kidney	595: SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	595		
Z85.528	Personal history of other malignant neoplasm of kidney	219: CANCER OF KIDNEY AND OTHER URINARY ORGANS	219		
Z85.53	Personal history of malignant neoplasm of renal pelvis	219: CANCER OF KIDNEY AND OTHER URINARY ORGANS	219		
Z85.54	Personal history of malignant neoplasm of ureter	Informational Diagnoses	Informational Diagnoses	219	Informational Diagnoses
Z85.59	Personal history of malignant neoplasm of other urinary tract organ	219: CANCER OF KIDNEY AND OTHER URINARY ORGANS	219		
Z85.6	Personal history of leukemia	Informational Diagnoses	Informational Diagnoses		
Z85.71	Personal history of Hodgkin lymphoma	120: HODGKIN'S DISEASE 139: HODGKIN'S DISEASE	120,139		
Z85.72	Personal history of non-Hodgkin lymphomas	Informational Diagnoses	Informational Diagnoses		
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues	Informational Diagnoses	Informational Diagnoses		
Z85.810	Personal history of malignant neoplasm of tongue	292: CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX	292		
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity, and pharynx	292: CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX	292		
Z85.819	Personal history of malignant neoplasm of unspecified site of lip, oral cavity, and pharynx	292: CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX	292		

Line:	All Lines			Recommendations	
Z85.820	Personal history of malignant melanoma of skin	234: MALIGNANT MELANOMA OF SKIN	234		
Z85.821	Personal history of Merkel cell carcinoma	595: SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	595		
Z85.828	Personal history of other malignant neoplasm of skin	280: CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA	280		
Z85.830	Personal history of malignant neoplasm of bone	205: CANCER OF BONES	205		
Z85.831	Personal history of malignant neoplasm of soft tissue	Informational Diagnoses	Informational Diagnoses		
Z85.840	Personal history of malignant neoplasm of eye	117: CANCER OF EYE AND ORBIT	117		
Z85.841	Personal history of malignant neoplasm of brain	299: CANCER OF BRAIN AND NERVOUS SYSTEM	299		
Z85.848	Personal history of malignant neoplasm of other parts of nervous tissue	299: CANCER OF BRAIN AND NERVOUS SYSTEM	299		
Z85.850	Personal history of malignant neoplasm of thyroid	215: CANCER OF THYROID	215		
Z85.858	Personal history of malignant neoplasm of other endocrine glands	595: SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS	595		
Z85.89	Personal history of malignant neoplasm of other organs and systems	Informational Diagnoses	Informational Diagnoses		
Z85.9	Personal history of malignant neoplasm, unspecified	Informational Diagnoses	Informational Diagnoses		
Z86.000	Personal history of in-situ neoplasm of breast	Informational Diagnoses	Informational Diagnoses		
Z86.001	Personal history of in-situ neoplasm of cervix uteri	Informational Diagnoses	Informational Diagnoses		
Z86.008	Personal history of in-situ neoplasm of other site	Informational Diagnoses	Informational Diagnoses		
Z86.010	Personal history of colonic polyps	170: ANAL, RECTAL AND COLONIC POLYPS	170		
Z86.011	Personal history of benign neoplasm of the brain	130: BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD	130		
Z86.012	Personal history of benign carcinoid tumor	Informational Diagnoses	Informational Diagnoses		
Z86.018	Personal history of other benign neoplasm	Informational Diagnoses	Informational Diagnoses		
Z86.03	Personal history of neoplasm of uncertain behavior	Informational Diagnoses	Informational Diagnoses		
Z86.11	Personal history of tuberculosis	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z86.12	Personal history of poliomyelitis	655: INFECTIOUS DISEASES WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	655	informational diagnoses	655
Z86.13	Personal history of malaria	Informational Diagnoses	Informational Diagnoses		
Z86.14	Personal history of Methicillin resistant Staphylococcus aureus infection	Informational Diagnoses	Informational Diagnoses		
Z86.19	Personal history of other infectious and parasitic diseases	Informational Diagnoses	Informational Diagnoses		
Z86.2	Personal history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	Informational Diagnoses	Informational Diagnoses		
Z86.31	Personal history of diabetic foot ulcer	Informational Diagnoses	Informational Diagnoses	169	
Z86.32	Personal history of gestational diabetes	Informational Diagnoses	Informational Diagnoses	1	
Z86.39	Personal history of other endocrine, nutritional and metabolic disease	Informational Diagnoses	Informational Diagnoses		
Z86.51	Personal history of combat and operational stress reaction	Informational Diagnoses	Informational Diagnoses		
Z86.59	Personal history of other mental and behavioral disorders	Informational Diagnoses	Informational Diagnoses		
Z87.728	Personal history of other specified (corrected) congenital malformations of nervous system and sense organs	Informational Diagnoses	Informational Diagnoses		
Z87.730	Personal history of (corrected) cleft lip and palate	Informational Diagnoses	Informational Diagnoses		
Z87.738	Personal history of other specified (corrected) congenital malformations of digestive system	Informational Diagnoses	Informational Diagnoses		
Z87.74	Personal history of (corrected) congenital malformations of heart and circulatory system	Informational Diagnoses	Informational Diagnoses		
Z87.75	Personal history of (corrected) congenital malformations of respiratory system	Informational Diagnoses	Informational Diagnoses		
Z87.76	Personal history of (corrected) congenital malformations of integument, limbs and musculoskeletal system	Informational Diagnoses	Informational Diagnoses		
Z87.790	Personal history of (corrected) congenital malformations of face and neck	Informational Diagnoses	Informational Diagnoses		
Z87.798	Personal history of other (corrected) congenital malformations	Informational Diagnoses	Informational Diagnoses		
Z87.81	Personal history of (healed) traumatic fracture	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z87.820	Personal history of traumatic brain injury	Informational Diagnoses 382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	Informational Diagnoses	382	Informational Diagnoses
Z87.821	Personal history of retained foreign body fully removed	Informational Diagnoses	Informational Diagnoses		
Z87.828	Personal history of other (healed) physical injury and trauma	Informational Diagnoses	Informational Diagnoses		
Z87.890	Personal history of sex reassignment	317: GENDER DYSPHORIA	317		
Z87.891	Personal history of nicotine dependence	Informational Diagnoses	Informational Diagnoses		
Z87.892	Personal history of anaphylaxis	Informational Diagnoses	Informational Diagnoses		
Z87.898	Personal history of other specified conditions	Informational Diagnoses	Informational Diagnoses		
Z88.0	Allergy status to penicillin	Informational Diagnoses	Informational Diagnoses		
Z88.1	Allergy status to other antibiotic agents status	Informational Diagnoses	Informational Diagnoses		
Z88.2	Allergy status to sulfonamides status	Informational Diagnoses	Informational Diagnoses		
Z88.3	Allergy status to other anti-infective agents status	Informational Diagnoses	Informational Diagnoses		
Z88.4	Allergy status to anesthetic agent status	Informational Diagnoses	Informational Diagnoses		
Z88.5	Allergy status to narcotic agent status	Informational Diagnoses	Informational Diagnoses		
Z88.6	Allergy status to analgesic agent status	Informational Diagnoses	Informational Diagnoses		
Z88.7	Allergy status to serum and vaccine status	Informational Diagnoses	Informational Diagnoses		
Z88.8	Allergy status to other drugs, medicaments and biological substances status	Informational Diagnoses	Informational Diagnoses		
Z88.9	Allergy status to unspecified drugs, medicaments and biological substances status	Informational Diagnoses	Informational Diagnoses		
Z89.011	Acquired absence of right thumb	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z89.012	Acquired absence of left thumb	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.019	Acquired absence of unspecified thumb	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.021	Acquired absence of right finger(s)	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.022	Acquired absence of left finger(s)	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.029	Acquired absence of unspecified finger(s)	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.111	Acquired absence of right hand	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.112	Acquired absence of left hand	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z89.119	Acquired absence of unspecified hand	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.121	Acquired absence of right wrist	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.122	Acquired absence of left wrist	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.129	Acquired absence of unspecified wrist	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.201	Acquired absence of right upper limb, unspecified level	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.202	Acquired absence of left upper limb, unspecified level	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.209	Acquired absence of unspecified upper limb, unspecified level	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z89.211	Acquired absence of right upper limb below elbow	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.212	Acquired absence of left upper limb below elbow	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.219	Acquired absence of unspecified upper limb below elbow	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.221	Acquired absence of right upper limb above elbow	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.222	Acquired absence of left upper limb above elbow	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.229	Acquired absence of unspecified upper limb above elbow	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.231	Acquired absence of right shoulder	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z89.232	Acquired absence of left shoulder	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.239	Acquired absence of unspecified shoulder	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.411	Acquired absence of right great toe	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.412	Acquired absence of left great toe	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.419	Acquired absence of unspecified great toe	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.421	Acquired absence of other right toe(s)	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.422	Acquired absence of other left toe(s)	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z89.429	Acquired absence of other toe(s), unspecified side	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.431	Acquired absence of right foot	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.432	Acquired absence of left foot	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.439	Acquired absence of unspecified foot	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.441	Acquired absence of right ankle	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.442	Acquired absence of left ankle	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.449	Acquired absence of unspecified ankle	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z89.511	Acquired absence of right leg below knee	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.512	Acquired absence of left leg below knee	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.519	Acquired absence of unspecified leg below knee	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.521	Acquired absence of right knee	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.522	Acquired absence of left knee	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.529	Acquired absence of unspecified knee	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.611	Acquired absence of right leg above knee	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		

Line:	All Lines			Recommendations	
Z89.612	Acquired absence of left leg above knee	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.619	Acquired absence of unspecified leg above knee	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.621	Acquired absence of right hip joint	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.622	Acquired absence of left hip joint	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.629	Acquired absence of unspecified hip joint	382: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382		
Z89.9	Acquired absence of limb, unspecified	Informational Diagnoses	Informational Diagnoses	382	Informational Diagnoses
Z90.01	Acquired absence of eye	Informational Diagnoses	Informational Diagnoses	382	Informational Diagnoses
Z90.02	Acquired absence of larynx	Informational Diagnoses 350 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS	Informational Diagnoses	350	Informational Diagnoses
Z90.09	Acquired absence of other part of head and neck	Informational Diagnoses	Informational Diagnoses		
Z90.10	Acquired absence of unspecified breast and nipple	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z90.11	Acquired absence of right breast and nipple	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		

Line:	All Lines			Recommendations	
Z90.12	Acquired absence of left breast and nipple	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z90.13	Acquired absence of bilateral breasts and nipples	195: CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	195		
Z90.2	Acquired absence of lung [part of]	Informational Diagnoses	Informational Diagnoses		
Z90.3	Acquired absence of stomach [part of]	Informational Diagnoses	Informational Diagnoses		
Z90.410	Acquired total absence of pancreas	Informational Diagnoses	Informational Diagnoses		
Z90.411	Acquired partial absence of pancreas	Informational Diagnoses	Informational Diagnoses		
Z90.49	Acquired absence of other specified parts of digestive tract	Informational Diagnoses	Informational Diagnoses		
Z90.5	Acquired absence of kidney	Informational Diagnoses	Informational Diagnoses		
Z90.6	Acquired absence of other parts of urinary tract	Informational Diagnoses	Informational Diagnoses		
Z90.710	Acquired absence of both cervix and uterus	Informational Diagnoses	Informational Diagnoses		
Z90.711	Acquired absence of uterus with remaining cervical stump	Informational Diagnoses	Informational Diagnoses		
Z90.712	Acquired absence of cervix with remaining uterus	Informational Diagnoses	Informational Diagnoses		
Z90.721	Acquired absence of ovaries, unilateral	Informational Diagnoses	Informational Diagnoses		
Z90.722	Acquired absence of ovaries, bilateral	Informational Diagnoses	Informational Diagnoses		
Z90.79	Acquired absence of other genital organ(s)	Informational Diagnoses	Informational Diagnoses		
Z90.81	Acquired absence of spleen	Informational Diagnoses	Informational Diagnoses		
Z90.89	Acquired absence of other organs	Informational Diagnoses	Informational Diagnoses		
Z91.010	Allergy to peanuts	Informational Diagnoses	Informational Diagnoses		
Z91.011	Allergy to milk products	Informational Diagnoses	Informational Diagnoses		
Z91.012	Allergy to eggs	Informational Diagnoses	Informational Diagnoses		
Z91.013	Allergy to seafood	Informational Diagnoses	Informational Diagnoses		
Z91.018	Allergy to other foods	Informational Diagnoses	Informational Diagnoses		
Z91.02	Food additives allergy status	Informational Diagnoses	Informational Diagnoses		
Z91.030	Bee allergy status	Informational Diagnoses	Informational Diagnoses		
Z91.038	Other insect allergy status	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z91.040	Latex allergy status	Informational Diagnoses	Informational Diagnoses		
Z91.041	Radiographic dye allergy status	Informational Diagnoses	Informational Diagnoses		
Z91.048	Other nonmedicinal substance allergy status	Informational Diagnoses	Informational Diagnoses		
Z91.09	Other allergy status, other than to drugs and biological substances	Informational Diagnoses	Informational Diagnoses		
Z91.11	Patient's noncompliance with dietary regimen	Informational Diagnoses	Informational Diagnoses		
Z91.120	Patient's intentional underdosing of medication regimen due to financial hardship	Informational Diagnoses	Informational Diagnoses		
Z91.128	Patient's intentional underdosing of medication regimen for other reason	Informational Diagnoses	Informational Diagnoses		
Z91.130	Patient's unintentional underdosing of medication regimen due to age-related debility	Informational Diagnoses	Informational Diagnoses		
Z91.138	Patient's unintentional underdosing of medication regimen for other reason	Informational Diagnoses	Informational Diagnoses		
Z91.14	Patient's other noncompliance with medication regimen	Informational Diagnoses	Informational Diagnoses		
Z91.15	Patient's noncompliance with renal dialysis	Informational Diagnoses	Informational Diagnoses		
Z91.19	Patient's noncompliance with other medical treatment and regimen	Informational Diagnoses	Informational Diagnoses		
Z91.410	Personal history of adult physical and sexual abuse	Informational Diagnoses	Informational Diagnoses		
Z91.411	Personal history of adult psychological abuse	Informational Diagnoses	Informational Diagnoses		
Z91.412	Personal history of adult neglect	Informational Diagnoses	Informational Diagnoses		
Z91.419	Personal history of unspecified adult abuse	Informational Diagnoses	Informational Diagnoses		
Z91.49	Other personal history of psychological trauma, not elsewhere classified	Informational Diagnoses	Informational Diagnoses		
Z91.5	Personal history of self-harm	Informational Diagnoses	Informational Diagnoses		
Z91.81	History of falling	3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	3		
Z91.82	Personal history of military deployment	Informational Diagnoses	Informational Diagnoses		
Z91.83	Wandering in diseases classified elsewhere	Informational Diagnoses	Informational Diagnoses		
Z91.89	Other specified personal risk factors, not elsewhere classified	Informational Diagnoses	Informational Diagnoses		
Z92.0	Personal history of contraception	Informational Diagnoses	Informational Diagnoses		
Z92.21	Personal history of antineoplastic chemotherapy	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z92.22	Personal history of monoclonal drug therapy	Informational Diagnoses	Informational Diagnoses		
Z92.23	Personal history of estrogen therapy	Informational Diagnoses	Informational Diagnoses		
Z92.240	Personal history of inhaled steroid therapy	Informational Diagnoses	Informational Diagnoses		
Z92.241	Personal history of systemic steroid therapy	Informational Diagnoses	Informational Diagnoses		
Z92.25	Personal history of immunosupression therapy	Informational Diagnoses	Informational Diagnoses		
Z92.29	Personal history of other drug therapy	Informational Diagnoses	Informational Diagnoses		
Z92.3	Personal history of irradiation	Informational Diagnoses	Informational Diagnoses		
Z92.81	Personal history of extracorporeal membrane oxygenation (ECMO)	Informational Diagnoses	Informational Diagnoses		
Z92.82	Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility	Informational Diagnoses	Informational Diagnoses		
Z92.83	Personal history of failed moderate sedation	Informational Diagnoses	Informational Diagnoses		
Z92.89	Personal history of other medical treatment	Informational Diagnoses	Informational Diagnoses		
Z93.0	Tracheostomy status	Informational Diagnoses	Informational Diagnoses		
Z93.1	Gastrostomy status	Informational Diagnoses	Informational Diagnoses		
Z93.2	Ileostomy status	Informational Diagnoses	Informational Diagnoses		
Z93.3	Colostomy status	Informational Diagnoses	Informational Diagnoses		
Z93.4	Other artificial openings of gastrointestinal tract status	Informational Diagnoses	Informational Diagnoses		
Z93.50	Unspecified cystostomy status	Informational Diagnoses	Informational Diagnoses		
Z93.51	Cutaneous-vesicostomy status	Informational Diagnoses	Informational Diagnoses		
Z93.52	Appendico-vesicostomy status	Informational Diagnoses	Informational Diagnoses		
Z93.59	Other cystostomy status	Informational Diagnoses	Informational Diagnoses		
Z93.6	Other artificial openings of urinary tract status	Informational Diagnoses	Informational Diagnoses		
Z93.8	Other artificial opening status	Informational Diagnoses	Informational Diagnoses		
Z93.9	Artificial opening status, unspecified	Informational Diagnoses	Informational Diagnoses		
Z94.0	Kidney transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.1	Heart transplant status	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z94.2	Lung transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.3	Heart and lungs transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.4	Liver transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.5	Skin transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.6	Bone transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.7	Corneal transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.81	Bone marrow transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.82	Intestine transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.83	Pancreas transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.84	Stem cells transplant status	Informational Diagnoses	Informational Diagnoses		
Z94.89	Other transplanted organ and tissue status	Informational Diagnoses	Informational Diagnoses		
Z94.9	Transplanted organ and tissue status, unspecified	Informational Diagnoses	Informational Diagnoses		
Z95.0	Presence of cardiac pacemaker	Informational Diagnoses	Informational Diagnoses		
Z95.1	Presence of aortocoronary bypass graft	Informational Diagnoses	Informational Diagnoses		
Z95.2	Presence of prosthetic heart valve	Informational Diagnoses	Informational Diagnoses		
Z95.3	Presence of xenogenic heart valve	Informational Diagnoses	Informational Diagnoses		
Z95.4	Presence of other heart-valve replacement	Informational Diagnoses	Informational Diagnoses		
Z95.5	Presence of coronary angioplasty implant and graft	Informational Diagnoses	Informational Diagnoses		
Z95.810	Presence of automatic (implantable) cardiac defibrillator	Informational Diagnoses	Informational Diagnoses		
Z95.811	Presence of heart assist device	Informational Diagnoses	Informational Diagnoses		
Z95.812	Presence of fully implantable artificial heart	Informational Diagnoses	Informational Diagnoses		
Z95.818	Presence of other cardiac implants and grafts	Informational Diagnoses	Informational Diagnoses		
Z95.820	Peripheral vascular angioplasty status with implants and grafts	Informational Diagnoses	Informational Diagnoses		
Z95.828	Presence of other vascular implants and grafts	Informational Diagnoses	Informational Diagnoses		
Z95.9	Presence of cardiac and vascular implant and graft, unspecified	Informational Diagnoses	Informational Diagnoses		
Z96.0	Presence of urogenital implants	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z96.1	Presence of intraocular lens	301: CATARACT	301		
Z96.20	Presence of otological and audiological implant, unspecified	Informational Diagnoses	Informational Diagnoses		
Z96.21	Cochlear implant status	Informational Diagnoses	Informational Diagnoses		
Z96.22	Myringotomy tube(s) status	Informational Diagnoses	Informational Diagnoses		
Z96.29	Presence of other otological and audiological implants	Informational Diagnoses	Informational Diagnoses		
Z96.3	Presence of artificial larynx	Informational Diagnoses	Informational Diagnoses		
Z96.41	Presence of insulin pump (external) (internal)	Informational Diagnoses	Informational Diagnoses		
Z96.49	Presence of other endocrine implants	Informational Diagnoses	Informational Diagnoses		
Z96.5	Presence of tooth-root and mandibular implants	Informational Diagnoses	Informational Diagnoses		
Z96.60	Presence of unspecified orthopedic joint implant	Informational Diagnoses	Informational Diagnoses		
Z96.611	Presence of right artificial shoulder joint	Informational Diagnoses	Informational Diagnoses		
Z96.612	Presence of left artificial shoulder joint	Informational Diagnoses	Informational Diagnoses		
Z96.619	Presence of unspecified artificial shoulder joint	Informational Diagnoses	Informational Diagnoses		
Z96.621	Presence of right artificial elbow joint	Informational Diagnoses	Informational Diagnoses		
Z96.622	Presence of left artificial elbow joint	Informational Diagnoses	Informational Diagnoses		
Z96.629	Presence of unspecified artificial elbow joint	Informational Diagnoses	Informational Diagnoses		
Z96.631	Presence of right artificial wrist joint	Informational Diagnoses	Informational Diagnoses		
Z96.632	Presence of left artificial wrist joint	Informational Diagnoses	Informational Diagnoses		
Z96.639	Presence of unspecified artificial wrist joint	Informational Diagnoses	Informational Diagnoses		
Z96.641	Presence of right artificial hip joint	Informational Diagnoses	Informational Diagnoses		
Z96.642	Presence of left artificial hip joint	Informational Diagnoses	Informational Diagnoses		
Z96.643	Presence of artificial hip joint, bilateral	Informational Diagnoses	Informational Diagnoses		
Z96.649	Presence of unspecified artificial hip joint	Informational Diagnoses	Informational Diagnoses		
Z96.651	Presence of right artificial knee joint	Informational Diagnoses	Informational Diagnoses		
Z96.652	Presence of left artificial knee joint	Informational Diagnoses	Informational Diagnoses		
Z96.653	Presence of artificial knee joint, bilateral	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z96.659	Presence of unspecified artificial knee joint	Informational Diagnoses	Informational Diagnoses		
Z96.661	Presence of right artificial ankle joint	Informational Diagnoses	Informational Diagnoses		
Z96.662	Presence of left artificial ankle joint	Informational Diagnoses	Informational Diagnoses		
Z96.669	Presence of unspecified artificial ankle joint	Informational Diagnoses	Informational Diagnoses		
Z96.691	Finger-joint replacement of right hand	Informational Diagnoses	Informational Diagnoses		
Z96.692	Finger-joint replacement of left hand	Informational Diagnoses	Informational Diagnoses		
Z96.693	Finger-joint replacement, bilateral	Informational Diagnoses	Informational Diagnoses		
Z96.698	Presence of other orthopedic joint implants	Informational Diagnoses	Informational Diagnoses		
Z96.7	Presence of other bone and tendon implants	Informational Diagnoses	Informational Diagnoses		
Z96.81	Presence of artificial skin	Informational Diagnoses	Informational Diagnoses		
Z96.89	Presence of other specified functional implants	Informational Diagnoses	Informational Diagnoses		
Z96.9	Presence of functional implant, unspecified	Informational Diagnoses	Informational Diagnoses		
Z97.0	Presence of artificial eye	Informational Diagnoses	Informational Diagnoses		
Z97.10	Presence of artificial limb (complete) (partial), unspecified	Informational Diagnoses	Informational Diagnoses		
Z97.11	Presence of artificial right arm (complete) (partial)	Informational Diagnoses	Informational Diagnoses		
Z97.12	Presence of artificial left arm (complete) (partial)	Informational Diagnoses	Informational Diagnoses		
Z97.13	Presence of artificial right leg (complete) (partial)	Informational Diagnoses	Informational Diagnoses		
Z97.14	Presence of artificial left leg (complete) (partial)	Informational Diagnoses	Informational Diagnoses		
Z97.15	Presence of artificial arms, bilateral (complete) (partial)	Informational Diagnoses	Informational Diagnoses		
Z97.16	Presence of artificial legs, bilateral (complete) (partial)	Informational Diagnoses	Informational Diagnoses		
Z97.2	Presence of dental prosthetic device (complete) (partial)	Informational Diagnoses	Informational Diagnoses		
Z97.3	Presence of spectacles and contact lenses	Informational Diagnoses	Informational Diagnoses		
Z97.4	Presence of external hearing-aid	Informational Diagnoses	Informational Diagnoses		
Z97.5	Presence of (intrauterine) contraceptive device	Informational Diagnoses	Informational Diagnoses		
Z97.8	Presence of other specified devices	Informational Diagnoses	Informational Diagnoses		
Z98.0	Intestinal bypass and anastomosis status	Informational Diagnoses	Informational Diagnoses		

Line:	All Lines			Recommendations	
Z98.1	Arthrodesis status	Informational Diagnoses	Informational Diagnoses		
Z98.2	Presence of cerebrospinal fluid drainage device	Informational Diagnoses	Informational Diagnoses		
Z98.3	Post therapeutic collapse of lung status	Informational Diagnoses	Informational Diagnoses		
Z98.41	Cataract extraction status, right eye	Informational Diagnoses	Informational Diagnoses		
Z98.42	Cataract extraction status, left eye	Informational Diagnoses	Informational Diagnoses		
Z98.49	Cataract extraction status, unspecified eye	Informational Diagnoses	Informational Diagnoses		
Z98.51	Tubal ligation status	Informational Diagnoses	Informational Diagnoses		
Z98.52	Vasectomy status	Informational Diagnoses	Informational Diagnoses		
Z98.61	Coronary angioplasty status	Informational Diagnoses	Informational Diagnoses		
Z98.62	Peripheral vascular angioplasty status	Informational Diagnoses	Informational Diagnoses		
Z98.810	Dental sealant status	Informational Diagnoses	Informational Diagnoses		
Z98.811	Dental restoration status	Informational Diagnoses	Informational Diagnoses		
Z98.818	Other dental procedure status	Informational Diagnoses	Informational Diagnoses		
Z98.82	Breast implant status	Informational Diagnoses	Informational Diagnoses		
Z98.83	Filtering (vitreous) bleb after glaucoma surgery status	Informational Diagnoses	Informational Diagnoses		
Z98.84	Bariatric surgery status	Informational Diagnoses	Informational Diagnoses		
Z98.85	Transplanted organ removal status	Informational Diagnoses	Informational Diagnoses		

Question: How can the Prioritized List have coding changes to allow treatment of bleeding into the vitreous when there is a retinal tear?

Question source: Andreas Lauer, MD, Casey Eye Institute

Issue: When a retinal tear occurs, there may be bleeding into the vitreous which needs to be removed to allow laser therapy or cryotherapy to the actual retinal tear itself. Dr. Lauer recommends adding a vitrectomy code to line 304 VITREOUS DISORDERS which allows vitrectomy with laser photocoagulation (CPT 67039). All other vitrectomy codes (CPT 67039, 67040-67043) appear on line 304. Dr. Lauer would like ICD-10 H43.1 (Vitreous hemorrhage) to pair with 67039. Currently 67039 appears on lines 100, 284, 290, 353, 365, 388, and 453.

Dr. Lauer also recommends adding two diagnosis codes for retinal tears and breaks (ICD-10 H33.30, H33.31) to the retinal detachment line (284 RETINAL DETACHMENT AND OTHER RETINAL DISORDERS) to allow pairing with vitrectomy with laser photocoagulation. Currently, H33.30 and H33.31 are only on line 379 RETINAL TEAR. The definition of these lines, however, would prevent this addition. His request is that H33.30 and H33.31 should pair with CPT 67039. A simpler solution would be to add 67039 to line 379.

HERC staff recommendation:

1) Add CPT 67039 (Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation) to lines 304 VITREOUS DISORDERS and 379 RETINAL TEAR
    a. All other vitrectomy codes appear on line 304
    b. Addition to line 379 would allow pairing with H33.30 (Unspecified retinal break) and H33.31 (Horseshoe tear of retina without detachment)

Ankle Arthritis

Question: Where should ankle arthritis be prioritized?

Question source: HERC staff

Issue: During the ICD-10 podiatry review, the podiatry experts recommended moving ankle arthritis (M24.17x Other articular cartilage disorders, ankle/foot) from line 545 DEFORMITIES OF FOOT to line 436 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT as they felt that ankle arthritis was of equivalent severity to knee arthritis. They also proposed moving a set of CPT codes for repair of ankle arthritis to this line (CPT codes 20920-20924,27612,27690-27692,28008,28010,28035,28050-28072,28086-28092,28110-28119,28126-28160,28220-28341,28360,28705-28760,29450,29750,29891-29907). This recommendation was discussed at two VBBS meetings, but never approved. However, M24.17 was moved to line 436 in error, but none of the proposed CPT codes for repair were moved. M24.17 also currently appears on line 392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS; it no longer appears on line 545. The relevant repair CPT codes for ankle arthritis appear on line 392. In a separate issue for this meeting, HERC staff are proposing deletion of line 392. The other M24.1 series codes for other non-ankle joints appear on line 392 and line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS other than the hip diagnosis (M24.15) which appears on the line 361 in addition to lines 392 and 530.

There are multiple other ICD-10 codes which can be used for ankle arthritis, which appear in the table below. These codes are on inconsistent lines and may or may not have CPT codes pairing with them that are appropriate for surgical repair.

Of note, major arthritis or recurrent dislocations of foot joints appear on line 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS. Another appropriate arthritis line is 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE.

HERC staff recommendations:

1) Consolidate all specific ankle arthritis ICD-10 diagnosis codes to the arthritis medical and surgical lines (lines 361 and 467) as shown in the table below
    a. Leave “not elsewhere classified” and other non-specific diagnoses on uncovered lines
    b. Appropriate surgical CPT codes appear on line 361 for repair
    c. ICD-10 M24.17 (Other articular cartilage disorders, ankle and foot) should only appear on an uncovered line as the primary types of arthritis (osteoarthritis, traumatic arthritis, etc.) are already on the upper lines
    d. Some codes appear on inappropriate lines (knee, upper limb deformities) and are proposed for more appropriate placement

Ankle Arthritis

ICD-10 Code	Code Description	Current line(s)	Recommended Line(s)
M12.57	Traumatic arthropathy, ankle and foot	361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE (surgical line) 467 OSTEOARTHRITIS AND ALLIED DISORDERS (medical line)	361, 467
M12.87	Other specific arthropathies, not elsewhere classified, ankle and foot	663 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	663
M13.17	Monoarthritis, not elsewhere classified, ankle and foot	663	663
M13.87	Other specified arthritis, ankle and foot	467	361, 467
M19.07	Primary osteoarthritis, ankle and foot	361,467	361,467
M19.17	Post-traumatic osteoarthritis, ankle and foot	361,467	361,467
M19.27	Secondary osteoarthritis, ankle and foot	361,467	361,467
M24.17	Other articular cartilage disorders, ankle or foot	392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS 436 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT	545 DEFORMITIES OF FOOT Remove from ~~392 and 436~~ Note: line 392 is proposed for deletion
M24.87	Other specific joint derangements of ankle, not elsewhere classified	364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS 545 DEFORMITIES OF FOOT	~~364,~~ 545
M25.87	Other specified joint disorders, ankle and foot	530 DEFORMITIES OF UPPER BODY AND ALL LIMBS	~~530~~, 545

Hallux Rigidus

Question: Where should hallux rigidus be prioritized?

Question source: HERC staff; HSD Hearings Division; Dr. Chris Seuferling DPM

Issue: Hallux rigidus is arthritis of the big toe joint. It causes pain and swelling of the toe, and may cause issues with walking. The treatment for this condition is typically NSAIDs, ice or heat packs, injections into the joint, physical therapy, and changes in footwear. Surgery may be required in patients with severe symptoms that do not respond to conservative measures. The main surgical options are fusion of the joint (arthrodesis), simple excision of the joint (Keller's procedure) and joint replacement with an artificial implant.

Hallux rigidus is generally categorized into 4 types, depending on severity of symptoms and radiographic findings.

Coughlin and Shurnas Classification		
	Exam Findings	*Radiographic Findings*
Grade 0	Stiffness	Normal
Grade 1	mild pain at extremes of motion	mild dorsal osteophyte, normal joint space
Grade 2	moderate pain with range of motion increasingly more constant	moderate dorsal osteophyte, <50% joint space narrowing
Grade 3	significant stiffness, pain at extreme ROM, no pain at mid-range	severe dorsal osteophyte, >50% joint space narrowing
Grade 4	significant stiffness, pain at extreme ROM, pain at mid-range of motion	same as grade III

VBBS/HERC history

The placement of hallux rigidus (ICD-10 M20.2) was reviewed by the podiatry and the orthopedics ICD-10 review groups. Prior to these reviews, the ICD-9 equivalent of M20.2 was on line 545 DEFORMITIES OF FOOT. The podiatry group suggested moving M20.2 to 467 OSTEOARTHRITIS AND ALLIED DISORDERS with the addition of a series of CPT codes (20920-20924, 27690-27692, 28008, 28010, 28050-28072, 28086-28092, 28111, 28126-28160, 28220-28341, 28705-28760) to allow treatment. This suggestion was discussed at length at two VBBS meetings, but no decision was reached. However, M20.2 was moved from line 545 to line 467 in error after these meetings, without any movement of CPT codes to allow treatment. Of note, line 467 is a medical line and does not contain other surgical procedures for other joints. The surgical line for osteoarthritis is 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE.

Hallux Rigidus

The orthopedic ICD-10 review group subsequently reviewed ICD-10 M20.2 and suggested moving it from line 545 to line 392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS, which was not approved. The orthopedics documents were incomplete and the discussion related to this change cannot be located. However, after the orthopedic review at VBBS, one treatment code for hallux ridigus (CPT 28289) was added to line 392 but the ICD-10 code was not. This appears to be an error as well.

Current Prioritized List status:

ICD-10 Code	Code Description	Current Location
M05.67	Rheumatoid arthritis of ankle and foot with involvement of other organs and systems	50 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES 361
M05.77	Rheumatoid arthritis with rheumatoid factor of ankle and foot without organ or systems involvement	50,361
M06.87	Other specified rheumatoid arthritis, ankle and foot	50,361
M19.07	Primary osteoarthritis, ankle and foot	361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE 467 OSTEOARTHRITIS AND ALLIED DISORDERS
M19.27	Secondary osteoarthritis, ankle and foot	361,467
M20.2	Hallux rigidus	467
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint	364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS 392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS 545 DEFORMITIES OF FOOT
28292	Correction, hallux valgus (bunion), with or without sesamoidectomy; Keller, McBride, or Mayo type procedure	545 DEFORMITIES OF FOOT
28750	Arthrodesis, great toe; metatarsophalangeal joint	297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 361,364,392,545

Hallux Rigidus

Evidence

Fusion or general surgery

1) **Zammit 2010**, Cochrane review of interventions for osteoarthritis of the big toe joint
    a. N=1 trial (20 patients) examining PT for osteoarthritis of the big toe joint
    b. Mean differences at four weeks follow up were 3.80 points (95% CI 2.74 to 4.86) for self reported pain, 28.30 ° (95% CI 21.37 to 35.23) for big toe joint range of motion, and 2.80 kg (95% CI 2.13 to 3.47) for muscle strength. Although differences in outcomes between treatment and control groups were reported, the risk of bias was high. The trial failed to employ appropriate randomisation or adequate allocation concealment, used a relatively small sample and incorporated a short follow up (four weeks). No adverse reactions were reported.
    c. **Authors' conclusions** The reviewed trial presented a high risk of bias, which limited conclusions that could be drawn from the presented data. The inclusion of only one trial indicates the need for more robust randomised controlled trials to determine the efficacy of interventions for this condition.
2) **Roukis 2010,** systematic review of cheilectomy with phalangeal dorsiflexory osteotomy for hallux rigidus
    a. N=11 studies (374 procedures)
    b. Pain was relieved or improved in 149/167 (89.2%) procedures, and 139/217 (77%) patients related being satisfied or very satisfied with their outcomes. A total of 18 (4.8%) procedures underwent surgical revision.
    c. cheilectomy with phalangeal dorsiflexory osteotomy should be considered a first-line surgical treatment for hallux rigidus. However, there is still a need for methodologically sound prospective cohort studies that focus on the use of this procedure for specific grades of hallux rigidus and compare the subjective and objective outcomes as well as the need for surgical revision with other procedures.
3) **Deland 2012,** review of surgical treatment of hallux rigidus (https://www.researchgate.net/publication/225095651_Surgical_Management_of_Hallux_Rigidus - Study not included due to length)
    a. Early to mid-stage hallux rigidus is best managed with cheilectomy or cheilectomy and proximal phalanx osteotomy. Arthrodesis and arthroplasty are reserved for late-stage hallux rigidus.

Joint implants

1) **NICE 2005**, review of joint implants for hallux rigidus
    a. Recommends coverage: Current evidence on the safety and efficacy of metatarsophalangeal joint replacement with an artificial implant of the hallux appears adequate to support the use of this procedure.
    b. The main outcome measures reported were pain relief and patient satisfaction. Three studies reported that 73% (8/11), 79% (46/58) and 100% (7/7) of joints with implants were pain free after mean follow-ups of 17 months, 12 years and 35 months, respectively. Another study including 86 implants reported a

statistically significant improvement in pain scores after the procedure. Two further studies reported pain relief in 66% (59/90) of implants and 94% (30/32) of patients (mean follow-ups of 3 years and 8 years, respectively).

c. Complications: The main complication reported was the formation of osteophytes around the implant. This affected between 4% (2/49) and 71% (41/58) of implants. Fractures were seen radiologically in 0% (0/106) to 29% (21/73) of implants, and frequency of fracture was related to the length of time that the implant had been in place. At the follow-up assessment, between 0% (0/11) and 8% (3/37) of implants had needed to be removed (mean follow-ups of 17 and 70 months, respectively). Other complications included malpositioning of the implant, infection, inflammation, dislocation and persistent pain.

2) **Roukis 2010**, review of autogenous soft tissue interpositional arthroplasty for hallux rigidus
   a. N=2 studies (23 patients)
   b. Both studies used the AOFAS First Metatarsal-Phalangeal-Hallux Scoring System, which had a mean of 26.0 preoperatively rising to 89.4 postoperatively. First metatarsal-phalangeal joint dorsiflexion had a mean of 16.7_ preoperatively rising to 51.1_ postoperatively. Complications occurred in 4 (14.3%) feet and no feet required surgical revision. The results of this systematic review demonstrate improvement in patient outcomes and first metatarsal-phalangeal joint dorsiflexion, as well as few complications following autogenous soft tissue interpositional arthroplasty for end-stage hallux rigidus. However, there is still a need for methodologically sound prospective cohort studies that compare autogenous soft tissue interpositional arthroplasty with other forms of arthroplasty and arthrodesis for end-stage hallux rigidus.

Other policies

1) NICE 2005
   a. Current evidence on the safety and efficacy of metatarsophalangeal joint replacement of the hallux appears adequate to support the use of this procedure

2) Aetna 2015
   a. Covers cheilectomy for hallux rigidus
   b. Covers arthrodesis for hallux rigidus only after failed cheilectomy
   c. Aetna considers total prosthetic replacement arthroplasty with silastic implants and hemiarthroplasty medically necessary for persons with disabling arthritis of the first metatarsal phalangeal joint (hallux rigidus).

Expert input:

Chris Seuferling, DPM

…my research supports surgical procedures, at least in advanced stage cases of hallux rigidus (M20.21/2). I would recommend approving 2 surgical procedures for advanced stage hallux rigidus diagnosis M20.21/2):

A) CPT-Code 28750: Arthrodesis 1st MPJ
B) CPT-Code 28292: Keller procedure (Though this is listed as bunionectomy, it is appropriate for advanced stage patient who is not candidate for fusion ie; older, inactive, or osteopenic patients)
C) I would also recommend covering surgical procedure 28289 (cheilectomy) for earlier stage cases.

Recommend covering stage 3 and 4 as the highest priority and cover fusion surgery (arthroplasty) only (not implants). Cheilectomy would be a lower priority for coverage as this is used for stage 1 and 2. Stages are based on radiographic findings. Stage 1 has a inflamed, painful joint with no radiographic findings; these patients have pain with exercise but not necessarily daily activities. Stage 2 has early radiographic findings; this stage can respond to conservative care (PT, injections, orthotics, etc.). Stage 3 and 4 have joint destruction and do not respond generally to conservative care.

HERC staff summary

Hallux rigidus is a disabling arthritic condition. The current evidence base for the efficacy of surgical treatment is of poor quality (small trials, methodological flaws) but there is generally poor quality literature in the podiatry field. Surgical treatments including joint implants are covered by most insurers and are recommended by NICE (based on 3 small studies).

ICD-10 diagnosis codes for other arthritic conditions of the big toe joint are currently covered on line 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE and pair with arthrodesis, but not cheilectomy or the Keller procedure.

Hallux Rigidus

HERC staff recommendations:

1) Keep medical treatments for hallux rigidus (ICD-10 M20.2) on line 467 OSTEOARTHRITIS AND ALLIED DISORDERS (medical line)
2) Prioritize surgical treatment of more severe forms hallux rigidus on line 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE in certain situations; prioritized this condition in other situations on line 545 DEFORMITIES OF FOOT
    a. Add ICD-10 M20.2 (Hallux rigidus) to lines 361
    b. Add CPT 28289 (Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint) to line 361 and keep on line 545
        i. Remove CPT 28289 from line 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS
        ii. CPT 28289 is also on line 392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS which is proposed for deletion as part of the 2018 Biennial Review
    c. Add CPT 28292 (Correction, hallux valgus (bunion), with or without sesamoidectomy; Keller, McBride, or Mayo type procedure) to line 361 and keep on line 545. Note: no bunion ICD-10 codes are present on line 361
    d. No changes required for CPT 28750 (Arthrodesis, great toe; metatarsophalangeal joint)--already located on lines 361 and 545
    e. Adopt the new guideline shown below regarding hallux rigidus
        i. Note that Dr. Seuferling recommended coverage of state 1 disease for cheilectomy when there is failure of conservative therapy
3) **2017 CPT code review**
    a. CPT 28291: Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant
    b. Recommend adding to line 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
        i. Use supported by NICE evidence review
        ii. Use is limited as shown in the proposed guideline note below

GUIDELINE NOTE XXX HALLUX RIGIDUS

Lines 361, 545

Surgical treatment of hallux rigidus is included on line 361 only for

1) Stage 3 and 4 disease when paired with arthroplasty (CPT 28750), the Keller procedure (CPT 28292), or cheilectomy with implant (CPT **28291**)
2) Stage 2 disease when paired with cheilectomy (CPT 28289) and there is documentation that conservative therapy (e.g. injection, physical therapy, orthotics) has been tried and failed to adequately control symptoms.

Otherwise surgical treatment of this diagnosis is included on line 545.

Posterior Tibialis Tendinopathy

Question: Should surgical correction of flat foot (posterior tibialis tendinopathy) be reprioritized higher on the Prioritized List?

Question source: Dr. Richard Owens, orthopedic surgery

Issue: Flatfoot diagnoses are generally on uncovered lines, and the diagnoses on the Prioritized List used for this condition generally do not pair with the most used repair codes. Dr. Owens has requested that the HERC consider coverage for flat foot due to posterior tibialis tendonopathy. Dr. Owens feels that lack of coverage for the early forms of this disorder results in patients developing more severe stages and finally getting coverage for an ankle fusion surgery for the late states, when earlier care might have prevented the need for such extensive surgery.

Flatfoot (hyperpronation and flattening-out of the longitudinal arch) (also known as pes planus or pes planovalgus) is a common deformity among children and adults. It may be congenital, or be acquired due to various conditions including posterior tibial tendon dysfunction. Lack of a functional arch affects the biomechanics of the lower leg and can result in pain. Flat feet are very common in children, and may resolve as the child grows. Flat feet can also develop as an adult ("adult acquired flatfoot") due to injury, illness, unusual or prolonged stress to the foot, faulty biomechanics, or as part of the normal aging process.

If a youth or adult appears flatfooted while standing in a full weight bearing position, but an arch appears when the person plantar flexes, or pulls the toes back with the rest of the foot flat on the floor, this condition is called flexible flatfoot. Most flexible flat feet are asymptomatic, and do not cause pain. In these cases, there is usually no cause for concern. In some patients, lower leg pain results from the flat foot, which can be treated with the use of shoes with properly fitting, arch-supporting orthotics.

Rigid flatfoot, a condition where the sole of the foot is rigidly flat even when a person is not standing, often indicates a significant problem in the bones of the affected feet, and can cause pain in about a quarter of those affected. Other flatfoot-related conditions, such as various forms of tarsal coalition (two or more bones in the midfoot or hindfoot abnormally joined) or an accessory navicular (extra bone on the inner side of the foot) should be treated promptly, usually by the very early teen years, before a child's bone structure firms up permanently as a young adult. Both tarsal coalition and an accessory navicular can be confirmed by X-ray. Rheumatoid arthritis can destroy tendons in the foot (or both feet) which can cause this condition, and untreated can result in deformity and early onset of osteoarthritis of the joint. Such a condition can cause severe pain and considerably reduced ability to walk, even with orthoses. Ankle fusion is usually recommended.

There are 4 stages of acquired flat foot deformity. Stage I is an inflammation of the tendon and normally is treated conservatively with braces. Stage II has the foot remaining flexible, with arch collapse and mild sinus tarsi pain. Stage III is a rigid fore and hindfoot, with severe sinus

tarsi pain and subtalar arthritis. Stage IV involves ankle pain, deltoid ligament compromise, and subtalar arthritis and talar tilt in ankle mortise are seen on xray. Acquired flat foot deformity is typically seen in middle aged patients with conditions such as diabetes.

Treatment of asymptomatic flat feet is not required. Foot or leg pain due to flat feet is treated with orthotics for arch support, NSAIDs, and/or foot exercises. Surgery may be done for more severe stages of flat foot or when conservative therapy fails.

From Dr. Rich Owen

> I am sending a review article from our orthopedic review journal. It discusses the four stages of adult acquired flatfoot deformity. Patients predictably progress from Stage 1 to at least Stage 3 and sometimes Stage 4 without treatment. Currently, OHP doesn't cover surgical or nonsurgical options. The condition is severely debilitating, and gets worse with time. Many times nonsurgical treatment does not work.

Dr. Owens recommended the following coverage for acquired flatfoot:

1) Stage 1: braces or orthotics to prevent progression.
2) Stage 2: braces or orthotics. Repair for patients less than 70 years of age (CPT 20902, 27687, 27690, 28090, 28300, 28306, 28307, 28715)
3) Stage 3: surgical repair (CPT 27605, 27687, 28715)
4) Stage 4: surgery-total ankle replacement (CPT 27702)

Current Prioritized List status

ICD-10 Code	Code description	Current Line(s)
M19.07	Primary osteoarthritis, ankle and foot	**361** RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE **467** OSTEOARTHRITIS AND ALLIED DISORDERS
M21.4	Flat foot [pes planus] (acquired))	**580** CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES
M21.6	Other acquired deformities of foot	**382** DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION **530** DEFORMITIES OF UPPER BODY AND ALL LIMBS
*M21.961	Unspecified acquired deformity of right lower leg	**382** **545** DEFORMITIES OF FOOT
*M66.9	Spontaneous rupture of unspecified tendon	**506** OTHER DISORDERS OF SYNOVIUM, TENDON AND BURSA, COSTOCHONDRITIS, AND CHONDRODYSTROPHY
M76.82	Posterior tibial tendinitis	**490 and 508** ERIPHERAL ENTHESOPATHIES
Q66.5	Congenital pes planus	**545**
Q66.9	Congenital deformity of feet, unspecified	**545**

*identified by Dr. Owens as appropriate diagnosis code

CPT code	Code Description	Current Line(s)
*20902	Bone graft, any donor area; major or large	**164** TRAUMATIC AMPUTATION OF ARM(S), HAND(S), THUMB(S), AND FINGER(S) (COMPLETE)(PARTIAL) WITH AND WITHOUT COMPLICATION **447** MALUNION AND NONUNION OF FRACTURE **488** ENOPHTHALMOS **587** ATROPHY OF EDENTULOUS ALVEOLAR RIDGE
*27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia	**297** NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS **364** DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS

CPT code	Code Description	Current Line(s)
		392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS
*27687	Gastrocnemius recession (eg, Strayer procedure)	**297**, **364**, **392** **530** DEFORMITIES OF UPPER BODY AND ALL LIMBS
*27690	Transfer or transplant of single tendon (with muscle redirection or rerouting); superficial (eg, anterior tibial extensors into midfoot)	**297,364,392,530** **545** DEFORMITIES OF FOOT
27700-27703	Arthroplasty, ankle	**361** RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
*28090	Excision of lesion, tendon, tendon sheath, or capsule (including synovectomy) (eg, cyst or ganglion); foot	**361,364,392, 545** **596** GANGLION
28238	Reconstruction (advancement), posterior tibial tendon with excision of accessory tarsal navicular bone (eg, Kidner type procedure)	**364, 392, 545**
*28300	Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation	**297,364,392,530,545**
*28306	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal	**545**
*28307	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal with autograft (other than first toe)	**297,364,392,545**
*28715	Arthrodesis; triple	**290** COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT **297,361,364,392,545**
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or	**364,392,545**

CPT code	Code Description	Current Line(s)
	transverse; with osteotomy (eg, flatfoot correction)	
29907	Arthroscopy, subtalar joint, surgical; with subtalar arthrodesis	**297** NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS **361,364,392** **447** MALUNION AND NONUNION OF FRACTURE **545**
HCPCS Code		
S2117	Arthroereisis, subtalar	**382** DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

*identified by Dr. Owens as appropriate procedure code
Other codes identified through literature and other insurer policy statements
Note: S2117 is a controversial procedure

Evidence

1) **Rome 2012**, Cochrane review of non-surgical treatments for pediatric flatfoot (study not included due to length)
   http://www.bcu.ac.uk/cmsproxyimage?path=/_media/docs/cd006311.pdf
   a. N=3 trials (305 children)
   b. Data from one trial (40 children with juvenile arthritis and foot pain) indicated that use of custom-made orthoses compared with supportive shoes alone resulted in significantly greater reduction in pain intensity (mean difference (MD) -1.5 points on a 10-point visual analogue scale (VAS), 95% CI -2.8 to -0.2; number need to treat to benefit (NNTB) 3, 95% CI 2 to 23), and reduction in disability (measured using the disability subscale of the Foot Function Index on a 100mm scale (MD -18.65mm, 95% CI -34.42 to -2.68mm).
   c. The second trial of seven to 11 year old children with bilateral flat feet (n = 178) found no difference in the number of participants with foot pain between custom-made orthoses, prefabricated orthoses and the control group who received no treatment.
   d. A third trial of one to five year olds with bilateral flat feet (n=129) did not report pain at baseline but reported the subjective impression of pain reduction after wearing shoes. No adverse effects were reported in the three trials.
   e. **Authors' conclusions** The evidence from randomised controlled trials is currently too limited to draw definitive conclusions about the use of non-surgical interventions for paediatric pes planus. Future high quality trials are warranted in this field. Only limited interventions commonly used in practice have been studied and there is much debate over the treatment of symptomatic and asymptomatic pes planus
2) **MacKenzie 2012**, review of treatment of pediatric flatfoot
   a. N=13 studies, generally poor quality
   b. Conclusions: evidence for efficacy of nonsurgical interventions for flexible pediatric flat feet is very limited. Future research needs validated foot type assessment, applicable outcome measures for the intervention, the use of control groups, allowance for independent effects of footwear, age range comparisons, larger samples, and prospective, longer follow-up.
3) **Bouchard 2014**, review of flatfoot in children and adolescents
   a. Most flexible flatfoot deformities are asymptomatic, will not lead to future pain or disability, and do not require treatment.
   b. Scant convincing evidence exists to support the use of inserts or shoe modifications for effective relief of symptoms, and there is no evidence that those devices change the shape of the foot.
   c. Surgery is rarely indicated, and in nearly all cases, an associated contracture of the heel cord is present
   d. Indications for flatfoot surgery are strict: failure of prolonged nonsurgical attempts to relieve pain that interferes with normal activities and occurs under the medial midfoot and/or in the sinus tarsi.

e. Osteotomies with supplemental soft-tissue procedures are the best proven approach for management of rigid flatfoot.

4) **Stegeman 2015**, review of outcomes after tarsal joint fusion
   a. Only one study was considered to have best evidence for flatfoot treatment by subtalar fusion
      i. An increase in the AOFAS score from 46 preoperatively to 70 points postoperatively was observed without concomitant use of low-intensity ultrasound (US) bone growth stimulation, and this score had increased from 50 to 84 when low-intensity US stimulation was used.
   b. Flatfoot treated using triple arthrodesis was described in 2 of the studies (12.5%); however, no best evidence could be deduced from those reports, and no study was found with flatfoot treated using talonavicular arthrodesis.
   c. van der Krans et al described 20 patients with posterior tibial tendon disease and calcaneocuboid distraction arthrodesis and noted improvement in the AOFAS score from a mean of 46 preoperative to a mean of 79 postoperatively, along with structural improvement in the alignment of the foot as measured radiographically, with the talar–first metatarsal angle decreasing from 15 deg preoperatively to 4.1 deg postoperatively.

<u>Submitted literature</u>

1) **Deland 2008**, acquired flatfoot deformity in adults
   a. Stage 1 should be treated conservatively with NSAIDs, orthotics, or immobilization with a cast or brace
      i. No study has been done to document whether these devices slow or prevent the progression of deformity
   b. Reviewed various surgical options for treating various stages of flatfoot deformity

Posterior Tibialis Tendinopathy

HERC staff summary:
Flatfoot generally does not require treatment. No evidence was identified on the rate of progression of early stages to later stages; similarly no evidence was identified on the ability of orthotics or braces to prevent such progression. If flatfoot progresses to ankle arthritis, there are effective surgical and non-surgical treatment available on the Prioritized List. Severe flat foot deformity treatment can also be pursued through the exceptions process.

HERC staff recommendations:

1) Consolidate diagnosis and treatment of flat foot onto line 580 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES
    1) Add ICD-10 Q66.5 (Congenital pes planus) to line 580 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES and remove from line 545 DEFORMITIES OF FOOT
    2) Add CPT 28735 (Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)) to line 580 and remove from lines 364, 392, 545
    3) Add the following CPT codes to line 580
        i. 20902, 27605, 27687, 27690, 27700-27703, 28090, 28238, 28300, 28306, 28307, 28715, 29907
        ii. See table above for procedure descriptions
2) Other "clean up" code movements
    1) Add ICD-10 M21.6 (Other acquired deformities of foot) to line 545 DEFORMITIES OF FOOT and remove from line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS

Acupuncture Guideline Clarification
October 2016

Question: How should the acupuncture guideline be modified to specify limits for tobacco cessation?

Question source: HERC staff

Issue: Tobacco cessation (line 4) was added to the acupuncture guideline in May, 2016. Previously, there were no session limits for acupuncture to tobacco cessation. The May, 2016 change added the restriction of 12 sessions per year. 12 sessions was chosen to be consistent with the session limits for other conditions. The staff evidence summary from the May meeting is below:

> Four meta-analyses (White 2014, Di 2014, Cheng 2012, and Tahiri 2012) came to varying conclusions [about whether acupuncture alone was effective for tobacco cessation], either finding superiority of acupuncture over control/sham at 0-6 months or inconclusive. The differences between the meta-analyses was most attributable to differing methods of pooling. In general, the widely varying acupuncture techniques and protocols used in RCTs let to the inability to draw firm conclusions on effectiveness.
>
> The general staff conclusion is that acupuncture may be helpful for smoking cessation, and is definitely not harmful. The number of visits used in study protocols ranged from 3-20, but were generally fewer than recommended by experts. There is insufficient evidence about the need to pair acupuncture with other therapies for smoking cessation.

The acupuncture guideline was updated at the August, 2016 meeting to limit treatments to a certain number "per year" or "per pregnancy." Tobacco cessation was left off that discussion, but will be included in the acupuncture guideline on the October, 2016 Prioritized List. To be consistent with the August, 2016 changes, the acupuncture sessions for tobacco cessation would be limited to 12 per year. However, the ACA mandates two quit attempts be covered per year. The acupuncture guideline could be modified to reflect that 12 sessions would be covered for each quit attempt as mandated by the ACA. Note: the ACA does not require acupuncture be covered for tobacco cessation at all.

HERC staff have received guidance from the Oregon Department of Justice that tobacco cessation is included under mental health parity and therefore may not be subjected to hard visit numbers. Two possible changes to the acupuncture guideline could be made to accommodate this: either remove tobacco from the guideline and therefore subject to no visit limits or add in wording to make the visit limits "soft limits."

Acupuncture Guideline Clarification
October 2016

HERC staff recommendations:

1) Modify GN92 as shown below regarding tobacco cessation
    a. Two versions are shown, one deleting tobacco cessation from the guideline and the other subjecting visits to soft limits
    b. Either version would comply with the ACA and mental health parity

Option 1: delete tobacco cessation from the guideline

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,208,366,407,415,467,543

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY

Acupuncture pairs on Line 1 for the following conditions and codes.

Hyperemesis gravidarum

ICD-10-CM: O21.0, O21.1

Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture per pregnancy.

Breech presentation

ICD-10-CM: O32.1

Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 ~~visits~~ sessions per pregnancy.

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions per pregnancy.

~~Line 5 TOBACCO DEPENDENCE~~

~~Acupuncture is included on this line for a maximum of 12 sessions~~

Line 208 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions per year, with documentation of meaningful improvement.

Line 366 SCOLIOSIS

Acupuncture is included on Line 366 with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 407 CONDITIONS OF THE BACK AND SPINE

Acupuncture is included on Line 407 with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 415 MIGRAINE HEADACHES

Acupuncture pairs on Line 415 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line 467 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 467 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 543 TENSION HEADACHES

Acupuncture is included on Line 543 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx

*Below the current funding line.

Option 2: provides soft limits for tobacco cessation limits

GUIDELINE NOTE 92, ACUPUNCTURE

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Breech presentation

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Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 ~~visits~~ sessions per pregnancy.

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions per pregnancy.

Line 5 TOBACCO DEPENDENCE

Acupuncture is included on this line for a maximum of 12 sessions per quit attempt up to two quit attempts per year; additional sessions may be authorized if medically appropriate.

Line 208 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions per year, with documentation of meaningful improvement.

Line 366 SCOLIOSIS

Acupuncture is included on Line 366 with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

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Acupuncture pairs on Line 415 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

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*Below the current funding line.

Tobacco smoking and surgical procedures

Question: Tobacco smoking and elective surgeries

Question source: Medical Directors from CCOs

Issue: At the November 2015, January 2016, and August 2016 VbBS meetings, a new proposed guideline on tobacco cessation and elective surgeries was discussed. At the most recent meeting, several changes were made to the proposed guideline.

1) Consider elimination or modification of the language around patients with serious and persistent mental illness
2) Expanding the guideline to include all elective surgical procedures, including podiatry, other dental procedures, and more. Add language about excluding specific categories (such as diagnostic, oncologic, and reproductive).
3) Modify the 6 month cessation language to be more clear for implementation

Selected excerpts from initial evidence summary

Thomsen, 2014 (document not included due to length)

1. Cochrane systematic review of RCTs looking at interventions for preoperative smoking cessation
2. 13 trials including 2010 participants
3. Smoking cessation at least 4 weeks prior to surgery results in improved morbidity
4. Smoking cessation counseling
    a. Brief interventions ineffective for either complication reduction or long term smoking cessation
    b. Intensive interventions, defined as weekly face to face for 4-8 weeks with telephonic support, and with pharmacotherapy (NRT) are effective
5. Optimal period unclear
6. Conclusion: There is evidence that preoperative smoking interventions providing behavioral support and offering NRT increase short-term smoking cessation and may reduce postoperative morbidity. Based on indirect comparisons and evidence from two small trials, interventions that begin four to eight weeks before surgery, include weekly counselling and use NRT are more likely to have an impact on complications and on long-term smoking cessation.

Information on cotinine testing in nicotine replacement therapy

1. *Thomsen 2012,* Cochrane review
    a. Most RCTs used exhaled carbon monoxide (CO) testing
        i. Self reported smoking cessation (Andrews, 2006; Lindstrom, 2008; Wolfenden, 2005)
        ii. Exhaled CO (≤ 10 ppm) (Lee, 2013; Moller, 2002, Ratner, 2004; Shi, 2013; Thomsen, 2010; Warner, 2012)

iii. Urine cotinine (Ratner, 2004)
iv. Expired CO and Sputum cotinine (Sorenson, 2007, Ostroff, 2013)
v. Exhaled CO and urinary cotinine (Sorenson, 2003a; Wong 2012)

2. *Jacob, 2002*
    a. Validation study of Anabasine and anatabine in users of nicotine replacement therapy compared to smokers
    b. 99 cigarette smokers and 205 smokeless tobacco users
    c. Objective: to evaluate the use of urine concentrations of the minor tobacco alkaloids anabasine and anatabine as outcome measures for persons undergoing NRT.
    d. Results: Subjects abstaining from smokeless tobacco and using nicotine gum did not excrete measurable amounts of anabasine or anatabine.
3. Mayo Clinic laboratories http://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/82510
    a. In addition to nicotine and metabolites, tobacco products also contain other alkaloids that can serve as unique markers of tobacco use. Two such markers are anabasine and nornicotine. Anabasine is present in tobacco products, but not nicotine replacement therapies. Nornicotine is present as an alkaloid in tobacco products and as a metabolite of nicotine. The presence of anabasine >10 ng/mL or nornicotine >30 ng/mL in urine indicates current tobacco use, irrespective of whether the subject is on nicotine replacement therapy. The presence of nornicotine without anabasine is consistent with use of nicotine replacement products. Heavy tobacco users who abstain from tobacco for 2 weeks exhibit urine nicotine values <30 ng/mL, cotinine <50 ng/mL, anabasine <2 ng/mL, and nornicotine <2 ng/mL.
    b. Passive exposure to tobacco smoke can cause accumulation of nicotine metabolites in nontobacco users. Urine cotinine has been observed to accumulate up to 20 ng/mL from passive exposure. Neither anabasine nor nornicotine accumulates from passive exposure.
4. NV Public Employee Benefits Program, "through consultation with their lab"
    a. Heavy smoker, cotinine will be positive for 7-10 days
    b. Average pack a day smoker, cotinine will be positive for 4-5 days
    c. Second hand smoke exposure would not result in a clinically significant positive cotinine

HERC staff summary

Smoking cessation at least 4 weeks prior to surgery may result in morbidity improvements for a wide range of elective surgeries. Intensive smoking cessation interventions that often included NRT showed improvements in postoperative morbidity. NRT is therefore an acceptable practice as part of intensive smoking

cessation interventions to reduce perioperative morbidity when the surgery is planned in the following 4-8 weeks.

HERC STAFF RECOMMENDATIONS

1. Discuss adoption of a new guideline note:

ANCILLARY GUIDELINE NOTE X, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES

Smoking cessation is required prior to elective surgical procedures for active tobacco users. Cessation is required for at least 4 weeks prior to the procedure and requires objective evidence of abstinence from smoking prior to the procedure.

Elective surgical procedures in this guideline are defined as surgical procedures which are flexible in their scheduling because they do not pose an imminent threat nor require immediate attention within 1 month. Reproductive, cancer-related and diagnostic procedures are excluded from this guideline.

The well-studied tests for confirmation of smoking cessation include cotinine levels and exhaled carbon monoxide testing. However, cotinine levels may be positive in nicotine replacement therapy (NRT) users (which is not a contraindication to elective surgery coverage). In patients using NRT the following alternatives to urine cotinine to demonstrate smoking cessation may be considered:

- Exhaled carbon monoxide testing (well studied)
- Anabasine or anatabine testing

~~For patients with psychosis or cognitive delay, intensive smoking cessation should be offered, but cessation is not required prior to elective surgery if quit attempts exacerbate their mental health.~~

Certain procedures, such as lung volume reduction surgery, bariatric surgery, erectile dysfunction surgery, and spinal fusion have 6 month tobacco abstinence requirements. See Guideline Notes 8, 100, and 112.

Additional issues:

Modify guideline notes 8, 100, and 112:

A) to be consistent in requiring cotinine level testing, and
B) consider adding language about the frequency of testing.

GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION
Lines 51,154,204,258,374,412,484,533,588

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking for 6 months prior to the planned procedure, as shown by negative cotinine levels at least 6 months apart. Patients should be given access to appropriate smoking cessation therapy.

GUIDELINE NOTE 8, BARIATRIC SURGERY

Lines 30,594

…Excerpt

Must remain free of abuse of or dependence on alcohol during the six-month period immediately preceding surgery. No current use of nicotine or illicit drugs and must remain abstinent from their use during the six-month observation period. Testing will, at a minimum, be conducted within one month of the surgery to confirm abstinence from ~~nicotine and~~ illicit drugs. Tobacco abstinence to be confirmed in active smokers by negative cotinine levels at least 6 months apart.

GUIDELINE NOTE 112, LUNG VOLUME REDUCTION SURGERY

Line 288

Lung volume reduction surgery (LVRS, CPT 32491, 32672) is included on Line 288 only for treatment of patients with radiological evidence of severe bilateral upper lobe predominant emphysema (diagnosis code ICD-10-CM J43.9/ICD-9-CM 492.0, 492.8) and all of the following:

1. BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
2. Stable with ≤20 mg prednisone (or equivalent) dose a day
3. Pulmonary function testing showing
   a. Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
   b. Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
   c. Residual volume (RV) ≥ 150% predicted post-bronchodilator
4. PCO 2, ≤ 60 mm Hg (PCO 2, ≤ 55 mm Hg if 1-mile above sea level)
5. PO 2, ≥ 45 mm Hg on room air (PO 2, ≥ 30 mm Hg if 1-mile above sea level)
6. Post-rehabilitation 6-min walk of ≥ 140 m
7. Non-smoking for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart.

The procedure must be performed at an approved facility (1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program or (2) approved as Medicare lung or heart-lung transplantation hospitals. The patient must have approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation. The patient must have approval for surgery by cardiologist if any of the following are present: unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF <45%; dobutamine radionuclide cardiac scan

indicates coronary artery disease or ventricular dysfunction; arrhythmia (>5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest).

1) Add a new guideline about surgical treatment of erectile dysfunction based on the November VbBS discussion.

GUIDELINE NOTE XXX SMOKING AND SURGICAL TREATMENT OF ERECTILE DYSFUNCTION

Line 526

Surgical treatment of erectile dysfunction is only included on this line when patients are non-smoking for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart.

Congenital Torticollis

Question: Where should congenital torticollis be prioritized?

Question source: VBBS

Issue: At the August, 2016 VBBS meeting, acquired torticollis (ICD-10 M43.6 Torticollis) was removed from line 407 CONDITIONS OF THE BACK AND SPINE and kept only on line 607 DISORDERS OF SOFT TISSUE as an errata. This placement was consistent with previous placement of this code prior to the implementation of the new back lines. At the August meeting, VBBS members expressed concerns that congenital torticollis (ICD-10 Q68.0) was not currently covered. ICD-10 Q68.0 (Congenital deformity of sternocleidomastoid muscle) is currently on line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS. HERC staff was directed to review the evidence for various treatments for congenital torticollis and propose a new line placement which would allow coverage for those treatments found to be effective. VBBS was most interested in having this condition covered in children.

G24.3 (Spasmodic torticollis) is on line 367 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM AND STENOSIS where it pairs with CPT 64616 (Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)) for botulinum toxin injection but not physical therapy CPT codes (97001, 97002 and similar).

The OHP medical directors felt that congenital torticollis was a condition that affected infants and very young children. Once a child has reached the age of approximately 3 years, the condition is harder to treat and neuroplasticity is no longer present. Defects in vision, hearing, and other complications from the torticollis will likely no longer respond to treatment of the torticollis at this point in neurodevelopment. Torticollis in older children may cause disabilities, but these disabilities would likely be treatable using different diagnosis codes.

HSC/HERC history

In August 2011, congenital torticollis (ICD-9 754.1 Congenital torticollis) was removed from lines 428 SPINAL DEFORMITY, CLINICALLY SIGNIFICANT and 596 SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT and added to line 551 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT by the HOSC/HSC. This decision was based on the fact that 50-70% of cases of congenital torticollis spontaneously resolve in the first year of life with minimal residual deficits. PT is indicated if complications are not resolving. One review cited (Do 2003) indicated that botulinum toxin and surgery may be considered for resistant cases after 6 months of physical therapy.

Congenital Torticollis

Evidence

1) **Suhr 2015**, review of treatment for congenital muscular torticollis (CMT)
    a. Review includes "early onset, ages birth to 3 months" and "later onset, ages 3 months to 6 months."
    b. Conservative management of CMT can achieve good-to-excellent outcomes in greater than 90% of cases. Prognosis and treatment duration vary depending on infant age at onset of treatment, severity of ROM restrictions
    c. CMT may have long-term developmental consequences.
    d. The major intervention is PT, and parent training
    e. Adjunct therapies may be added to the first-choice interventions if appropriate, such as microcurrent, myokinetic stretching, kinesiological taping, Tscharnuter Akademie for Motor Organization approach, and orthoses such as a tubular orthosis for torticollis (TOT) collar, soft foam collar, and custom-fabricated cervical orthoses
2) **Cheng 2000**, prospective case series of PT for congenital muscular torticollis (CMT)
    a. N=1,086 infants
    b. Interventions:
        i. N=266 (24.5% of patients): home treatment for deficit of passive rotation of less than 10 degrees
            1. Results: no deterioration detected in any patient. 5% changed to manual stretching group when no improvement was seen without 4 weeks after start of treatment. All patients had excellent results at final assessment, none required surgical intervention.
        i. N=820 (75.5% of patients): Manual stretching by PT for deficits of passive rotation of the neck of more than 10 degrees, with 3 sessions per week. Therapy stopped when full passive rotation of the neck was regained or there was no further improvement after 6 months of treatment
            a. Results: Most cases treated with manual stretching showed progressive improvement of the range of side flexion, rotation, the head tilt, the craniofacial asymmetry, and a decrease in the tumor size in the SMT group.
            b. The overall mean duration of treatment with physiotherapy was 118 days (3.9 months).
            c. The overall final outcome scores for the manual stretch group were excellent and good in 91.1%.
        ii. Surgical treatment: The indications for surgery were for patients with significant head tilt and deficits of passive rotation and side flexion of the neck greater than 10° to 15° and the presence of tight band or tumor in the SCM. They either have not responded to or improved additionally after at least 6 months of physiotherapy manual stretching. For the majority of patients a uniform method of distal unipolar open release and partial excision of the clavicular and sternal heads of the sternomastoid muscle was done. Postoperatively, an intensive program

of physiotherapy was prescribed that included scar treatment, maintenance of full passive range of motion of the

   a. **Conclusions:** Patients with initial deficits of passive rotation of less than 10° showed excellent and good outcome with active home positioning and stimulation program. The remaining cases with rotation deficits of over 10° and treated with manual stretching program showed an overall excellent to good results in 91.1% with 5.1% requiring subsequent surgical treatment.

3) **Cheng 2001,** subgroup analysis of PT group from Cheng 2000
   a. Adverse events with manual stretching: Sudden giving-way or snapping of the sternomastoid was observed during treatment with manual stretching in 8%. This group had good outcomes
   b. Conclusion: This large prospective study demonstrated that controlled manual stretching is safe and effective in the treatment of congenital muscular torticollis when a patient is seen before the age of one year.
4) **Kim 2015**, meta-analysis of surgical treatment for neglected congenital cervical torticollis
   a. N=12 studies (220 patients)
      i. All studies used an interrupted time-series design
      ii. Surgical intervention were unipolar or bipolar release
      iii. Patients were 8-27 years of age
      iv. Follow up 2-9 years
      v. All studies rated as having high risk of bias
   b. Results: Surgical treatment was successful in 81 percent of cases, based on the scoring systems for surgical outcome. The summary effect size of a successful result of surgical treatment was 0.81 (95 percent CI, 0.73 to 0.87). The range of motion of the neck and skeletal deformities showed significant improvement after surgery.
   a. **Conclusions:** Surgical treatment for neglected congenital muscular torticollis produced satisfactorily successful results, with improvement in both the range of motion of the neck and secondary skeletal deformities.
   b. **LEVEL OF EVIDENCE:** IV.
5) **Collins 2006**, case series of botulinum A for congenital muscular torticollis
   a. N=7 patients (pediatric an adult) with CMT since birth/neonatal period
   b. Only two patients had a modest benefit with improved range of motion

<u>Physical therapy for spasmodic cervical dystonia</u>

1) **De Pauw 2014**, systematic review of PT for cervical dystonia
   a. N=16 studies
      i. 7 clinical trials, 9 case reports or case series
      ii. most low quality (small sample sizes, lack of blinding, etc.)
      iii. Included both spasmodic dystonia and congenital dystonia
      iv. PT interventions: EMG biofeedback training, muscular elongation, postural exercises and electrotherapy.

b. Results: Improvements in head position, pain, cervical range of motion, quality of life and ADL have been reported
c. Conclusions: Cautious interpretation on the effectiveness of physiotherapy as an adjuvant therapy is required. Before firm conclusions can be drawn, additional high quality trials are needed.

Expert guidelines

1) **American Physical Therapy Association 2013**, evidence based guideline on Physical Therapy Management of Congenital Muscular Torticollis (http://www.pt.or.th/download/cpg/P01.pdf Study not included in packet due to length)
    a. Action Statement 2: REFER INFANTS WITH ASYMMETRIES TO PHYSICIAN AND PHYSICAL THERAPIST. Physicians, nurse midwives, obstetrical nurses, nurse practitioners, lactation specialists, PTs, or any clinician or family member should refer infants identified as having positional preference, reduced cervical range of motion, sternocleidomastoid masses, facial asymmetry and/or plagiocephaly to the primary pediatrician, and a PT as soon as the asymmetry is noted. (Evidence Quality: II; Recommendation Strength: Moderate)

HERC staff summary

Congenital muscular torticollis with <10 degrees of rotation can be safely and effectively managed with home based interventions. CMT with >10 degrees of rotation has good outcomes with manual stretching physical therapy. Surgical interventions are rarely required. Botulinum toxin injection is not an effective treatment for CMT. The majority of studies are in infants (<1 year of age).

Spasmodic dystonia is effectively treated with botulinum toxin, but not physical therapy.

Congenital Torticollis

HERC staff recommendations

1) Add ICD-10 Q68.0 (Congenital deformity of sternocleidomastoid muscle) to line 407 CONDITIONS OF THE BACK AND SPINE
    a. Remove Q68.0 from line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS
    b. Will pair with physical therapy CPT codes but not botulinum toxin injection or surgery
    c. Surgical intervention is rarely required and can be handled through the exceptions process
2) Adopt a new guideline as shown below regarding congenital torticollis
    a. Age 3 yrs or younger as the outcomes in older children is poor and the vast majority of patients are diagnosed in infancy
    b. Alternative: children aged 18 and younger
3) Keep ICD-10 G24.3 (Spasmodic torticollis) on line 367 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM AND STENOSIS
    a. Continue pairing only with botulinum injection and not physical therapy
4) Keep ICD-10 M43.6 (Torticollis) on line 607 DISORDERS OF SOFT TISSUE

GUIDELINE NOTE XXX CONGENITAL MUSCULAR TORTICOLLIS

Line 407

Congenital muscular torticollis (ICD-10 Q68.0 Congenital deformity of sternocleidomastoid muscle) is paired with physical therapy on this line only in the following circumstances:

1) The patient is a child aged 3 years or younger
2) For patients with deficits of passive rotation of the neck of < 10 degrees, one therapy visit is included for instructing caregivers on home treatment.
3) For patients with deficits of passive rotation of the neck of > 10 degree or with deficits of passive rotation of the neck of < 10 degrees who have had no improvement after 4 weeks of home treatment, physical therapy is included on this line according to GN6 REHABILITATIVE AND HABILITATIVE THERAPIES

2018 Biennial Review
Deletion of Line 392 DEFORMITY/CLOSED DISLOCATION
OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS

Issue: Line 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS and line 392 are closely prioritized, and have almost entirely the same ICD-10 codes. There are only approximately 20 ICD-10 codes on line 392 that do not also appear on line 364. There is no clear definition of what is considered a major vs a minor joint. The diagnoses on line 392 include hip, wrist, shoulder, ankle, finger and toe conditions, while the diagnoses of line 364 include basically all joints.

The ICD-10 Orthopedics group never finished their review due to the overwhelming number of new ICD-10 codes and their complexity. Therefore, there is not clear guidance on how these lines should be treated.

On review, HERC staff found very few codes on line 392 that could not be easily placed elsewhere, and did not see a good rationale for maintaining both of these lines. Additionally, these two lines have caused confusion and beewn sadfasdasd source of numerous questions from providers and plans about what diagnoses were intended to appear on each.

Line 392 contains only 2 CPT codes not found on line 364 (CPT 26045 and 26426). CPT 26045 is on one other appropriate line. CPT 26426 is on two other inappropriate lines and needs to be added to the line containing the diagnosis of boutonniere deformity.

HERC staff recommendations:

1) Delete line 392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS
    a. All ICD-10 codes also appearing on line 364 should remain on line 364
    b. The ICD-10 codes on line 392 that do not appear line 364 should be moved to the lines shown in the table below
        i. Some are also moved from other current lines as more appropriate placement
2) Rename line 364 DEFORMITY/CLOSED DISLOCATION OF ~~MAJOR~~ JOINT AND RECURRENT JOINT DISLOCATIONS
3) Add CPT 26426 (Repair of extensor tendon, central slip, secondary (eg, boutonniere deformity); using local tissue(s), including lateral band(s), each finger) to line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS to pair with M20.02
    a. Remove CPT 26426 from lines 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT and 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

ICD-10 code	Code description	Current lines (other than line 392)	Recommended placement
M21.75 M21.76	Unequal limb length (acquired)	382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS Note: other unequal limb length diagnoses are on line 530
M20.02	Boutonniere deformity of finger(s)	382	382, 530 Note: all other finger deformities are on line 530
M20.03	Swan-neck deformity of finger(s)	382	382, 530
M21.53	Acquired clawfoot	382 M21.539 (unspecified foot deformity) is also on line 545 DEFORMITIES OF FOOT	545 DEFORMITIES OF FOOT
M24.074- M24.076	Loose body in toe joint(s)		545
M24.08	Loose body, other site	407 CONDITIONS OF THE BACK AND SPINE	407 CONDITIONS OF THE BACK AND SPINE
M24.10	Other articular cartilage disorders, unspecified site	663 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	663 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
M24.11	Other articular cartilage disorders, shoulder	443 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6	443 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6
M24.12	Other articular cartilage disorders, elbow	530 DEFORMITIES OF UPPER BODY AND ALL LIMBS	530
M24.13	Other articular cartilage disorders, wrist	530	530
M24.14	Other articular cartilage disorders, hand	530	530

M24.15	Other articular cartilage disorders, hip	361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE 530	361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE 530
M24.171-M24.173	Other articular cartilage disorders, ankle	436 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT	530 DEFORMITIES OF UPPER BODY AND ALL LIMBS Note: May be revisited at October meeting with other podiatry issues
M24.174-M24.176	Other articular cartilage disorders, foot	436	545 DEFORMITIES OF FOOT Note: May be revisited at October meeting with other podiatry issues
M24.30	Pathological dislocation of unspecified joint, not elsewhere classified		663
M24.40	Recurrent dislocation, unspecified joint		663
M24.444-M24.446	Recurrent dislocation, finger		530 Note: all other finger deformities are on line 530
M24.477-M24.479	Recurrent dislocation, toe(s)		545

2018 Biennial Review
Repair of Inguinal and Ventral Hernias

Question: Should repair of uncomplicated inguinal hernias and any type of ventral hernias be covered?

Question source: Carl Stevens, MD, OHP Medical Director with CareOregon

Issue: Dr. Stevens requested that coverage for uncomplicated inguinal hernias in adults and for any type of umbilical or ventral hernia be reviewed. He feels that lack of coverage for uncomplicated hernias in adults limits many symptomatic patients and affects their ability to work. He feels that elective repair of hernias, especially in young patients with symptomatic abdominal wall hernias that limit their ability to work, would allow return to functional status. He also argues that such repair is the community standard of care. The current guideline may result in undue morbidity and disability in members with symptomatic hernias.

Historically, repair of uncomplicated hernias has not been covered as the complication rate with watchful waiting was felt to be very low. Hernia repair surgery is the most common elective surgery in the US. Coverage for repair of uncomplicated ventral and/or inguinal hernia has been discussed extensively at the Health Services Commission and HERC (see below).

History:

1) In 1994, move uncomplicated hernias in children under age 18 to covered line due to significantly higher rate of complication if left untreated (>30% in children vs <2% in adults).
2) 1998 biennial review considered moving uncomplicated hernias for patients over age 18 from the low uncovered line to a covered line. Noted that complicated/obstructed hernias had a death rate of 10% if untreated, and 0.5% if treated. No change was made with that review other than adding some surgical CPT codes missing from the covered line.
3) 2002 biennial review looked at coverage for uncomplicated hernia. In that review, ventral hernias were added to the lower, uncovered hernia line.
4) In 2005, ventral hernias were considered for addition to the upper hernia line, but not moved. Reducible umbilical hernias in children were moved to the lower, uncovered line.
5) In 2006, the current guideline was added to clarify when hernias were on the covered upper line.
6) In 2007, coverage for hernias in children were reviewed, and coverage maintained due to evidence of higher rates of complications for children.
7) In 2008, the guideline was clarified that all incarcerated hernias are on the upper line. Laparoscopic repair codes were added to the upper hernia line
8) In 2008, repair of large ventral hernias was reviewed. The outcomes of repair of large ventral hernias, with our without mesh, was found to be poor.
9) In 2010, Dr. Gubler, a surgeon on the HOSC, recommended coverage of inguinal hernias, as femoral hernias were covered. He also felt that fat incarceration rather than

intestinal incarceration, should be a covered indication for repair. No changes were made based on his recommendations.

10) In 2012, the ICD-10 general surgery review group proposed dividing the two hernia lines into 3 lines. The evidence supporting the safety of expectant management was discussed. Members decided to continue the current line structure for hernias. All ventral hernias were moved to the lower, uncovered line.
11) In 2014, ventral hernias were again discussed and the hernia guideline modified to clarify coverage.
12) In 2015, ventral hernias were again discussed and lack of any coverage, even when incarcerated, was clarified again.

Evidence

Inguinal hernia, watchful waiting (WW) vs surgical repair

1) **AHRQ 2012**, comparative effectiveness review of inguinal hernia repair
    a. For pain-free hernia, watchful waiting was compared to surgical repair
    b. Two studies met inclusion criteria. One compared WW with Lichtenstein repair, and the other compared WW with "tension-free mesh repair" (which might have been Lichtenstein repair). Both studies were considered to have moderate risk of bias for all outcomes reported.
    c. For this Key Question, we considered the following outcomes to be major: long-term QOL, which was reported as "overall change in health status in previous 12 months"; long-term pain; and acute hernia/ strangulation. The evidence was sufficient to permit a conclusion for one outcome: long-term QOL, for which the results favored repair over WW. Estimated difference on a 0-11 scale, 7 points (CI: 0.4 to 14.3)
    d. Evidence level was considered low
2) **Fitzgibbons 2006 and 2013**, RCT of WW vs surgical repair
    a. N=720 men (364 watchful waiting, 356 surgical repair)
    b. At 4.5 years, primary intention-to-treat outcomes were similar at 2 years for watchful waiting vs surgical repair: pain limiting activities (5.1% vs 2.2%, respectively; *P*=.52); PCS (improvement over baseline, 0.29 points vs 0.13 points; *P*=.79). Twenty-three percent of patients assigned to watchful waiting crossed over to receive surgical repair (increase in hernia-related pain was the most common reason offered); 17% assigned to receive repair crossed over to watchful waiting. Self-reported pain in watchful-waiting patients crossing over improved after repair. Occurrence of postoperative hernia-related complications was similar in patients who received repair as assigned and in watchful-waiting patients who crossed over. One watchful-waiting patient (0.3%) experienced acute hernia incarceration without strangulation within 2 years; a second had acute incarceration with bowel obstruction at 4 years, with a frequency of 1.8/1000 patient-years inclusive of patients followed up for as long as 4.5 years.

c. After 11.5 years, the estimated cumulative cross over rates using Kaplan-Meier analysis was 68%. Men older than 65 years crossed over at a considerably higher rate than younger men (79% vs 62%). The most common reason for cross over was pain (54.1%).A total of 3 patients have required an emergency operation, but there has been no mortality.
d. **Conclusions** Watchful waiting is an acceptable option for men with minimally symptomatic inguinal hernias. Delaying surgical repair until symptoms increase is safe because acute hernia incarcerations occur rarely. The later study added that patients should be counseled that symptoms will likely progress and an operation will eventually be needed.

3) **Chung 2010,** RCT of WW vs surgical repair
   a. N=160 mean, with painless inguinal hernia (80 surgery, 80 WW)
   b. Mean follow-up of 7.5 years
      i. 42 men had died (19 in the observation and 23 in the operation group)
      ii. 46 of the 80 men randomized to observation had conversion to operation.
      iii. The estimated conversion rate (using the Kaplan–Meier method) for the observation group was 16 (95 per cent confidence interval 9 to 26) per cent at 1 year, 54 (42 to 66) per cent 5 years and 72 (59 to 84) per cent at 7.5 years. The main reason for conversion was pain in 33 men, and two presented with an acute hernia. Sixteen men developed a new primary contralateral inguinal hernia and three had recurrent hernias.
      iv. Conclusion: Most patients with a painless inguinal hernia develop symptoms over time. Surgical repair is recommended for medically fit patients with a painless inguinal hernia.
4) **Mizrahi 2012**, systematic review of WW vs surgery for inguinal hernia
   a. N=41 articles
   b. No significant difference in pain scores and general health status were found when comparing the patients who were followed up with the patients who had surgery. A significant crossover ratio ranging between 23% and 72% from watchful waiting to surgery was found. In patients with watchful waiting, the rates of IH strangulation were 0.27% after 2 years of follow-up and 0.55% after 4 years of follow-up. In patients who underwent elective surgery, the range of operative complications was 0% to 22.3% and the recurrence rate was 2.1%.
   c. **Conclusion:** Both treatment options for asymptomatic IH are safe, but most patients will develop symptoms (mainly pain) over time and will require operation.
5) **Hwang 2014**, retrospective cohort study in NHS of WW vs surgery for asymptomatic inguinal hernia
   a. NHS instituted a nationwide policy of WW for asymptomatic inguinal hernias in 2010
   b. A total of 1,032 patients undergoing inguinal hernia repair in the 16 months after the policy change were compared with 978 patients in the 16 months before.

c. RESULTS The period after the policy change was associated with 59% higher odds of emergency repair (3.6% vs 5.5%, adjusted odds ratio [OR]: 1.59, 95% confidence interval [CI]: 1.03–2.47). In turn, emergency repair was associated with higher odds of adverse events (4.7% vs 18.5%, adjusted OR: 3.68, 95% CI: 2.04–6.63) and mortality (0.1% vs 5.4%, p<0.001, Fisher's exact test).
d. CONCLUSIONS Introduction of a watchful waiting policy for asymptomatic inguinal hernias was associated with a significant increase in need for emergency repair, which was in turn associated with an increased risk of adverse events. Current policies may be placing patients at risk.

6) **Van den Heuval 2011**, review of WW vs surgery for asymptomatic inguinal hernia
   a. The risk of incarceration is approximately 4 per 1,000 patients with a groin hernia per year. Risk factors for incarceration are age above 60 years, femoral hernia site and duration of signs less than 3 months.
   b. The recurrence rate after tension-free mesh repair in the management of emergency groin hernias is comparable to that of elective repair.
   c. There is no divergence in pain and quality of life after elective repair compared to watchful waiting. There is no advantage in cost-effectiveness of elective repair compared to watchful waiting.
   d. *Conclusion* Watchful waiting for asymptomatic groin hernias is a safe and cost-effective modality in patients who are under 50 years old, have an ASA class of 1 or 2, an inguinal hernia, and a duration of signs of more than 3 months.

1) **INCA 2011**, review of WW vs surgery for inguinal hernias for asymptomatic or mildly symptomatic inguinal hernia
   a. Mortality associated with elective hernia repair was investigated as a primary outcomes measure in 11 studies and as secondary outcomes measure in 65. Mean mortality associated with elective hernia repair was 0.2% (range 0% to 1.8%)
   b. Mortality associated with emergency hernia repair was investigated as a primary outcomes measure in 13 studies and as secondary outcomes measure in 7. Mean mortality associated with emergency hernia repair was 4.0% (range 0% to 22.2%)
   c. Rate of incarceration and/or strangulation has been investigated by 4 retrospective cohort studies as primary outcomes and 2 randomized trials as secondary outcomes. The yearly rate of irreducibility associated with a nonoperative approach was 0.4% (range 0.2% to 2.7%)
   d. The crossover from watchful waiting to operation has been reported by 2 randomized trials. Combining these figures, 13% (range 8.0% to 19.5%) of mild symptomatic and asymptomatic inguinal hernia patients assigned to watchful waiting management will cross over for inguinal hernia repair.
   e. A meta-analysis of long-term follow-up studies concerning recurrence is reported by inguinal hernia guideline of the European Hernia Society.Data of all trials with a follow-up of >48 months were reported comparing recurrences after Lichtenstein and endoscopic repair. We converted the observed probabilities of recurrence into annual rates, assuming a constant rate of recurrence. Because

no substantial difference in recurrence rate between the Lichtenstein technique and endoscopic repair was reported, we calculated a mean yearly recurrence rate of 0.9% (range 0.2% to 4.0%).

f. Conclusions: the available data suggest that life expectancy for elderly male inguinal hernia patients associated with watchful waiting or operation differs very little. Therefore, the general doubt about operating on mild symptomatic and asymptomatic elderly hernia patients, illustrated by 2 recent randomized trials investigating pre and postoperative pain for these types of management, is justified. In case of asymptomatic and mild symptomatic patients, there seems to be no difference in pain relief between watchful waiting and operation.

Ventral hernia repair, watchful waiting vs surgical repair

1) **Bellows 2014**, longitudinal cohort study of WW
    a. N=41 patients
        i. 11 patients lost to follow up, 7 died of other causes
    b. 24 patients followed for 2 years
        i. 1 had incarceration
        ii. There was no deterioration in the AAS score (baseline vs 24 months 5 28 vs 25, P 5 0.60). There was deterioration of the physical functioning dimension of the SF-36 (baseline vs 24 months 5 40 vs 32, P\0.01), but the mental functioning dimension was improved (45 vs 51; P 5 0.01).
    c. Conclusions: Watchful waiting was a safe option for patients in this study with ventral hernias.
2) **Stey 2014**, cohort study of WW vs surgical repair
    a. N=243 patients
        i. 80 were observed, 69 underwent repair of an incarcerated hernia, and 94 underwent repair of a nonincarcerated hernia.
    b. Quality of life as measured by utility score was less at 0.68 (95% CI, 0.65–0.71) in patients who did not undergo repair compared with those after repair of a nonincarcerated hernia, 0.76 (95% CI, 0.73–0.79; P <.001). The elective repair of a nonincarcerated hernia was cost-effective with an incremental cost effectiveness ratio of $8,646 per quality-adjusted lifeyear.
    c. Conclusion. The prompt elective repair of ventral hernias is cost-effective.

HERC staff summary;
Based on two large RCTs as well as several meta-analyses, there appears to be a low rate of progression of inguinal hernia to incarceration or obstruction. When obstruction or incarceration does occur, the complication rate for emergency surgery compared to elective repair appears to be similar. It is important to note that these studies were all done in asymptomatic or minimally symptomatic patients, and patients who developed pain were no longer followed by watchful waiting. In several large studies, the rate of eventual surgical repair, mainly due to the development of pain, was very high. The AHRQ report found that quality of life was significantly improved with surgical repair. Repair of inguinal hernia was not generally associated with improved function, but the functional measures may have been skewed by the repair of painful hernias. One cost study found no cost-effectiveness advantage in elective repair compared to watchful waiting.

Based on several small studies, watchful waiting for ventral hernia appears to be a safe strategy that did not affect disability or quality of life.

HERC staff recommendations:

1) Discuss what outcomes would lead to consideration for reprioritization of inguinal hernia repair
    a. Traditionally have only covered repair for children (higher risk of incarceration or other complication), and adults with obstruction, gangrene or otherwise complicated. Evidence still shows that watchful waiting is safe and that emergent repair has little increase in surgical complication compared to elective repair
    b. Does quality of life, pain, or function constitute an outcome which should lead to consideration for coverage?
2) Make no change in the current non-coverage of repair for ventral hernia
    a. Good evidence for lack of benefit for repair
    b. See separate issue for minor guideline clarification

Ventral hernias

Question: Should the complicated hernia guideline be edited for clarity?

Question source: Alison Little, MD, Medical Director, PacificSource

Issue: There is still confusion about obstructed versus incarcerated ventral hernias and whether they fall on Line 172 or on Line 527.

GUIDELINE NOTE 24, COMPLICATED HERNIAS
Lines 172,527
Complicated hernias are included on Line 172 if they cause symptoms of obstruction and/or strangulation. Incarcerated hernias (defined as non-reducible by physical manipulation) are also included on Line 172, excluding ventral hernias. Incarcerated ventral hernias are included on Line 527, because the chronic incarceration of large ventral hernias does not place the patient at risk for impending strangulation.

HERC Staff Recommendation:

1) Modify Guideline Note 24 as follows:

   GUIDELINE NOTE 24, COMPLICATED HERNIAS
   Lines 172,527
   Complicated hernias are included on Line 172 if they cause symptoms of intestinal obstruction and/or strangulation. Incarcerated hernias (defined as non-reducible by physical manipulation) are also included on Line 172, excluding incarcerated ventral hernias. Incarcerated ventral hernias are included on Line 527, because the chronic incarceration of large ventral hernias does not place the patient at risk for impending strangulation.

Questions:

1) Should cervical fusion be included on the upper surgical line with cervical decompression surgery?
2) In what situations should lumbar fusion be included on the upper surgical line with lumbar decompression surgery?
3) Is fusion included on the upper surgical line for treatment of spondylolisthesis?
4) Is radiculopathy that meets the clinical criteria in GN37 eligible for surgery on the upper line?
5) When is spinal surgery emergent for the purposes of the spinal surgery smoking cessation guideline?

Question source: HERC staff, OHSU Neurosurgery and Orthopedic Surgery, CCO Medical Directors, HSD

Issue: New back surgery guidelines went into effect July 1, 2016 with the new back line changes. The back surgery group at OHSU has had multiple questions and concerns about the new guidelines. Additionally, similar questions have been raised by CCO medical directors and by community based neurosurgeons/orthopedic surgeons and by Health Services Division at OHA. These questions mainly concern when spinal fusion should be covered with decompression surgery. A second question has been raised about when radiculopathy is covered for surgical treatment; specifically, why there is a definition of radiculopathy in GN37 when that particular diagnosis ICD-10 code is not included on the upper surgical line. Additionally, questions have been raised about the spinal cessation prior to spinal surgery guideline and when a surgery is considered urgent enough to justify not requiring smoking cessation. Based on input from the spinal surgery community and the CCO medical directors, HERC staff has drafted revisions to the back surgery guideline and the smoking cessation in back surgery guideline.

1) Regarding coverage for cervical spinal stenosis: the CCO medical directors and OHSU back surgery group felt that the current national neurosurgical guidelines and the evidence support the use of fusion with cervical decompression because of the increase in complications including kyphosis when fusion is not included.

2) Regarding other exceptions to the clause not allowing fusion for spinal decompression: the OHSU back surgery group recommended the following exceptions to the non-coverage of spinal fusion for lumbar spinal stenosis:
    a. If >50% of joint resected for foraminal stenosis, this creates instability and therefore needs fusion
    b. Spondylolisthesis
    c. Scoliosis >10 degrees
    d. No evidence that multilevel surgery causes lumbar spinal instability. Ok to not have fusion.

3) There is general confusion among the CCO medical directors and surgeons regarding the back surgery guideline in terms of the coverage for spinal stenosis with spondylolisthesis. Currently, there is confusing wording about spondylolisthesis which requires spinal stenosis to be present before spondylolisthesis is covered, but then the spinal stenosis clause restricts fusion even when spondylolisthesis is present. Experts argue is not standard of care. Review of the Back Pain Lines Reorganization Task Force (BPLRTF) meeting notes finds that the intent was to pair

spondylolisthesis with decompression AND fusion. The guideline appears poorly worded and should be clarified.

4) GN37 includes a definition of radiculopathy. However, radiculopathy was not included on the upper surgical line intentionally by the BPLRTF. The intent was to not cover surgical correction of radiculopathy unless there was another diagnosis such as spondylolisthesis or spinal stenosis. Review of the BPLRTF meeting notes finds that the neurosurgical member, Dr. Keenan, did not feel that this definition was needed, as the diagnoses on the upper surgical line had neurologic complications included by definition. The two surgical lines would be differentiated by diagnosis rather than by a definition of neurologic complication. However, the definition was left in the guideline as the OHP medical directors at that time felt that they would be useful and requested their continued inclusion. The only diagnoses included on the upper surgical line include myelopathy, spinal stenosis, spondylolisthesis, or spinal instability. Radiculopathy is only included on the lower back surgery line.

   The Prioritized List prior to the new back lines contained a GN37 with this definition of clinically significant radiculopathy. This GN37 tied into another previous guideline (GN41), and which defined when spinal stenosis was clinically significant: "Clinically significant spinal stenosis is defined as having MRI evidence of moderate to severe central or foraminal spinal stenosis in addition to a history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings (see Guideline Note 37)."

5) The OHSU back surgery group was strongly in support of our smoking cessation guideline for spinal surgery. The OHP medical directors have requested clarification on when back surgery should be considered emergent and the smoking cessation requirement waived. The back surgery group at OHSU provided HERC staff with wording regarding when back surgery is considered emergent.

Evidence—Cervical Laminectomy +/- Fusion

1) **Yoon 2013**, systematic review of cervical laminoplasty vs laminectomy and fusion for the treatment of cervical myelopathy
    a. N=4 retrospective cohort studies
    b. For patients with cervical spondylotic myelopathy (CSM), data from 3 class of evidence III retrospective cohort studies suggest that there is no difference between treatment groups in severity of myelopathy or pain: 2 studies reported no significant difference between treatment groups in severity of myelopathy, and 3 studies found no significant difference in pain outcomes between treatment groups. For patients with ossification of the posterior longitudinal ligament, one small class of evidence III retrospective cohort study reported significant improvements in myelopathy severity after laminectomy and fusion compared with laminoplasty, but no differences in long-term pain between treatment groups. The overall evidence on the comparative safety of laminoplasty compared with laminectomy and fusion is inconsistent. Reoperation rates were lower after laminoplasty in 2 of 3 studies reporting. However, the incidence of debilitating neck pain was higher after laminoplasty as reported by one study; results on neurological complications were inconclusive, with 2 studies reporting. Results on kyphotic deformity were inconsistent, with opposite results in the 2 studies reporting. After laminectomy and fusion, 1% to 38% of patients had pseudarthrosis. Infection rates were slightly lower after laminoplasty, but the results are not likely to be statistically significant.
    c. Conclusion. For patients with CSM, there is low-quality evidence that suggests that laminoplasty and laminectomy and fusion procedures are similarly effective in treating CSM. For patients with ossification of the posterior longitudinal ligament, the evidence regarding the effectiveness of these procedures is insufficient. For both patient populations, the evidence as to whether one procedure is safer than the other is insufficient. Higher-quality research is necessary to more clearly delineate when one procedure is preferred compared with the other.
2) **Ryken 2009**, systematic review of cervical laminectomy without fusion for the treatment of CSM
    a. N=26 studies, mostly case series from the 1960's and 1970's
    b. Studies suggested that the incidence of postlaminectomy kyphosis ranged from 14 to 47%.
    c. Recommendations:
        i. *Indications.* Laminectomy is recommended as a surgical treatment option for symptomatic CSM in selected patients in whom the risk of postoperative kyphosis is felt to be minimal (quality of evidence, Class III; strength of recommendation, D).
        ii. *Technique.* Laminectomy is recommended as a surgical treatment option for symptomatic cervical myelopathy. The limitations of the technique are an increased risk of postoperative kyphosis compared to anterior techniques, laminoplasty, or laminectomy with fusion. However, the development of kyphosis does not appear to diminish clinical outcome (quality of evidence, Class III; strength of recommendation, D)
3) **Anderson 2009**, systematic review of cervical laminectomy and fusion for the treatment of CSM
    a. Three studies compared results of laminectomy and fusion to other surgical techniques. These were all class III studies and had important methodological defects that limited their conclusions

i. Comparison of results according to surgical method revealed that laminectomy and posterior fusion yielded significantly better neurological recovery compared to all other methods.

b. Summary: Class I or II evidence to support the use of laminectomy and fusion for treatment of myelopathy secondary to cervical spondylosis or ossification of the posterior longitudinal ligament (OPLL) does not exist. Class III evidence shows consistently that 70–95% of patients show postoperative neurological improvement. Laminectomy and fusion consistently results in ventral and dorsal spinal cord decompression.

a. *Recommendations:*

i. Indications: Cervical laminectomy with arthrodesis is recommended in the treatment of patients with CSM and OPLL (quality of evidence, Class III; strength of recommendation, D).

ii. Technique: Cervical laminectomy with arthrodesis is recommended as an equivalent strategy to laminectomy or laminoplasty for functional improvement in the treatment of patients with CSM and OPLL. There is conflicting data as to whether fusion improves functional outcome relative to laminectomy with one study showing arthrodesis superior and one showing equivalency (quality of evidence, Class III; strength of recommendation, D).

2) **Fehlings 2013**, cohort study of decompression with fusion for cervical myelopathy

a. N=260 patients at multiple centers, follow up for 1 year after surgery

b. Results: There was a significant improvement from baseline to one year postoperatively ($p < 0.05$) in the mJOA score, Nurick grade, NDI score, and all SF-36v2 health dimensions (including the mental and physical health composite scores) except general health. With the exception of the change in the mJOA, the degree of improvement did not depend on the severity of the preoperative symptoms. These results remained unchanged after adjusting for relevant confounders in the multivariate analysis.

c. Fifty-two patients experienced complications (prevalence, 18.7%)

d. Conclusions: Surgical decompression for the treatment of cervical spondylotic myelopathy was associated with improvement in functional, disability-related, and quality-of-life outcomes at one year of follow-up for all disease severity categories. Furthermore, complication rates observed in the study were commensurate with those in previously reported cervical spondylotic myelopathy series.

e. Level of Evidence: Therapeutic Level II.

Evidence/Society Guidelines—Lumbar Laminectomy +/- Fusion

1) **Resnick 2014**, Evidence review and Neurosurgical Society guidelines on spinal fusion for spinal stenosis with spondylolisthesis

a. As a result of the decompression, the inherent instability associated with the spondylolisthesis may progress and lead to further misalignment that results in pain or recurrence of neurological complaints. Under these circumstances, lumbar fusion is considered appropriate to stabilize the spine and prevent delayed deterioration. Since publication of the original guidelines there have been a significant number of studies published that continue to support the utility of lumbar fusion for patients presenting with stenosis and spondylolisthesis. Several recently published trials, including the Spine Patient Outcomes Research Trial, are among the largest prospective randomized investigations of this issue. Despite limitations of study design or execution, these trials

have consistently demonstrated superior outcomes when patients undergo surgery, with the majority undergoing some type of lumbar fusion procedure.

b. Recommendations:
    i. Surgical decompression and fusion is recommended as an effective treatment alternative for symptomatic stenosis associated with a degenerative spondylolisthesis in patients who desire surgical treatment. (Grade B)
c. Evidence based on 31 articles (5 systematic reviews)

2) **Resnick 2014**, Evidence review and Neurosurgical Society guidelines on spinal fusion for spinal stenosis without spondylolisthesis
    a. For those patients [with lumbar stenosis] who do not improve with conservative care, surgery is considered an appropriate treatment alternative. The role of fusion, in the absence of a degenerative deformity, is uncertain. The previous guideline recommended against the inclusion of lumbar fusion in the absence of spinal instability or a likelihood of iatrogenic instability. Since the publication of the original guidelines, numerous studies have demonstrated the role of surgical decompression in this patient population; however, few have investigated the utility of fusion in patients without underlying instability. The majority of studies contain a heterogeneous cohort of subjects, often combining patients with and without spondylolisthesis who received various surgical interventions, limiting fusions to those patients with instability. It is difficult if not impossible, therefore, to formulate valid conclusions regarding the utility of fusion for patients with uncomplicated stenosis. Lower-level evidence exists, however, that does not demonstrate an added benefit of fusion for these patients; therefore, in the absence of deformity or instability, the inclusion of a fusion is not recommended.
    b. Recommendations:
        i. Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who elect to undergo surgical intervention (Level II/III evidence). Grade B recommendation
        ii. In the absence of deformity or instability, lumbar fusion has not been shown to improve outcomes in patients with isolated stenosis, and therefore it is not recommended. (Level IV evidence). Grade C recommendation
    c. Evidence based on N=36 studies

<u>HERC staff summary of evidence</u>:
Based on case series studies, many from the 1960's and 1970's, fusion in addition to laminectomy for cervical myelopathy appears to result in equivalent clinical outcomes to laminectomy alone but has lower risk of complications such as kyphosis.

Specialty society evidence-based guidelines recommend laminectomy without fusion for spinal stenosis without spondylolisthesis or other instability. For spinal stenosis with spondylolisthesis or other instability, these guidelines and expert input support decompression with fusion.

HERC staff recommendations:

1) Discuss possible changes to GN 37 as shown below. Several changes are generally agreed upon by the back surgeons and the CCO medical directors; other changes appear to require further clarification
    a. Allow fusion with decompression surgery for cervical spinal stenosis
    b. Clarify that spondylolisthesis grades 2 and 3 that results in spinal stenosis can be paired with decompression and fusion procedures
        i. There has been a request for clarification of whether grade 1 spondylolisthesis should be paired with fusion procedures
    c. Allow fusion with lumbar decompression without spondylolisthesis in situations of spinal instability
        i. Needs further work to better define when spinal instability exists or is created. For example, the medical directors have questions about how to determine when >50% of the foraminal joint is resected, as this is never documented in chart notes
    d. Consider whether central canal stenosis and foraminal stenosis should be combined together or better separated out
    e. Consider deleting the definition of radiculopathy, or somehow indicating that this definition applies to foraminal stenosis
    f. Consider coverage of very limited types of radicular pain without myelopathy
2) Modify GN 100 as shown below
    a. Defines emergent surgical need

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 351,532

~~Surgical consultation/consideration for surgical intervention are included on these lines only for patients with neurological complications, defined as showing objective evidence of one or more of the following:~~

~~A. Markedly abnormal reflexes~~
~~B. Segmental muscle weakness~~
~~C. Segmental sensory loss~~
~~D. EMG or NCV evidence of nerve root impingement~~
~~E. Cauda equina syndrome~~
~~F. Neurogenic bowel or bladder~~
~~G. Long tract abnormalities~~

Spondylolisthesis (ICD-10-CM M43.1, Q76.2) is included on Line 351 to pair only when it results in spinal stenosis with signs and symptoms of neurogenic claudication. Otherwise, these diagnoses are included on Line 532. Decompression and fusion surgeries are both included on these lines for spondylolisthesis.

Surgical correction of spinal stenosis (ICD-10-CM M48.0) is only included on Line 351 for patients with:

1) MRI evidence of moderate to severe central or foraminal spinal stenosis AND

2) A history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings.

Otherwise, these diagnoses are included on Line 532. Only decompression surgery is included on these lines for lumbar spinal stenosis; spinal fusion procedures are not included on either line for ~~this diagnosis~~ lumbar spinal stenosis unless one of the following is present:

1) Spondylolisthesis
2) Scoliosis >10 degrees
3) Foraminal stenosis when >50% of the joint is resected

Spinal fusion is included on these lines with decompression surgery for cervical spinal stenosis.

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- facet joint corticosteroid injection
- prolotherapy
- intradiscal corticosteroid injection
- local injections
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- sacroiliac joint steroid injection
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- radiofrequency denervation
- epidural steroid injections

GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION

Lines 51,154,205,259,351,366,406,482,532,561

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking for 6 months prior to the planned procedure. Patients should be given access to appropriate smoking cessation therapy. Non-emergent spinal arthrodesis is defined as surgery for a patient with a lack of myelopathy or rapidly declining neurological exam.

Question: should mechanical chest wall oscillation to facilitate lung function (CPT 94669) be included on the Prioritized List?

Question source: Kim Wentz, MD, HSD medical director; Hill-Rom

Issue: Chest wall oscillation involves using devices/systems for clearing excess mucus from lung airways (bronchi and bronchioles). It is principally used in the treatment of cystic fibrosis, but is gaining use in the treatment of other diseases, such as bronchiectasis, COPD, cerebral palsy and muscular dystrophy, in which excessive mucus can block airways due to excessive production or impaired clearance.

Chest wall oscillation was a new CPT code for 2014. This code was reviewed during the CPT code review in late 2013. At that time, a Cochrane review (Morrison 2011) was reviewed, which did not find good evidence that chest wall oscillation was more or less effective that other treatments (mainly PT). Other major insurers (CMS, Aetna, NHS) were covering this procedure and the initial staff recommendation was for coverage. The VBBS discussion involved the fact that this modality was no more effective that other treatment modalities; a cost-effectiveness comparison was requested. That cost comparison was done in January, 2014, and mechanical chest was oscillation was found to be substantially more expensive that other treatments ($37-45/month rental or $1,100 purchase vs one time PT training for caregivers); although comparable to some therapies ($50/mo for flutter device, $39/mo for PEP device). The VBBS/HERC decision was to add this therapy to the Services Recommended for Non-Coverage List as being less cost effective than equally efficacious therapies.

Dr. Wentz has requested reconsideration of coverage for mechanical chest wall oscillation due to multiple requests for this service that have been received by HSD. The cases HSD are seeing are those in which a patient fails other therapy or for whom therapies like home PT are not feasible. The HSD request is for consideration of chest wall oscillation as a second line therapy.

Evidence--cystic fibrosis

I. **Morrison 2014** (update of previous review), Cochrane review of chest oscillation devices for cystic fibrosis (CF)
    i. N=35 studies (total of 1050 participants)
    ii. One long-term study (seven months) compared oscillatory devices with either conventional physiotherapy or breathing techniques and found statistically significant differences in some lung function parameters in favour of oscillating devices.
    iii. One study identified an increase in frequency of exacerbations requiring antibiotics whilst using high frequency chest wall oscillation when compared to positive expiratory pressure.
    iv. There were some small but significant changes in secondary outcome variables such as sputum volume or weight, but not wholly in favour of oscillating devices.
    v. **Authors' conclusions** There was no clear evidence that oscillation was a more or less effective intervention overall than other forms of physiotherapy. The findings from one study showing an increase in frequency of exacerbations requiring antibiotics whilst using an oscillating device compared to positive expiratory pressure may have significant resource implications. More adequately-powered long-term randomised controlled trials are necessary and

outcomes measured should include frequency of exacerbations, patient preference, adherence to therapy and general satisfaction with treatment. Increased adherence to therapy may then lead to improvements in other parameters, such as exercise tolerance and respiratory function. Additional evidence is needed to evaluate whether oscillating devices combined with other forms of airway clearance is efficacious in people with cystic fibrosis.

II. **Main 2013,** Cochrane comparison of PT vs other airway clearance techniques for cystic fibrosis
    i. N=15 studies (475 participants)
    ii. There was insufficient evidence to confirm or exclude any differences, between CCPT and other airway clearance techniques in terms of respiratory function measured by standard lung function tests. Studies undertaken during acute exacerbations demonstrated relatively large gains in respiratory function irrespective of airway clearance technique. Longer-term studies demonstrated smaller improvements or deterioration over time. Ten studies reported individual preferences for technique, with participants tending to favour self-administered techniques. Heterogeneity in the measurement of preference precluded these data from meta-analysis.
    iii. **Authors' conclusions:** This review was unable to demonstrate any advantage of CCPT over other airway clearance techniques in terms of respiratory function, but this may have reflected insufficient evidence rather than real equivalence between methods. There was a trend for participants to prefer self-administered airway clearance techniques. Limitations of this review included a paucity of well-designed, adequately powered, long-term trials.

Evidence--Bronchiectasis

III. **Lee 2013**, Cochrane comparison of airway clearance techniques for bronchiectasis) http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD008351.pub2/epdf Study not included due to length)
    i. N=5 studies (51 participants)
        1. 4 adult, 1 pediatric
        2. Looked at a variety of airway clearance techniques, including mechanical chest oscillation
    ii. Heterogeneity between studies precluded these data from meta-analysis and the review was therefore narrative.
    iii. One study on 20 adults comparing an airway oscillatory device with no treatment found no significant difference in the number of exacerbations at 12 weeks (low-quality evidence).
    iv. No data were available to assess the impact of ACTs on the time to exacerbation, duration of, incidence of hospitalisation or total number of hospitalised days. The same study reported clinically significant improvements in health-related quality of life in both disease-specific and cough-related measures. While based on a small number of participants and the data were skewed, the median difference in the change in total St George's Respiratory Questionnaire (SGRQ) score over three months in this study was 8.5 units (P value = 0.005 (Wilcoxon), low-quality evidence).
    v. Two studies reported mean increases in volume of sputum expectorated with airway oscillatory devices in the short term of 8.4 mL (95% CI 3.4 to 13.4 mL)

and in the long term of 3 mL (P value = 0.02), with no significant effect on lung function.

vi. One study reported an immediate reduction in pulmonary hyperinflation in adults with non-positive expiratory pressure (PEP) ACTs (difference in functional residual capacity (FRC) of 19%, P value < 0.05) and with airway oscillatory devices (difference in FRC of 30%, P value < 0.05) compared to no ACTs. A similar decrease in pulmonary hyperinflation (difference in FRC of 6%) was found in children using an airway oscillatory device for 3months compared to sham therapy.

vii. No studies reported on the effects of gas exchange, people's symptoms or antibiotic usage.

viii. **Authors' conclusions:** ACTs appear to be safe for individuals (adults and children) with stable bronchiectasis, where there may be improvements in sputum expectoration, selected measures of lung function and health-related quality of life. The role of these techniques in people with an acute exacerbation of bronchiectasis is unknown. In view of the chronic nature of bronchiectasis, more data are needed to establish the clinical value of ACTs over the short and long term on patient-important outcomes, including symptoms, on physiological outcomes which may clarify the rationale for each technique and on long-term parameters that impact on disease progression in individuals with stable bronchiectasis. This is necessary in order to provide further guidance of specific ACT prescription for people with bronchiectasis. It may also be important to establish the comparative effect of different types of ACTs in people with bronchiectasis.

Evidence—neuromuscular disease

1) **Hull 2010,** British Thoracic Society guidelines for children with neuromuscular disease (http://thorax.bmj.com/content/67/Suppl_1/i1.full.pdf+html Study not included due to length)
   a. Oscillatory techniques such as high-frequency chest wall oscillation and intrapulmonary percussive ventilation should be considered in children who have difficulty mobilising secretions or who have persistent atelectasis, despite use of other airway clearance techniques. [D]
2) **Lechtzin 2016**, Impact of High-Frequency Chest Wall Oscillation on Healthcare Use in Patients with Neuromuscular Diseases
   a. Cohort study of claims data, patients with a variety of neuromuscular disease
   b. N=426 patients
   c. Total medical costs per member per month decreased by $1,949 (18.6%) after initiation of HFCWO (P = 0.002). Inpatient admission costs decreased by $2,392 (41.7%) (P = 0.001), and pneumonia costs decreased by $514 (18.1%) (P = 0.015).
   d. Conclusions: Total medical costs, hospitalizations, and pneumonia claims were less after than before initiation of HFCWO in a broad group of patients with neuromuscular disease. Subject to the limitations that administrative data did not capture how HFCWO was used and that HFCWO may be a marker of generally better care, our findings lend support to the routine use of this intervention in the care of patients with neuromuscular diseases.

Other policies

I. United Health Care 2015

i. High-frequency chest wall compression (HFCWC), as a form of chest physical therapy, is proven and medically necessary for treating or preventing pulmonary complications of the following conditions:
   1. Cystic fibrosis (CF)
   2. Bronchiectasis

ii. High-frequency chest wall compression (HFCWC), as a form of chest physical therapy, is unproven and not medically necessary for diagnoses other than cystic fibrosis and bronchiectasis, including, but not limited to respiratory symptoms attributed to neuromuscular disorders when they compromise respiration, such as amyotrophic lateral sclerosis (ALS), cerebral palsy, familial dysautonomia, muscular dystrophy or quadriplegia.

II. Aetna 2016

i. Aetna considers high-frequency chest compression systems (e.g., the Frequencer, the SmartVest, the MedPulse Respiratory Vest System, the Vest Airway Clearance System, the ABI Vest, Respin11 Bronchial Clearance System, and the InCourage Vest/System) medically necessary in lieu of chest physiotherapy for the following indications, where there is a well documented failure of standard treatments to adequately mobilize retained secretions:
   1. Bronchiectasis, confirmed by CT scan, characterized by daily productive cough for at least 6 continuous months or by frequent (i.e., more than 2 times/year) exacerbations requiring antibiotic therapy; *or*
   2. Cystic fibrosis or immotile cilia syndrome; *or*
   3. The member has one of the following neuromuscular disease diagnoses:
      a. Acid maltase deficiency
      b. Anterior horn cell diseases, including amyotrophic lateral sclerosis
      c. Hereditary muscular dystrophy
      d. Multiple sclerosis
      e. Myotonic disorders
      f. Other myopathies
      g. Paralysis of the diaphragm
      h. Post-polio
      i. Quadriplegia regardless of underlying etiology.
   4. Lung transplant recipients, within the first 6 months post-operatively, who are unable to tolerate standard chest physiotherapy.
   5. Aetna considers high-frequency chest compression systems experimental and investigational for other indications (e.g., alpha 1-antitrypsin deficiency, childhood atelectasis, cerebral palsy, coma, kyphosis, leukodystrophy, scoliosis, and stiff-person (stiff-man) syndrome; not an all-inclusive list) because their effectiveness for these indications has not been established.

II. CMS 2013

i. There is a diagnosis of cystic fibrosis (ICD-9 277.00, 277.02).

ii. There is a diagnosis of bronchiectasis (ICD-9 011.50-011.56, 494.0, 494.1, 748.61) which has been confirmed by a high resolution, spiral, or standard CT scan and which is characterized by:
    1. Daily productive cough for at least 6 continuous months; or
    2. Frequent (i.e., more than 2/year) exacerbations requiring antibiotic therapy.
    3. Chronic bronchitis and chronic obstructive pulmonary disease (COPD) in the absence of a confirmed diagnosis of bronchiectasis do not meet this criterion.

iii. The beneficiary has one of the following neuromuscular disease diagnoses:
Post-polio (138)
Acid maltase deficiency (277.6)
Anterior horn cell diseases (335.0-335.9)
Multiple sclerosis (340)
Quadriplegia (344.00-344.09)
Hereditary muscular dystrophy (359.0, 359.1)
Myotonic disorders (359.21-359.29)
Other myopathies (359.4, 359.5, 359.6, 359.89)
Paralysis of the diaphragm (519.4)

iv. There must be well-documented failure of standard treatments to adequately mobilize retained secretions.

HERC staff summary

There is weak evidence that high frequency chest wall oscillation devices are equally efficacious to other forms of chest wall therapy for cystic fibrosis and bronchiectasis. There is economic data and expert recommendations supporting the use of high frequency chest wall oscillation for neuromuscular diseases.

HERC staff recommendations:

1) Add mechanical chest oscillation (CPT 94669) to the following lines:
    I. **24** CYSTIC FIBROSIS
    II. **62** BRONCHIECTASIS
    III. **75** NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
2) Adopt the following new guideline regarding mechanical chest oscillation

GUIDELINE NOTE XXX

Lines 24, 62, 75

Mechanical chest oscillation (CPT 94669) is included on these lines only when there is a well-documented failure of standard treatments to adequately mobilize retained secretions.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: METABOLIC AND BARIATRIC SURGERY

DRAFT for 10/6/2016 VbBS/HERC meeting materials

HERC Coverage Guidance

Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass, gastric banding, and sleeve gastrectomy) is recommended for:

- Adult obese patients (BMI ≥ 35) with
  - Type 2 diabetes *(strong recommendation)* OR
  - at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea *(weak recommendation)*
- Adult obese patients (BMI ≥ 40) *(strong recommendation)*

Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program *(weak recommendation).*

Metabolic and bariatric surgery is not recommended for coverage in:

- Patients with BMI <35, or 35-40 without the defined comorbid conditions above *(weak recommendation)*
- Children and adolescents *(weak recommendation)*

Note: Definitions for strength of recommendation are provided in Appendix B: GRADE Informed Framework – Element Descriptions.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are several elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by the Commission based on assessment of two independent reviewers from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the Commission.

Coverage question: Should bariatric surgery be recommended for coverage in adults?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
All-cause mortality (*Critical outcome)*	Odds ratio: 0.48 (95% CI 0.35 to 0.64) Crude event rates 3.6% with surgery and 11.4% without surgery Number needed to treat = 13 ●●○○ *(low certainty based on consistent but indirect observational studies)*	Bariatric surgery costs tens of thousands of dollars per surgery, but has been shown to be cost effective across BMI thresholds and surgery types.	Patients would balance surgery and its risks with risks of living with morbid obesity. Many patients who have failed conservative attempts at weight loss may elect surgery. The benefits of decreased mortality, dramatic weight loss, and regression of diabetes are important outcomes that patients and society would	The greatest benefit may be with BMI ≥ 40 but otherwise specific subpopulations which would benefit the most from bariatric surgery are not well characterized. The pre-operative requirements for achieving optimal outcomes are unclear. Given the rate of complications and need
Major adverse cardiovascular events (*Critical outcome*)	Odds ratio: 0.54 (95% CI 0.41 to 0.70) Crude event rates 2.4% with surgery and 4.0% without surgery Number needed to treat = 62 ●●○○ (*low certainty based on consistent but indirect observational studies)*			

Coverage question: Should bariatric surgery be recommended for coverage in adults?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Type 2 DM remission/resolution (*Important outcome*)	Odds ratio: 3.6 to 52.4 (favoring surgery) Number needed to treat: 1 to 5 ●●●○ *(moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects)*		strongly value. However, there would still be moderate variability because of the risks and costs associated with surgery, as well as the intensive peri- and post-operative follow up.	for reoperation reported in the summary literature, benefit plans may wish to consider alternative payment methodologies like bundled payments or a pay-for-outcomes approach. Surgeon case volume, and to a lesser extent hospital case volume, appear to affect outcomes for patients undergoing bariatric surgery and requirements regarding surgeon or facility volume may be reasonable.
Hypertension remission/ resolution (*Important outcome*)	Odds ratio: 2.99 to 3.12 (favoring surgery) Number needed to treat: 4 ●●●○ *(moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects)*			
Change in BMI (*Important outcome*)	Mean difference at 1 year: -5.5 to -33.35 kg/m^2 (favoring surgery) Pooled mean difference: -7.4 kg/m^2 (favoring surgery) ●●●○ *(moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects)*			

Coverage question: Should bariatric surgery be recommended for coverage in adults?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Rationale: Bariatric surgery appears to lower all-cause mortality and major adverse cardiovascular events in obese adults (low certainty), and significantly reduces BMI, and results in resolution of type 2 diabetes and hypertension. The greatest benefit appears to be with BMI ≥ 40. Though bariatric surgery is costly and carries significant perioperative risks, the clear long-term positive health benefits leads to a recommendation for coverage. The strength of the recommendation is based on the fact that there is a strong benefit on critical outcomes (particularly in diabetics), and patients desiring surgery would strongly prefer this intervention. For those without diabetes, and other comorbidities are present, the evidence is less clear, leading to a weak recommendation.				

Recommendation:
 	
Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass, gastric banding, and sleeve gastrectomy) is recommended for:
 	
• Adult obese patients (BMI ≥ 35 and <40) with:
  ○ Type 2 diabetes *(strong recommendation)* OR
  ○ at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea *(weak recommendation)*
• Adult obese patients (BMI ≥ 40) *(strong recommendation)*
 	
Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program *(weak recommendation).*
 	
Metabolic and bariatric surgery is not recommended for coverage in:
 	
• Patients with BMI <35, or 35-40 without the defined comorbid conditions above *(weak recommendation)*				

Note: GRADE framework elements are described in Appendix B. A GRADE evidence profile is provided in Appendix C.

Coverage question: Should bariatric surgery be recommended for coverage in children and adolescents?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
All-cause mortality (*Critical outcome*)	Insufficient evidence in this population *Insufficient evidence*	High cost (tens of thousands of dollars) but may be cost effective especially given the long time horizon if weight loss is maintained. However, uncertainty about the long-term balance of benefits and harms could significantly alter estimates of cost-effectiveness.	High variability. If conservative treatments have failed, children, adolescents and their parents would be highly motivated to find an effective alternative intervention. Children may have a significant fear of surgery, but the profound social and emotional impact of obesity may override their concerns. Parents are likely to be more concerned about the long term health impacts of obesity than children, and may be concerned about the uncertainty about the long term benefits.	Parental involvement in weight management plans is likely necessary to assist the effectiveness of obesity treatments (based on expert opinion). Pediatric bariatric surgery is likely to be available at only a few highly specialized centers. The American Academy of Pediatrics has 10 criteria that pediatric bariatric surgery programs should meet.
Major adverse cardiovascular events (*Critical outcome*)	Insufficient evidence in this population *Insufficient evidence*			
Type 2 DM remission/resolution (*Important outcome*)	Rates of remission of T2DM ranged from 50 to 100% ●○○○ *(very low certainty based on mostly small observational trials with imprecise effects)*			
Hypertension remission/ resolution (*Important outcome*)	Rates of remission of hypertension ranged from 50 to 100% ●○○○ (*very low certainty based on mostly small observational trials with imprecise effects)*			

Coverage question: Should bariatric surgery be recommended for coverage in children and adolescents?				
Change in BMI (*Important outcome*)	Mean weighted difference in BMI at 1 year (from baseline): -10.5 to -17.2 kg/m^2 ●●○○ *(low certainty based on mostly small observational trials)*			
Rationale: Bariatric surgery likely results in significant reductions in BMI (low certainty) and is associated with remission of type 2 diabetes and hypertension (very low certainty). However, coverage is not recommended because of the limited evidence about overall long-term benefits and harms of bariatric surgery in this population as well as the high variability in values and preferences.				
Recommendation: Bariatric surgery is not recommended for coverage in children and adolescents *(weak recommendation).*				

Note: GRADE framework elements are described in Appendix B. A GRADE evidence profile is provided in Appendix C.

Coverage question: Should reoperative bariatric surgery for inadequate weight loss be recommended for coverage?					
Outcomes		**Estimate of Effect for Outcome** **Confidence in Estimate of Effect**	**Resource allocation**	**Values and Preferences**	**Other considerations**
Critical outcomes	All-cause mortality	Insufficient evidence in this population *Insufficient evidence*	A second high cost procedure (tens of thousands of dollars), with a history of prior failure may be more costly in	There would be high variability in patient preferences. With a prior failure of a bariatric procedure, some patients would be hesitant to try an additional procedure given the burdens of	There is evidence of greater complications rates with reoperation. There is insufficient evidence in the reoperation group to know if their outcomes
	Major adverse cardiovascular events	Insufficient evidence in this population *Insufficient evidence*			

Coverage question: Should reoperative bariatric surgery for inadequate weight loss be recommended for coverage?					
Outcomes		**Estimate of Effect for Outcome** **Confidence in Estimate of Effect**	**Resource allocation**	**Values and Preferences**	**Other considerations**
Important outcomes	Type 2 DM remission / resolution	Insufficient evidence in this population *Insufficient evidence*	total and less effective, however, the cost –effectiveness in this group is unknown.	surgery and prior ineffectiveness. Others would be motivated to try a different procedure in hopes that it would work better. Patients seeking reoperation have likely no other good potential option given failure of multiple previous alternatives (e.g. clinical, pharmacological, nutritional, physical activity, and surgical).	would be substantially different that those undergoing their first operation. A significant proportion of these patients would be going from a band to a RYGB (from a procedure with a higher failure rate to a lower failure rate).
	Hypertension remission/ resolution	Insufficient evidence in this population *Insufficient evidence*			
	Change in BMI	Mean change in BMI (from baseline): +2.4 kg/m^2 to -17.2 kg/m^2 (follow-up ranging from 8 to 48 months) ●○○○ *(very low certainty based on small case series)*			
Rationale: Reoperation is associated with higher complication rates but also effective weight loss (based on very low quality evidence). While there are not long term health outcomes available, there is no reason to believe that significant weight loss in the reoperation group would be associated with less future health benefits. Therefore, the subcommittee makes no recommendation that the coverage criteria should be different between reoperation and primary surgery. Surgeons will also evaluate their patients and consider reasons for failure when deciding if the patient is a good candidate for reoperation.					
Recommendation: No recommendation that coverage criteria for re-operation should be different than for primary surgery.					

Note: GRADE framework elements are described in Appendix B GRADE evidence profile is provided in Appendix C.

EVIDENCE OVERVIEW

Clinical background

Obesity, generally defined as a body mass index (BMI) ≥ 30 kg/m^2 in adults or above the 95th percentile of age- and sex-specific BMI growth charts in children and adolescents, is common. Information from the National Health and Nutrition Examination Survey published in 2014 provides estimates of obesity prevalence of 35% of adults, 17% of 2 to 19 year olds, and 8.1% of infants and toddlers (Ogden, Carroll, Kit, & Flegal, 2014). Obesity is a risk factor for several medical conditions including heart disease, type 2 diabetes mellitus (T2DM), stroke, cancer, sleep apnea, osteoarthritis and others. The Centers for Disease Control and Prevention estimates that obesity is the second leading cause of preventable death and will likely overtake tobacco use as the leading cause of preventable death within the next decade. Older estimates from 2009 found that medical spending attributable to obesity is between $147 billion and $210 billion annually with at least $60 billion of those costs accruing to Medicare and Medicaid programs (Finkelstein, Trogdon, Cohen, & Dietz, 2009).

Data from the Oregon Behavioral Risk Factor Surveillance system in 2009 found that the overall prevalence of adult obesity in Oregon is 24%, though the prevalence of obesity in adults covered by the Oregon Health Plan is greater at 38%. The Oregon Healthy Teens Survey in 2009 estimated that approximately 11% of 8th graders were obese. The Oregon Department of Public Health estimated that costs of obesity related medical care in the Medicaid program alone exceeded $333 million in 2006 (State of Oregon, Department of Human Services, 2012).

There are a number of commonly used medical treatments for obesity including structured programs to promote improved nutrition and physical activity, intensive behavioral counseling for individuals or families, and medications. The Food and Drug Administration (FDA) approved pharmaceutical treatments for obesity include orlistat (Xenical®, Alli®), lorcaserin (Belviq®), phentermine/topiramate (Qsymi®), liraglutide (Victoza®, Saxenda®), and bupropion/naltrexone (Contrave®). Several other medications and herbal supplements are also promoted for weight loss. The FDA also recently approved a weight loss device called the Maestro® Rechargable System that works by blocking signals along the vagal nerve.

Bariatric surgical procedures (sometimes also referred to as metabolic surgery) are another treatment option for obesity.

Indications

Bariatric surgery (alone or in conjunction with non-surgical treatments) is indicated for the treatment of obesity. Guidelines regarding indications for bariatric surgery vary based on BMI thresholds and the presence of obesity-related comorbid conditions.

Technology description

Bariatric procedures commonly performed in the United States include adjustable gastric banding (AGB), vertical sleeve gastrectomy (VSG), Roux-en-Y gastric bypass (RYGB), and biliopancreatic diversion/

duodenal switch (BPD/DS). An excellent overview of the anatomic details of these procedures is available in the executive summary of the Washington Health Technology Assessment (WA HTA) report published in April 2015 (WA HTA, 2015).

The use of bariatric surgical procedures is growing, and approximately 179,000 procedures were performed in 2013 in the United States (U.S.). The distribution of procedure types in the U.S. has shifted with greater use of vertical sleeve gastrectomy and declining use of gastric banding. The estimated number and distribution of surgical procedures in the U.S. is summarized in Table 1.

Table 1. Estimated number and distribution of bariatric surgical procedures in the United States between 2011 and 2013.

	2011	2012	2013
Total	158,000	173,000	179,000
RYGB	36.7%	37.5%	34.2%
Gastric band	35.4%	20.2%	14.0%
Sleeve gastrectomy	17.8%	33.0%	42.1%
BPD/DS	0.9%	1.0%	1.0%
Revisions	6.0%	6.0%	6.0%
Other	3.2%	2.3%	2.7%

Reproduced from the American Society of Bariatric and Metabolic Surgeons, http://connect.asmbs.org/may-2014-bariatric-surgery-growth.html.

Abbreviations: BPD/DS – Biliopancreatic diversion/duodenal switch; RYGB – Roux-en-Y gastric bypass

Adjustable gastric banding and VSG are procedures that either functionally or anatomically reduce the size of the stomach. Adjustable gastric banding, alone among the bariatric surgical procedures, is completely reversible. Roux-en-Y gastric bypass and BPD/DS are more complicated procedures that reduce the size of the stomach and connect more distal portions of the small intestine to the gastric remnant thus bypassing varying lengths of small intestine and reducing the absorption of nutrients. For this reason, these surgeries are sometimes referred to as malabsorptive procedures, with the degree of malabsorption correlating to the length of small intestine that is bypassed. Vertical sleeve gastrectomy is sometimes performed as part of a two stage procedure for patients with extremely high BMIs (the second stage of the procedure is usually a malabsorptive procedure that is more technically feasible after the initial weight loss achieved by VSG).

These procedures can be performed laparoscopically and with robotic assistance. Adjustable gastric banding is sometimes performed on an outpatient basis, but the other procedures generally require a hospital stay that varies from one to seven days after surgery depending on the procedure and patient-specific characteristics. Recovery times vary from one to four weeks. All procedures require frequent follow-up, but AGB may require a greater number of follow-up visits to make adjustments to the band (done through a port located underneath the skin of the abdomen).

All of the bariatric surgical procedures entail operative and post-operative risks, though these vary by the type of procedure. Data regarding perioperative mortality, complications, need for reoperation, and serious adverse events reported in four systematic reviews are summarized in Table 2. It should be noted that definitions of complications and adverse events varied widely across studies. Operative risks include bleeding, infection, and damage to various abdominal organs. Nausea and vomiting are common after all these procedures and the malabsorptive surgeries sometimes cause persistent diarrhea. The malabsorptive procedures are associated with an increased risk of vitamin and mineral deficiencies, and certain types of kidney stones may become more common. Gastrointestinal bleeding from ulcers occurring at the surgical anastamoses also occurs. Infections of the subcutaneous port and erosion of the gastric band into the stomach are risks unique to AGB. The overall median complication rates reported in the Washington HTA report range from 8.8% for VSG to 26.9% for BPD (WA HTA, 2015).

Table 2. Mortality, complications, reoperations, and serious adverse events reported in four systematic reviews.

	Chang (2014)	Colquitt (2014)	Puzziferri (2014)	WA HTA (2015) Range, Median
Mortality <30 days	0.08% in RCTs 0.22% in OSs	NR	NR	NR
Mortality >30 days or not specified	0.31% in RCTs 0.35% in OSs	NR	1% for bypass procedures 0.2% for banding procedures	BPD: 0%-2.9%, 1.4% LAGB: 0%-2.0%, 0.15% RYGB: 0%-4.3%, 1.94% VSG: 0%-3.9%, 0.07%
Complication rate	17% in RCTs 10% in OSs	NR	NR	BPD: 8%-83%, 26.9% LAGB: 0%-53%, 10.1% RYGB: 0%-78%, 9.2% VSG: 0%- 80%, 8.8%
Reoperation rate	7% in RCTs 6% in OSs	2%-13%	NR	BPD: 0%-30%, 3.6% LAGB: 0%-44%, 7.4% RYGB: 0%-22%, 5.8% VSG: 0%-17%, 3.9%
Serious adverse event rate	NR	0-37% in surgical groups 0-25% in non-surgical groups	NR	NR

Abbreviations: BPD – Biliopancreatic diversion; LAGB – Laparoscopic adjustable gastric banding; NR – Not reported; OS – Observational study; RCT – Randomized controlled trial; RYGB – Roux-en-Y gastric bypass; VSG – Vertical sleeve gastrectomy

Key Questions

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods please see Appendix A.

1. Should coverage be recommended for bariatric surgery in each of the scenarios in the table below? (Note that the "resolution of diabetes" would not be an applicable outcome in scenarios 4-9)

	BMI 30 – 34.9	BMI 35 – 39.9	BMI ≥ 40
With DM2	Scenario 1	Scenario 2	Scenario 3
W/o DM2 nor other comorbidities	Scenario 4*	Scenario 5*	Scenario 6*
w/o DM2 but with other comorbidities	Scenario 7*	Scenario 8*	Scenario 9*

*Resolution of type 2 diabetes isn't a relevant outcome for this population

2. What is the appropriate minimum age for bariatric surgery?
3. What components and systems of care are associated with improved health outcomes (e.g., centers of excellence, surgeon's experience, etc.)?
4. What preoperative assessments or requirements for preoperative weight loss should be recommended in patients being considered for bariatric surgery?

Critical outcomes selected for inclusion in the GRADE table were all-cause mortality and major adverse cardiovascular events. Important outcomes selected for inclusion in the GRADE table were weight loss (change in BMI), and remission or resolution of T2DM or hypertension.

Evidence review

General Limitations

The literature on bariatric surgery is voluminous. The search conducted by Center staff yielded more than 20 systematic reviews published in the last two years (see Appendix A for a detailed methods description). These reviews span more than 600 individual studies. It should be noted that there is little consistency in the inclusion of individual studies across reviews and that many of the systematic reviews did not perform meta-analysis, in part due to high levels of heterogeneity.

Furthermore, there are important concerns about the quality of much of the published research on bariatric surgery. As the Washington HTA report summarized:

> While the comparative evidence base for either head-to-head comparisons of bariatric procedures or comparisons of bariatric surgery to nonsurgical interventions has grown considerably over time, major challenges with the quality and applicability of available studies remains. Of the 179 comparative studies identified for this evaluation, we rated only 26 (15%) to be of good quality,

based on comparable groups at baseline, comparable duration of follow-up, and limited sample attrition. An additional 74 studies (41%) were rated fair quality; issues with comparability, duration of follow-up, and/or attrition were identified in these studies, but attempts were made to control for confounding in the analytic methods (e.g., survival analysis techniques, multivariate regression). However, we considered another 79 studies (44%) to be of poor quality because at least one key quality issue was present and not adequately addressed in either study design or analysis. (WA HTA, 2015, p ES-6).

Additionally, there are at least nine ongoing trials of bariatric surgery that are expected to publish results over the next four years.

Systematic Reviews Addressing Effectiveness in Adults

Eight good quality systematic reviews address the effectiveness of bariatric surgery in adults (Chang et al., 2014; Colquitt, Pickett, Loveman, & Frampton, 2014; Hayes, 2014; Kwok et al., 2014; Muller-Stich et al., 2014; Puzziferri et al., 2014; Wang et al., 2015; WA HTA, 2015). These studies are summarized in Table 3 and discussed below by systematic review.

Table 3. Summary of Systematic Reviews – Effectiveness of Bariatric Surgery for Adults

Systematic Review (Quality) Total N	No. and Type of Included Studies	Population	Outcomes of Interest
Chang, 2014 (Good) N = 161,756	37 RCTs 127 observational studies	Pre-surgical BMI (mean): 45 kg/m^2 T2DM: 26% Hypertension: 47%	Mortality (within 30 days of surgery) Complication rate BMI (mean change at 1 and 5 years) T2DM remission Hypertension remission
Colquitt, 2014 (Good) N ~ 600	7 RCTs	Average pre-surgical BMI (mean): 27 – 55 kg/m^2 5 out of 7 studies required participants have T2DM	BMI T2DM remission Hypertension remission Serious adverse events
Hayes, 2014 (Good) N = 1,734	18 controlled or comparative studies	Pre-surgical BMI (mean): 25 – 55 kg/m^2 T2DM	BMI T2DM remission

Systematic Review (Quality) Total N	No. and Type of Included Studies	Population	Outcomes of Interest
Kwok, 2014 (Good) N = 195,408	14 comparative cohorts	Most studies enrolled participants with BMI > 35 kg/m2	All-cause mortality Cardiovascular adverse events
Muller-Stich, 2014 (Good) N = 766	7 RCTs 6 Comparative observational studies	Pre-surgical BMI (mean): < 35 – 37 kg/m^2	BMI T2DM remission Hypertension remission
Puzziferri, 2014 (Good) N = 8,678	10 RCTs 8 cohort studies 11 case series	Pre-surgical BMI (mean): 44 – 61 kg/m^2	Weight loss T2DM remission Hypertension remission Perioperative mortality
Wang, 2015 (Good) N = 256	4 RCTs	Pre-surgical BMI (mean): 30 – 47 kg/m^2	BMI T2DM remission
WA HTA, 2015 (Good) N = 2,083	14 RCTs 7 comparative cohort studies	Pre-surgical BMI (mean): 30 – 56 kg/m^2	BMI T2DM remission Perioperative mortality and complications

Abbreviations: BMI – body mass index; RCT – randomized controlled trial; T2DM – type 2 diabetes mellitus; WA HTA – Washington Health Technology Assessment Program

Chang (2014)

Chang et al. (2014) is a good quality systematic review and meta-analysis of 164 contemporary studies (37 randomized controlled trials [RCTs] and 127 observational studies) of bariatric surgery published between 2003 and 2012. The included studies spanned over 161,000 patients with an average age of 45 years and an average pre-surgical BMI of 45 kg/m^2. Twenty six percent of the included patients had T2DM and 47% had hypertension. More than two years of follow-up was available for 133,000 of the included patients. Results of RCTs and observational studies were reported separately in the meta-analysis.

The review and meta-analysis focused on surgical mortality and complications, change in BMI, and resolution of obesity-related comorbid conditions. The overall rate of mortality within 30 days of surgery was 0.08% (95% confidence interval [CI] 0.01% to 0.24%) in the RCTs and 0.22% (95% CI 0.14% to 0.31%) in the observational studies. The overall complication rate was 17% (95% CI 11% to 23%) in the RCTs and 9.8% (95% CI 7.4 to 13.0) in the observational studies.

The overall mean change in BMI at 1 year was -13.53 kg/m^2 in the RCTs and -11.79 kg/m^2 in the observational studies. For those studies reporting outcomes at five years of follow-up, the overall mean change in BMI was -11.40 kg/m^2 in the RCTs and -14.32 kg/m^2 in the observational studies.

In the RCTs, the T2DM remission rates in the surgical groups was 92% (95% CI 84.68 to 97.18) compared with a rate of 17.4% (95% CI 0.98 to 69.27) in the control groups. The observational studies found a T2DM remission rate of 86.5%. In the RCTs, the hypertension remission rate was 75% (95% CI 61.52 to 86.35) in the surgical groups compared with a rate of 49% (95% CI 0 to 99%). These comparisons are both indirect and imprecise because so few of the included studies compared surgical and non-surgical groups directly. Additionally, duration of follow-up for the studies examining comorbid conditions was unclear.

Colquitt (2014)

Colquitt et al. (2014) is a good quality systematic review by the Cochrane Collaboration that includes 22 RCTs, of which 7 studies, comprising approximately 600 patients, compared bariatric surgery to non-surgical controls. Because of differences in the characteristics of participants, interventions, and comparators, meta-analysis was considered inappropriate, and the results were reported narratively.

In terms of BMI, the included studies reported mean changes of -7.4 kg/m^2 to -33.3 kg/m^2 with surgery compared to -0.5 kg/m^2 to -4.7 kg/m^2 in non-surgical controls. The authors conclude that "the direction of the effect was consistently in favour of surgery" based on moderate quality of evidence.

In terms of remission of T2DM, the included studies reported rates of remission ranging from 42% to 90% at 12 to 24 months in surgical groups (73% to 90% if one study with a more stringent definition of A1c < 6 is excluded) compared to remission rates of 0% to 32% in non-surgical controls. The authors conclude that "more people experienced remission following surgery" based on moderate quality of evidence.

Three studies included in the Cochrane review also reported on hypertension outcomes. Two studies reported rates of reduction or discontinuation of antihypertensive medications ranging from 49% to 80% between 12 and 24 months in the surgical groups compared to 0% to 70% in non-surgical controls. One additional study reported that the proportion of patients with systolic blood pressure less than130 mmHg at 12 months was 84% in the surgical group and 79% in non-surgical controls. The authors did not draw any conclusions based on these data.

Hayes (2014)

Hayes (2014) is a good quality systematic review and health technology assessment based on 18 controlled or comparative studies of RYGB in adults with T2DM published between2007 and 2014. Seven of the included studies (5 RCTs and 2 non-randomized controlled trials) compared RYGB with non-surgical treatments while the remaining 11 compared RYGB with other bariatric surgical procedures. The average follow-up across the included studies was 12 months to 5 years.

In patients undergoing RYGB, BMI was reduced by 20 to 33% compared to baseline and T2DM remission was reported in 38 to 90% of patients. In the non-surgical treatment groups, BMI change ranged from -10% to 1%, and T2DM remission rates ranged from 0 to 33%. Based on this, Hayes concluded that RYGB

is superior to intensive lifestyle or medical interventions for the treatment of T2DM. The authors further conclude that RYGB and sleeve gastrectomy are equally effective in the treatment of T2DM. Finally, the authors note that preliminary evidence (from a single study) suggests the RYGB may be equally effective for treatment of T2DM in patients with BMI<35 kg/m^2 and BMI>35 kg/m^2, but that additional studies are needed to establish the safety and effectiveness of RYGB in patients with lower BMIs.

Kwok (2014)

Kwok et al. (2014) is a good quality systematic review and meta-analysis of 14 comparative cohort studies reporting mortality and cardiovascular outcomes amongst 29,208 bariatric surgery patients and 166,200 non-surgical controls. The follow-up period of the included studies ranged from 2 years to 14.7 years. The surgical procedures in the studies included AGB, RYGB, SG, banded gastroplasty, as well as other unspecified bariatric surgical procedures. Most of the included studies reported enrolling patients with BMI >35 kg/m^2. Of the 14 included studies, 10 were deemed to be at low to moderate risk of bias, while four studies were deemed to be at moderate-high risk of bias due to concerns over loss to follow-up and inadequate adjustment for confounding. See Appendix D for a detailed description of the included studies.

In the 14 studies included in the meta-analysis of all-cause mortality, the crude event rate was 1059/29,208 (3.6%) in the surgical group and 18,962/166,200 (11.4%) in the non-surgical control group. The odds ratio (OR) for mortality in the surgical group compared with the non-surgical group was 0.48 (95% CI 0.35 to 0.64). Considering only the 10 studies that reported adjusted estimates, the association was consistent but more conservative with an odds ratio for mortality of 0.60 (95% CI 0.49 to 0.74) favoring the surgical group over the non-surgical controls.

In the four studies included in the meta-analysis of composite cardiovascular adverse events, the crude event rate was 407/17,262 (2.4%) in the surgical group and 1108/27,726 (4.0%) in the non-surgical control group. The odds ratio for composite cardiovascular adverse events in the surgical group compared with the non-surgical group was 0.54 (95% CI 0.41 to 0.70). The pooled estimates for the odds ratio of myocardial infarction and stroke for surgical patient compared to non-surgical controls were 0.46 (95% CI 0.30 to 0.69) and 0.49 (95% CI 0.32 to 0.75) respectively.

Overall, the authors conclude that long-term follow-up data from comparative cohort studies suggest that bariatric surgery is associated with lower rates of mortality (3.6% vs 11.4% for non-surgical controls, number needed to treat [NNT] = 13) and composite adverse cardiovascular events (2.4% vs 4.0% for non-surgical controls, NNT = 62).

Muller-Stich (2014)

Muller-Stich et al. (2014) is a good quality systematic review and meta-analysis of studies comparing surgical and medical treatment of T2DM in non-severely obese patients. The systematic review included seven RCTs and six comparative observational studies comprising 818 diabetic patients. All of the studies included patients with BMI <35 kg/m^2 and eight of the studies were performed exclusively in patients with BMI <35 kg/m^2; among the remaining seven studies the highest average BMI was 37.1 kg/m^2. The surgical procedures performed in the included studies were AGB, BPD, RYGB, and SG. The follow-up periods ranged from 12 to 36 months.

In the meta-analysis of studies reporting remission of T2DM, 129 of 280 patients achieved remission in the surgical group compared with 6 of 252 patients in the medical treatment group. The combined odds ratio for T2DM resolution after surgery compared with medical treatment was 14.11 (95% CI 6.67 to 29.86).

In the meta-analysis of studies reporting change in BMI, the absolute mean difference in BMI was -5.5 kg/m^2 (95% CI -6.7 to -4.3) favoring the surgical group.

In the meta-analysis of studies reporting presence of arterial hypertension at the end of the study, the 76 of 274 patients in the surgical group and 101/189 patients in the medical treatment group had arterial hypertension. The combined odds ratio for arterial hypertension after surgery compared with medical treatment was 0.25 (95% CI 0.12 to 0.50).

The authors performed a network meta-analysis to compare the treatment effects of the different surgical procedures. Although point estimates of the odds ratio for T2DM remission compared to medical treatment ranged from 12.23 for AGB to 55.05 for RYGB, the 95% confidence intervals overlapped for all four included procedures, and all were superior to medical treatment.

Overall, the authors conclude that among non-severely obese patients with T2DM bariatric surgery results in greater short-term improvements in diabetes remission, weight loss, and arterial hypertension when compared with medical treatment.

Puzziferri (2014)

Puzziferri et al. (2014) is a good quality systematic review and meta-analysis of 29 studies with long-term follow-up and low rates of attrition. Specifically, only studies of gastric bypass, gastric band, or sleeve gastrectomy performed in patients with a BMI of >35 and that reported outcomes with a minimum of two years of follow-up and at least 80% of the original study participants were included in the review. Only 29 studies (of nearly 8,000 citations reviewed) met the inclusion criteria. Among the included studies were 10 RCTs, one matched cohort, six prospective cohorts, one retrospective cohort, and 11 case series.

Weight loss outcomes in this review were reported as percentage of mean excess weight loss (EWL). The sample size weighted mean EWL was 65.7% after gastric bypass, 64.5% after sleeve gastrectomy, and 45% after gastric banding.

Six of the included studies reported on remission of T2DM (defined as glycated hemoglobin <6.5% without medications). Sample size weighted T2DM remission rates were 66.7% after gastric bypass and 28.6% after gastric banding.

Three of the included studies reported on remission of hypertension (defined as blood pressure <140/90 without medications). The reported hypertension remission rate was 38.2% after gastric bypass and 17.4% after gastric banding.

Wang (2015)

Wang et al. (2015) is a good quality, though narrowly focused, systematic review and meta-analysis of randomized controlled trials comparing laparoscopic RYGB with sleeve gastrectomy in overweight or obese adults with T2DM. Three RCTs judged to be at low risk of bias and one RCT with an unclear risk of

bias were included. The average baseline BMI in the studies ranged from 30 to 46 kg/m^2. Laparoscopic RYGB and sleeve gastrectomy resulted in similar improvements in HbA1c, fasting plasma glucose, need for any diabetic medication, and BMI. Improvements in HDL and LDL cholesterol were statistically significantly greater in the RYGB group. The absolute or relative improvements in these outcomes compared to baseline were not included. Overall, the authors conclude that RYGB and sleeve gastrectomy offer equivalent results in terms of weight loss and T2DM remission, but that RYGB affords greater improvements in lipid parameters and may thus significantly decrease cardiovascular risk.

Washington Health Technology Assessment Report (2015)

The WA HTA report (2015) is a good quality systematic review and health technology assessment summarizing results from 179 comparative studies (35 RCTs, 59 prospective cohorts, 85 retrospective cohorts). Notably, one large cohort study with long-term follow-up, the Swedish Obese Subjects study, was not included as a primary source for the Washington HTA report because most of the patients in that study received a surgical procedure (gastroplasty) that is no longer widely performed. Only 15% of the included studies were judged to be of high quality, with an additional 41% deemed fair quality. When performing meta-analysis, the authors included only good or fair quality RCTs.

Overall or cause-specific mortality was not directly addressed in the WA HTA report because none of the included comparative studies reported those outcomes. However, the WA HTA report does note that evidence from at least one recent comparative cohort study found significantly lower all-cause mortality at 1 to 14 years of follow-up in surgical subjects (hazard ratio [HR] 0.45, 95% CI 0.36 to 0.56) (Arterburn, 2015).

The comparison of bariatric surgery to non-surgical management included 21 good- or fair-quality studies (14 RCTs, 7 comparative cohorts). These studies reported on RYGB (13 studies), AGB (6 studies), VSG (4 studies) and BPD/DS (3 studies). The non-surgical comparators included diet and lifestyle interventions and/or medical interventions (some variably defined as “intensive”). Meta-analytic results were available for weight loss and resolution of T2DM. The pooled mean difference in BMI was 7.4 (95% CI 6.2 to 8.6) favoring surgery, based on 10 studies. Resolution of T2DM had a log odds ratio of 3.62 (95% CI 2.49 to 4.73) favoring surgery, based on nine studies. Meta-analysis of studies reporting resolution of HTN was not done, but the report noted that “[o]ther individual comorbidities commonly evaluated in these comparative studies included hypertension and hyperlipidemia. In studies evaluating resolution of these conditions and/or discontinuation of relevant medications as a binary variable, bariatric surgery was associated with two- to three-fold reductions in the prevalence of these comorbidities [hypertension and hyperlipidemia] at the end of follow-up, while nonsurgical management resulted in no appreciable change from baseline…” (WA HTA, 2015, p. 34).

The WA HTA report is the only systematic review staff identified that summarizes key clinical outcomes stratified by procedure and mean pre-operative BMI. Those tables are included in Appendix G. Nine good- or fair-quality RCTs and prospective cohorts comparing bariatric surgery and non-surgical management enrolled patients with BMI<35. Seven of those studies included presence of T2DM or metabolic syndrome as an entry criterion, while two did not report comorbid condition-based entry criteria. The authors conclude that for those with a mean pre-operative BMI of 30 to 35.9 “patterns of

weight loss across procedures were similar to those in studies of patients at higher BMI" (WA HTA, 2015, p. ES-41). Furthermore, among studies of patients at lower BMI levels that reported on remission of T2DM at 12 to 24 months the results favored surgery (remission rates of 26% to 73%) over non-surgical treatment (remission rates of 0% to 16%).

Systematic Reviews Addressing Effectiveness in Children and Adolescents

Three fair or good quality systematic reviews address the effectiveness of bariatric surgery in children and adolescents (Aikenhead, Knai, & Lobstein, 2011; Black, White, Viner, & Simmons, 2013; Treadwell, Sun, & Schoelles, 2011). These studies are summarized in Table 4 and discussed below by systematic review.

Table 4. Summary of Systematic Reviews – Effectiveness of Bariatric Surgery for Children and Adolescents

Systematic Review (Quality) Total N	No. and Type of Included Studies	Population	Outcomes of Interest
Aikenhead, 2011 (Fair) N = 831	1 RCT 8 cohort studies 14 observational studies 12 case series	≤ 19 years old	BMI
Black, 2013 (Fair) N = 637	1 RCT 22 observational studies	Pre-surgical BMI (mean): 46 – 52 Age: 5 – 23 years	BMI
Treadwell, 2008 (Treadwell) N = 644	18 Observational studies	Pre-surgical BMI (mean): 46 – 52 Age: 9 – 21 years	BMI

Abbreviations: BMI – body mass index; RCT – randomized controlled trial

Aikenhead (2011)

Aikenhead et al. (2011) is a fair quality narrative systematic review of 37 studies of effectiveness of bariatric surgery spanning 831 patients age 19 years old or younger. The authors note several general limitations of the pediatric bariatric surgery literature including predominately observational study designs, small sample sizes (the largest of the included trials had 68 patients), and sparse information on low frequency outcomes.

Thirteen of the included studies (all but one observational) assessed gastric banding. Twelve of these studies reported mean BMI reductions of 8.5 kg/m^2 to 43 kg/m^2, while one study (a case report of gastric banding and truncal vagotomy in an adolescent with a rare mutation in a gene implicated in

regulation of appetite and energy balance) found an increase in BMI of 2.2 kg/m^2. Rates of resolution of comorbid conditions ranged from 11 to 100%.

Eight of the included studies (all observational) assessed RYGB. The studies reported mean reductions in BMI of 9 kg/m^2 to 25 kg/m^2. The authors note that four of the studies reported on comorbid conditions and three of those four studies found 100% rates of resolution for dyslipidemia, degenerative joint disease, asthma, and gastroesophageal reflux disease.

Fourteen of the included studies (all observational) reported on other bariatric procedures (sleeve gastrectomy, BPD/DS, vertical banded gastroplasty). These studies reported mean BMI reductions of 9 kg/m^2 to 24 kg/m^2. The authors note that changes in comorbid conditions were reported in 12 of the 14 studies, but additional details are not included.

The authors' overall conclusion is that "[i]n the context of a general lack of effective tools for primary prevention or behavioural treatment of obesity, surgical treatment may be advocated as a preferred and cost-effective solution for certain children and adolescents" (Aikenhead, 2011, p. 18)

Black (2013)

Black et al. (2013) is a fair quality systematic review and meta-analysis of bariatric surgery for obese children and adolescents. Twenty-three studies (22 observational and 1 RCT) comprising 637 patients undergoing RYGB, AGB, or SG were included. The mean pre-surgical BMI was 52.4 kg/m^2 in the RYGB studies, 49.6 kg/m^2 in the SG studies, and 46.1 kg/m^2 in the AGB studies. The ages of patients in the included studies ranged from 5 to 23 years old.

Overall, the average weighted BMI difference from baseline to one year postoperatively was -13.5 kg/m^2 (95% CI -15.1 to -11.9). The greatest BMI reductions were observed in patients undergoing RYGB (average weighted difference of -17.2 kg/m^2) and the smallest BMI reductions were observed in the AGB group (average weighted difference of -10.5 kg/m^2).

The authors note that they were unable to provide summary estimates of the effects on comorbidity resolution because the data were of poor quality and adequate definitions of resolution were not provided. The rates of reported resolution of T2DM from baseline to follow-up ranged from 0 to 100% in the eight studies that reported this outcome. However, excluding one study with only a single T2DM patient who did not experience resolution, the rate of resolution for T2DM would range from 50 to 100%. The rates of reported resolution of hypertension from baseline to follow-up ranged from 50 to 100% in the 10 studies that reported this outcome.

Treadwell (2008)

Treadwell et al. (2008) is a good quality systematic review and meta-analysis of bariatric surgery for pediatric obesity. This review included 18 studies of children ages 9 to 21 years (mean age 16.7 years) with mean BMI ranging from 45.8 kg/m^2 to 51.8 kg/m^2. In 14 of the 18 studies, patients must have failed a trial of non-surgical weight loss before undergoing bariatric surgery. Only one of the included studies reported a non-surgical control group and significant differences in baseline characteristics between the groups were noted including baseline BMI and comorbidities. Thus, the authors note that, in effect, the included studies were all case series.

Meta-analysis of change in BMI in six studies of AGB found a 95% CI of -13.7 kg/m^2 to -10.6 kg/m^2 at mean length of follow-up of one to three years. Two of the studies of AGB reported T2DM remission rates of 80 to 100% and three of the studies reported hypertension remission rates of 50 to 100%.

Meta-analysis of change in BMI in six studies of RYGB found a 95% CI of -17.8 kg/m^2 to -22.3 kg/m^2 at mean length of follow-up of one to six years. Only one of the studies of RYGB reported remission of T2DM. Three studies of RYGB reported rates of hypertension remission of 50 to 100%.

Because of the small number of studies and patients undergoing other procedures, summary information on weight changes or comorbidity resolution was not presented.

Overall, the authors conclude that there is weak to moderate evidence that AGB achieves weight loss at one year or longer and weak evidence of resolution of T2DM and hypertension. For RYGB, the authors conclude that there is weak to moderate evidence of weight loss at one year or longer, weak evidence of resolution of hypertension, and insufficient evidence of resolution of T2DM. There was insufficient evidence for any outcomes from other bariatric procedures.

Systematic Reviews Addressing Bariatric Reoperation Procedures

As the use of primary bariatric surgical procedures has increased, so too has the rate of bariatric reoperation. The term "bariatric reoperation" captures several types of procedures (conversion, correction, revision, or reversal) that are performed for various indications. Inadequate weight loss (commonly, but not uniformly, defined as <50% EWL) is the most common indication for revision or conversion procedures. Reoperation is also performed to address both acute complications (including anastomotic leaks, bleeding, strictures, obstruction, and perforation) and chronic complications (including protein calorie malnutrition, severe GERD, band erosion, late or recurrent leaks, late strictures, and band intolerance.) Reversal procedures are rare, but are sometimes performed to address intractable nausea and vomiting, excessive or uncontrolled weight loss, severe malnutrition, recurrent anastomotic ulcers, severe hypoglycemia, and recalcitrant hypocalcaemia.

In general, bariatric reoperation is thought to be more technically challenging than primary bariatric surgery, at least in part because of the likelihood of surgical adhesions from the primary procedure. Nevertheless, many reoperative bariatric procedures can still be performed laparoscopically, though the complication rates may be higher when compared with primary bariatric procedures.

Five fair quality and one low quality systematic reviews address the effectiveness of bariatric reoperative procedures (Brethauer et al., 2014; Cheung, Switzer, Gill, Shi, & Kamali, 2014; Coblijn, Verveld, van Wagensveld, & Lagard, 2013; Elnahas, Graybiel, Farrokhyar, Gmora, Anvari, & Hong, 2013; Mahawar, Graham, Carr, Jennings, Schroeder, Balupuri, & Small, 2015; Schouten, Japink, Meesters, Nelemans, & Greve, 2011).

These systematic reviews of bariatric reoperation provide very low certainty evidence that revisional or conversion procedures performed after an initial bariatric surgery may achieve additional weight loss (particularly those procedures that convert AGB to RYGB or BPD/DS), but at the expense of a higher rate of complications. The systematic reviews offer no evidence that bariatric reoperation improved co-morbidity resolution. Most of the studies included in the systematic reviews were not methodologically

rigorous and there are concerns about publication bias in this literature. Furthermore, the indications for bariatric reoperation varied across and within individual studies.

Brethauer (2014)

Brethauer et al. (2014) is a systematic review on indications for and outcomes of reoperative bariatric surgery that was conducted by the ASMBS Bariatric Surgery Revision Taskforce. The review was supported by an unrestricted educational grant from Covidien, a company that manufactures equipment used in bariatric surgical procedures. While the review states that 175 articles were included in the systematic review, the majority of these were single center retrospective case series and the evidence tables in the review provide details on only 35 "selected studies." Thus, the degree to which the narrative review and recommendations reflect an unbiased inclusion of studies identified in the systematic review is uncertain. Furthermore, the reporting of quantitative outcomes across indications and reoperative procedures was erratic. The conclusions of the authors, summarized here with the above caveats, are 1) reoperation for inadequate or failed weight loss generally improves weight loss, and 2) complication rates are generally higher with reoperative procedures.

Cheung (2014)

Cheung et al. (2014) is a systematic review of studies of revisional bariatric surgery following laparoscopic sleeve gastrectomy. The review includes 11 studies spanning a total of 218 patients. In most of the studies patients underwent revisional procedures because of insufficient weight loss or weight regain, although the former indication was variably defined. Intractable gastroesophageal reflux disease was an additional indication in 5 of the studies. The revisional procedures included laparoscopic butterfly gastroplasty, laparoscopic omega loop mini gastric bypass, laparoscopic re-sleeve gastrectomy, laparoscopic duodenal switch, and laparoscopic or open RYGB. Nine of the studies were cases series and two studies were case-controls. The largest single study enrolled 40 patients. The primary outcomes were change in BMI at various time points. At 24 months or greater, revisional procedures were associated with reductions in BMI. Revision of LSG to gastric bypass resulted in an average change in BMI of -6.2 kg/m^2. Revision of LSG to re-sleeve gastric bypass resulted in an average change in BMI of -3.2 kg/m^2. Revision of LSG to other surgical interventions (all other conversion procedures) resulted in an average change in BMI of -17.2 kg/m^2. In the three studies that examined the effects of revisional procedures on GERD complications, there was a 100% complete resolution rate, though it should be noted that the sample size for this outcome was very small (n=15). The authors note that their review was limited by the small number of studies and patients, the very low methodological rigor of the study designs, and the absence of postoperative complication rates after revision.

Coblijn (2013)

Coblijn et al. (2013) is a systematic review of studies of revisional bariatric surgery (LSG or LRYGB) after an initial adjustable gastric banding procedure. The review includes 15 studies of LRYGB spanning 588 patients and 8 studies of LSG spanning 286 patients. Not all studies reported the indication for revisional surgery, but in those that did the most common indication was insufficient weight loss or weight regain (approximately 65% of patients). Most of the studies were consecutive case series and there were no randomized controlled trials. The primary outcomes of interest were perioperative morbidity and mortality. In the LRYGB studies that reported this outcome there were no perioperative deaths and the

overall perioperative complication rate was 8.5%. In the LSG studies that reported this outcome, there were 3 perioperative deaths and the overall perioperative complication rate was 12.2%. The rate of reoperation after the revisional procedures was 6.5% for LRYGB and 3.5% for LSG. Though weight loss was not of primary interest for this review, the authors did note that 11 of the 15 LRYGB studies reported mean EWL of 23% to 74%, though the follow-up time was not clear. Weight loss achieved with revisional LSG appeared to be nearly comparable. The authors note several limitations to their review including the very low methodological rigor of the study designs and the possibility of publication bias, particularly for studies reporting on morbidity and mortality.

Elnahas (2013)

Elnahas et al. (2013) is a systematic review of conversion bariatric procedures after failed adjustable gastric banding. The review includes 24 studies reporting outcomes of conversion to LSG (n=106 patients), LRYGB (n=514 patients), and laparoscopic BPD/DS (n=71 patients). Patients in these studies underwent the conversion procedure due to inadequate weight loss or surgical complications with AGB. All of the included studies were retrospective case series. The primary outcome of interest was weight loss measured by change in BMI or percentage EWL. The mean change in BMI at 24 to 48 months after reoperation was -2.8 kg/m^2 for LSG, -8.5 kg/m^2 for LRYGB, and -13.3 kg/m^2 for BPD/DS. The weighted mean complication rates for conversion to LSG, LRYGB, and BPD/DS were 4.1%, 10.7%, and 24.4% respectively. The authors note several limitations to their study including the very low methodological rigor of the study designs and significant heterogeneity across studies.

Mahawar (2015)

Mahawar et al. (2015) is a systematic review of studies that compare the outcomes of revisional bariatric procedures to the outcomes of the same primary procedures. The review includes 14 studies comparing revisional and primary RYGB and 7 studies comparing revisional and primary SG. The designs of the primary studies were not made explicit, but all appeared to be case-control or retrospective cohort studies. Quantitative cumulative outcomes reported in the studies comparing revisional with primary RYGB included mortality (1.3% revisional vs 0.2% primary), complications (29.5% revisional vs 13.9% primary), reoperation (8.4% revisional vs 8.6% primary), and leaks (5.8% revisional vs 1.0% primary). Quantitative cumulative outcomes reported in the studies comparing revisional SG with primary SG included mortality (0% revisional vs 0.1% primary), complications (10.5% revisional vs 5.2% primary), reoperation (4.8% revisional vs 1.6% primary), and leaks (1.9% revisional vs 1.5% primary). Weight loss outcomes were not cumulatively analyzed because of heterogeneity in the studies, but the authors do note that most of the studies that reported on weight loss outcomes found that the weight loss achieved with revisional procedures was either inferior to (10/14 studies of RYGB, 2/5 studies of SG) or not significantly different from the weight loss achieved with primary procedures (4/14 studies of RYGB, 3/5 studies of SG). The authors do not comment on limitations of their review other than noting the absence of any level I evidence on revisional bariatric surgery.

Schouten (2011)

Schouten et al. (2011) is a systematic review of studies examining reoperation following gastric banding procedures. The review included 11 studies of re-banding, 12 studies of conversion to LRYGB, 5 studies of conversion to laparoscopic BPD/DS, and 5 studies of conversion to LSG.

Among the 11 studies that examined re-banding, the most common indications were slippage, erosion, or pouch dilation. Ten of the 11 studies presented level III or level IV evidence, while one presented level II evidence. The follow-up period varied from 8 to 48 months after reoperation. The early complication rate ranged from 0% to 11%, the late complication rate ranged from 0% to 41%, and the reoperation rate ranged from 0% to 45%. Change in BMI was reported in 6 studies and ranged from +2.4 kg/m^2 to -5.8 kg/m^2.

Among the 12 studies of conversion to LRYGB, the most common indications were insufficient weight loss, band, erosion, and pouch dilation. Ten of the 12 studies presented level III or level IV evidence, while the remaining 2 presented level II evidence. The follow-up period ranged from 8.3 to 36 months after reoperation. The early complication rate ranged from 3% to 36%, the late complication rate ranged from 2% to 23%, and the reoperation rate ranged from 0% to 20%. Change in BMI was reported in 9 studies and ranged from -6.1 kg/m^2 to -13.2 kg/m^2. Percentage EWL was reported in 2 studies and ranged from 33% to 43%.

Among the 5 studies of conversion to BPD/DS, the most common indication was insufficient weight loss. All 5 studies presented level III or level IV evidence. The follow-up period ranged from 12 to 38 months after reoperation. The early complication rate ranged from 8% to 62%, the late complication rate ranged from 20.6% to >23.5%, and the reoperation rate ranged from 0% to 20.6%. Percentage of EWL was reported in 3 studies and ranged from 44% to 70%.

Among the 5 studies of conversion to LSG, the most common indication was insufficient weight loss. Four studies presented level IV evidence while 1 study presented level II evidence. The follow-up period ranged from 12 to 24 months after reoperation. The early complication rate ranged from 0% to 13.8%, the late complication rate ranged from 0% to 10.3%, and the reoperation rate ranged from 0% to 10.3%. Percentage of EWL was reported in 2 studies and ranged from 20% to 65.7% while change in BMI was reported in 1 study as -4.4 kg/m^2.

The authors conclude that adjustable gastric banding should remain a first line procedure with re-banding or conversion to RYGB or BPD/DS as options for managing band failure.

Systematic Reviews Addressing Patient Selection

One poor quality and two good quality systematic reviews address patient selection criteria (Ochner, Dambkowski, Teomans, Teizeira, & Xavier Pi-Sunyer, 2012; Thomas & Agrqwal, 2012; WA HTA, 2015).

Ochner (2012)

Ochner et al. (2012) is a good quality narrative systematic review of 29 studies examining the effects of preoperative weight loss requirements on postoperative outcomes. The authors note that heterogeneity in the included studies precluded formal quantitative synthesis. Overall, the included studies were

mostly observations and were mixed on the effects of preoperative weight loss requirements on postoperative weight loss outcomes. As the authors note, "studies of the relation between pre- and post-operative changes in body weight range from a positive relationship (preoperative weight loss associated with greater postoperative weight loss) to a negative relationship (preoperative weight loss associated with less postoperative weight loss) and many in between (no relationship)" (Ochner et al., 2012, p. 1381). The only included RCT deemed "viable" by the authors randomized 100 patients undergoing RYGB to a group with a requirement of 10% preoperative weight loss or a group with no preoperative weigh loss requirement. At six months after surgery, patients in the preoperative weight loss group had lost 54% of excess body weight compared to 51% excess body weight loss in the in the group without a preoperative weight loss requirement, but because only 37% of the original sample was analyzed at six months there was insufficient power to detect an effect.

The review also examined studies reporting on the effects of preoperative weight loss requirements on other outcomes including resolution of comorbid conditions. One study of 90 RYGB patients found that preoperative weight loss of >5% of excess body weight was associated with shorter operative times (36 minutes on average) but no difference in complications or resolution of comorbid conditions. Another study demonstrated that patients with preoperative weight loss of >5% of excess body weight were less likely to have a postoperative length of stay of >4 days. The RCT referenced above found no difference in the complication rate or resolution of comorbid conditions at six months. A fourth study found no correlation between preoperative weight changes and remission of diabetes or hypertension.

The authors' overall conclusion is that "[g]iven the inconsistency and questionable validity of the extant research…on the question of the effect of preoperative weight loss on peri- and postoperative outcomes, it is the opinion of these authors that insufficient evidence is currently available to justify a pre-bariatric surgery weight loss mandate" (Ochner et al., 2012, p. 1386).

Thomas (2012)

Thomas & Agarwal (2012) is a poor quality systematic review of a preoperative risk stratification tool known as the obesity surgery mortality risk score (OS-MRS). The OS-MRS assigns one point each for age greater than 45 years, male gender, BMI > 50 kg/m^2, hypertension, and known risk factors for pulmonary embolism. Scores of 0 to 1 are considered class A or lowest risk, scores of 2 to 3 reflect class B or intermediate risk, and scores of 4 to 5 are class C or high risk. This review included six studies reporting on 9,382 patients evaluating the validity of OS-MRS to predict postoperative mortality risk. Overall, there were 83 death in the 9,382 patients (0.88%). There were 13 deaths among the 4,912 class A patients (0.26%), 55 deaths among the 4,124 class B patients (1.33%), and 14 deaths among the 346 class C patients (4.34%). The mortality difference between classes were statistically significant at $p<0.05$. The authors conclude that use of the OS-MRS can stratify mortality risk in patients undergoing bariatric surgery (particularly RYGB which was the predominately studied procedure in the included studies).

WA HTA (2015)

The WA HTA report included a single retrospective comparative cohort study that stratified outcomes by patient adherence to preoperative program recommendations. In the laparoscopic AGB group, patients who did not attend >75% of their pre-procedure appointments had attenuated weight loss at 12 months

of follow-up (23% EWL vs 32% EWL in patients with fewer missed appointment, p=0.01). There were no differences in RYGB performance related to pre-procedure appointment adherence.

A single study included in the WA HTA report concluded that patients with congestive heart failure and cardiac arrhythmias had a significantly increased risk of post-surgical complications compared with the overall cohort (40% vs 13.4% for open RYGB, 21.1% vs 8.6% for laparoscopic RYGB, and 17.4% vs 3.1% for laparoscopic AGB, all p-values <0.001). The same study reported that patients with peripheral vascular disease undergoing RYGB had significantly increased complication rates compared to those without peripheral vascular disease (32.0% vs 8.4%, p<0.001).

The WA HTA report also notes that it did not find studies that stratified outcomes by smoking status or psychosocial health that met inclusion criteria.

Systematic Reviews Addressing Systems of Care

One good quality systematic review addresses the effect of systems of care on bariatric surgery outcomes (Zevin, Aggarwal, & Grantcharov, 2012).

Zevin (2012)

Zevin et al. (2012) is a good quality systematic review of volume-outcome associations in bariatric surgery. The article reviews 24 observational studies comprising almost 460,000 patients. Meta-analysis was not performed due to a high level of heterogeneity that resulted, in part, from differences in duration of follow-up and risk-adjustment.

Thirteen studies addressed the relationship between annual surgeon case volume and patient outcomes. Across the five cohort studies that were included, there was consistent evidence of improved outcomes with increasing surgeon volume. The results of lower quality studies (primarily retrospective cohorts) were mixed, but six of the eight studies supported an association between surgeon volume and outcomes.

Seventeen studies addressed the association between hospital volume and outcomes. While the two case-control studies that were included did not support an association between facility volume and outcomes, the preponderance of retrospective case series (14/15 studies) that were included found an association between facility volume and outcomes.

The authors conclude that there is strong evidence to support the association between surgeon volume and patient outcomes, and that weaker evidence supports the association between hospital volume and outcomes. Overall, they conclude that the literature "supports the BSCOE accreditation and the bariatric surgery fellowship training programs" (Zevin et al., 2012, p. 70).

WA HTA (2015)

The WA HTA report notes that pre-procedure support groups have shown little benefit, but that there is some evidence that patients in postoperative support groups experience improvements in psychological comorbidities and achieve greater weight loss. The WA HTA report cites one RCT of 144 Hispanic-American RYGB patients randomized to "comprehensive nutrition and lifestyle support or brief, printed healthy lifestyle guidelines…" At one year after surgery, patients in the comprehensive support group had greater reductions in BMI (6.48 kg/m^2 vs 3.63 kg/m^2, p<0.001).

Systematic Reviews Addressing Cost-effectiveness

WA HTA (2015)

The WA HTA report (2015) performed a cost-effectiveness analysis based on a model constructed by the authors. This analysis assumed a public payer perspective. The base-case analysis compared RYGB with standard care over a 10 year time horizon; other base-case assumptions included a procedural cost of $24,277, 20% worsening in BMI after 12 months, mean BMI at baseline of 40 kg/m^2, and a discounting rate of 3%. In the base-case analysis, the incremental cost-effectiveness of RYGB compared to standard care was $37,423 per quality-adjusted life year (QALY) gained. In the deterministic sensitivity analyses, the incremental cost-effectiveness estimates ranged from $5,444 per QALY to $84,971 per QALY. The estimates were most sensitive to changes in the time horizon, the cost of the bariatric surgical procedure, maintenance of weight loss after surgery, and baseline BMI. The WA HTA cost-effectiveness estimates, stratified by procedure and baseline BMI, are included in Appendix H.

There is very sparse evidence on the cost-effectiveness of bariatric surgery in children and adolescents. The only included systematic review which addresses this question is Aikenhead et al. (2011). The conclusions of this review are limited by the small number of studies, use of economic models that are not directly applicable to the U.S., and inferences from cost-effectiveness studies of bariatric surgery in adults.

EVIDENCE SUMMARY

Despite the existence of a large number of studies and systematic reviews, there remain substantial limitations to the evidence regarding bariatric surgery. Differences in patient characteristics, choice of surgical procedure, and individual components and intensity of non-surgical management arms make it difficult to summarize effects across studies. Variable measures of weight loss and wide variation in definitions of remission or resolution of comorbid conditions pose additional problems. Many of the studies included in the reviews were non-comparative, and the comparative observational studies suffer from risk of bias related to patient selection and residual confounding. The data from RCTs is limited by questions regarding proper allocation concealment and the universal absence of blinding. Perhaps the greatest concern is the limited long term follow-up of patients from RCTs and incomplete outcomes data due to high rates of attrition in most studies.

Overall, the following conclusions can be drawn based on review of the summary literature:

1. Bariatric surgery is associated with lower rates of all-cause mortality and major adverse cardiovascular events in adults, despite a short term increased risk of perioperative mortality and complications (based on low certainty evidence from cohort studies with long term follow-up, with study populations consisting predominantly of patients with BMI ≥35).
2. Bariatric surgery is associated with significant reductions in BMI in adults, despite a short term increased risk of perioperative mortality and complications (based on moderate certainty evidence from a mix of observational and randomized trials). The effects on weight loss appear to be greatest in patients with baseline BMI ≥40 based on the BMI stratification provided in the WA HTA report.

3. Bariatric surgery is associated with remission or resolution of T2DM and hypertension in adults with BMI ≥ 35, despite a short term increased risk of perioperative mortality and complications (based on moderate certainty evidence from a mix of observational and randomized trials).
    - The effects on remission of T2DM appear to be greatest in patients with baseline BMI ≥40 based on the BMI stratification provided in the WA HTA report.
    - Preliminary evidence suggests that adults with BMI < 35 may also achieve significant reductions in BMI and improvement in comorbid T2DM and hypertension, though the long term effects are not yet clear.
4. Bariatric surgery is associated with significant reductions in BMI in children and adolescents, despite a short term increased risk of perioperative mortality and complications (based on low certainty evidence primarily from small, non-comparative observational trials of bariatric surgery for pediatric obesity).
5. Bariatric surgery is associated with remission or resolution of T2DM and hypertension in children or adolescents, despite a short term increased risk of perioperative mortality and complications (based on very low certainty evidence from a small number of trials).
6. There is no evidence-based minimum age recommendation for pediatric bariatric surgery. Patients as young as five years old were included in the studies reported in the summary literature.
7. There is low certainty conflicting evidence on the effects of preoperative weight loss requirements.
8. The obesity surgery mortality risk score (OR-MRS) is a validated preoperative assessment of perioperative mortality risk (particularly for RYGB procedures) and may be useful in selecting patients for surgery or counseling them on surgical risks.
9. Harms of bariatric surgery include a perioperative mortality rate that probably ranges from 0.10 to 2%, and an overall complication rate that is probably on the order of 8 to 25%. The estimated reoperation rate is likely between 2 and 13%. There is limited evidence from a single study that comorbid congestive heart failure, cardiac arrhythmias, and peripheral vascular disease are associated with higher rates of complications after bariatric surgery.
10. There is low certainty evidence that surgeon experience is associated with improved outcomes and very low certainty evidence that hospital bariatric surgical volume is associated with improved outcomes.
11. There is very low certainty evidence that revisional or conversion procedures performed after an initial bariatric surgery may achieve additional weight loss (particularly those procedures that convert AGB to RYGB or BPD/DS), but at the expense of a higher rate of complications. Systematic reviews offer no evidence that bariatric reoperation improved co-morbidity resolution.

OTHER DECISION FACTORS

Resource allocation

Bariatric surgery for adults is costly, but improved outcomes compared with non-surgical management may offset these costs. The WA HTA report cites total costs of bariatric surgical procedures as ranging from $17,483 for gastric banding to $36,160 for biliopancreatic diversion. By comparison, standard non-surgical care has a reported total cost of $3,746. Accounting for reductions in BMI, resolution of comorbid conditions, and complications of surgery and projecting costs and effectiveness over a 10-year horizon, bariatric surgical procedures are uniformly cost-effective at a willingness-to-pay threshold of $100,000 per QALY gained. This was true across BMI thresholds and surgical procedures. Excerpts from the economic analysis in the WA HTA report are provided in Appendix H.

Bariatric surgery for children is also costly, but improved outcomes may offset these costs, and the beneficial effects could accrue over the longer time horizon afforded by earlier intervention in children and adolescents. However, there is very limited evidence of cost-effectiveness of pediatric bariatric surgery. The pediatric cost-effectiveness information included in the review by Aikenhead et al. in 2011 used assumptions from Australia that are likely too indirect to influence deliberations on resource allocation.

Reoperations for additional weight loss are sometimes requested; a second high cost procedure (tens of thousands of dollars), with a history of prior failure is unlikely to show a favorable cost-effectiveness ratio.

Values and preferences

Adults

Most people would prefer to avoid surgery and its attendant risks if similar results could be attained through safer and less invasive interventions. However, patients who have failed to achieve adequate weight loss with less invasive interventions may decide that the superior outcomes of bariatric surgery (including long term improvements in all-cause mortality, complete remission of diabetes, and significant weight loss) outweigh the upfront risks of surgery. Overall, there would be a moderate variability given these considerations.

Children and adolescents

Similar to adults, most children and their parents would prefer to avoid surgery and its attendant risks if similar results could be attained through safer and less invasive interventions. However, patients who may have failed to achieve adequate weight loss with less invasive interventions may decide that bariatric surgery offers the best chance at weight reduction. The significant social pressures of obesity at a young age may also push children and their parents to have strong interest in an effective treatment. Children though would likely have a great fear of surgery and the associated procedures and loss of social/academic participation. However, additional uncertainties related to malnutrition in this age group and its effects on growth, development, and reproductive capacity may make surgery less appealing in children and adolescents (to their caregivers). Long term remission rates of morbid obesity

and recurrence of the comorbidities are unknown; most studies report outcomes at one year, although a few studies report outcomes at up to three years. Given these considerations, there would be high variability in children's and parents preferences.

Re-operations for inadequate weight loss

There would be high variability in patient preferences regarding reoperation. With a prior failure of the procedure, some patients would be hesitant to try an additional procedure given the burdens of surgery and prior ineffectiveness, but others would be motivated to try a different procedure in hopes that it would work. Patients seeking reoperation likely have no other good option given failure of multiple previous alternatives (e.g. clinical, pharmacological, nutritional, physical activity, surgical).

Other factors

Adults

The greatest health benefits may be with BMI ≥ 40 but otherwise specific subpopulations which would benefit the most from bariatric surgery are not well characterized.

The pre-operative requirements for achieving optimal outcomes are unclear.

Given the rate of complications and need for reoperation reported in the summary literature, benefit plans may wish to consider alternative payment methodologies like bundled payments or a pay-for-outcomes approach.

Surgeon case volume, and to a lesser extent hospital case volume, appear to affect outcomes for patients undergoing bariatric surgery and requirements regarding surgeon or facility volume may be reasonable.

Children and adolescents

Parental involvement in weight management plans is likely necessary to assist the effectiveness of obesity treatments (based on expert opinion).

Pediatric bariatric surgery is likely to be available at only a few highly specialized centers. The American Academy of Pediatrics has 10 criteria that pediatric bariatric surgery programs should meet.

Re-operations for inadequate weight loss

It is unclear from the evidence which modifiable patient factors that resulted in surgical failure would predict a high likelihood of success or failure of a second procedure.

POLICY LANDSCAPE SOURCES

Quality measures

One bariatric surgery-specific quality measure was identified when searching the National Quality Measures Clearinghouse:

- Prevention and management of obesity for adults: percentage of patients with a BMI greater than or equal to 40 who have been provided with a referral to a bariatric specialist (Institute for Clinical Systems Improvement)

Payer coverage policies

Medicare (National Coverage Determination [NCD] 100.1), Washington Medicaid, Aetna, Cigna, Regence Blue Cross Blue Shield, and Moda all provide coverage of bariatric surgery. Each coverage policy outlines specific coverage criteria that must be met prior to bariatric surgery being approved. These criteria are described below and provided in more detail in Appendix E.

Age

All six payers provide coverage of bariatric surgery for adults (defined as at least 18 years), and Aetna and Cigna additionally provides coverage for adolescents (defined as an individual with completed skeletal growth). Washington limits the procedure type to LAGB only for individuals aged 18 to 20 years.

Body Mass Index

For adults, Aetna, Cigna and Moda require individuals have a BMI of greater than or equal to 40 kg/m^2, or greater than or equal to 35 kg/m^2 with specific comorbidities. Washington and NCD 100.1 cover individuals with a BMI of greater than or equal to 35 kg/m^2 with comorbidities, and Regence BCBS requires that an individual have a BMI of greater than or equal to 40 kg/m^2 or a BMI of greater than, or equal to 35 kg/m^2 with type 2 diabetes or at least two other specified comorbidities. Washington is the only identified payer that explicitly requires individuals not be pregnant at the time of the surgery.

For adolescents, Aetna covers individuals with a BMI of greater than 40 kg/m^2 who have serious comorbidities, or individuals with a BMI of greater than 50 kg/m^2 with less serious comorbidities. Cigna uses the same BMI criteria as the adult population.

Comorbidities

Diabetes is the only comorbidity specified by all five payers. Payers specify various combinations of other comorbid conditions including coronary heart disease, dyslipidemia, hypertension, lower extremity lymphatic or venous obstruction, mechanical arthopathy in major weight bearing joint, rare comorbid conditions (e.g., pseudo tumor cerebri), and obstructive sleep apnea. Aetna specifies several less severe comorbidities for adolescents with a BMI of over 50 including gastroesphageal reflux disease, intertriginous soft-tissue infection, nonalcoholic steatohepatitis, obesity-related psychosocial distress, significant impairments in daily living, and stress urinary incontinence.

Pre-Surgical Requirements

Five payers require individuals to undergo a comprehensive psychosocial evaluation and participate in a formal weight loss program prior to being approved for bariatric surgery (Aetna, Cigna, Moda, Regence BCBS, and Washington). Three payers require a separate medical evaluation (Washington, Cigna, Moda), surgical evaluation (Washington, Cigna), and nutritional evaluation (Cigna, Moda) prior to surgery. The NCD 100.1 requires that individuals have been previously unsuccessful with medical treatment for obesity.

Payers require an individual attend a formal weight loss program within six months (Washington) to two years of surgery (Aetna, Regence BCBS, Moda). The weight loss program must be greater than or equal to three (Cigna) to six months in duration (Washington, Aetna, Regence BCBS, Moda). Both Washington and Moda require that individuals lose 5% of their initial body weight as part of the weight loss program prior to surgery. Aetna's policy states that there can be no net weight gain during weight loss program attendance. Payer coverage policies include a variety of additional required program components including counseling by a registered dietitian, patient journal of participation, regular face-to-face provider visits, behavior modification, supervised exercise regimen, and hypocaloric diet changes.

Provider Requirements

Washington Medicaid and Moda state that bariatric surgery is only covered if provided by an approved facility, defined by Moda as a Center of Excellence and by Washington with specific criteria. Bariatric surgery facilities approved by Washington Medicaid must have performed a minimum of 100 bariatric surgical procedures, be under the direction of an experienced board-certified surgeon, been in operation for at least five years, have a 2% or less mortality rate, have a 15% or less morbidity rate, have at least five years of patient follow-up data, have an average of at least 50% patient weight loss at five years, and have a reoperation/revision rate of 5% or less.

The Centers for Medicaid and Medicare have approved six facilities in Oregon to perform bariatric surgery: Bay Area Hospital, Legacy Good Samaritan Hospital and Medical Center, Oregon Health & Science University, Sacred Heart Medical Center, Salem Hospital, St. Charles Medical Center – Bend.

Repeat Surgery Coverage

Aetna, Cigna and Regence BCBS address repeat bariatric surgery and outline specific circumstances under which it is covered. All three payers provide coverage to correct complication from the initial surgery, and conversion from gastric banding to sleeve gastrectomy, RYGB or BPD/DS. Aetna and Cigna specify that conversion surgery is covered for individuals who have not lost more than 50% of their body weight two years following the primary bariatric surgery. Cigna will cover the adjustment of the silicone gastric band and repeat surgery for a failed dilation of a gastric pouch. Aetna will additionally cover removal of a gastric band, replacement of adjustable band, and repeat surgery for a failed dilation of a gastric pouch.

Non-Covered Procedures

Aetna, Cigna, and Regence BCBS outline specific conditions and procedures that are not in the coverage of bariatric surgery. Across all three payers, gastroplasty ("stomach stapling"), laparoscopic gastric plication, mini gastric bypass, transoral endoscopic surgery (e.g., OverStich suturing device, StomaphX™,

TOGA®), are not covered. In addition, Aetna and Cigna do not cover gastrointestinal liners (e.g., EndoBarrier™), intragastric balloon, loop gastric bypass, silastic ring vertical gastric bypass (e.g., Fobi pouch), or vagus nerve blocking. Aetna and Regence BCBS do not cover band over bypass surgeries, band or sleeve gastrectomy surgeries, sclerotherapy for the treatment of dilated gastrojejunostomy following bariatric surgery, or for gastroesophageal reflux disease in non-obese individuals. Cigna and Regence BCBS do not cover intestinal bypass (jejunoileal bypass) or restorative obesity surgery (e.g., ROSE). Regence BCBS specifically does not cover vertical banded gastroplasty; Aetna covers this procedure for members who are at increased risk of adverse consequences from Roux-en-Y gastric bypass due to certain gastrointestinal conditions (see Appendix E).

The NCD 100.1 does not provide coverage for open adjustable gastric banding, open sleeve gastrectomy, open and laparoscopic vertical banded gastroplasty, intestinal bypass surgery, and gastric balloon for treatment of obesity.

Professional society guidelines

Adults

The Institute for Clinical Systems Improvement (ICSI) (Fitch et al., 2013a) (good quality), Veterans Administration (VA) (Management of Overweight and Obesity Working Group, 2014) (good quality), the American Association of Clinical Endocrinologists, Obesity Society, American Society for Metabolic & Bariatric Surgery (Mechanick et al., 2013) (poor quality primarily), the Australian National Health and Medical Research Council (NHMRC) (NHMRC, 2013) (good quality), and the National Institute for Health and Care Excellence (NICE) (NICE, 2014) (good quality) provide recommendations on the use of bariatric surgery in adults. The guideline from the American Heart Association/American College of Cardiology/The Obesity Society (Jensen et al., 2014) (good quality) provides a summary of the evidence related to the long-term effectiveness of bariatric surgeries and the long-term effects of these procedures on varying BMI levels with and without comorbidities. The guideline does not provide clinical practice recommendations.

All identified guidelines consistently recommend bariatric surgery for individuals with a BMI of greater than 40 kg/m^2, or greater than 35 kg/m^2 with significant comorbidities. There is some variance between guidelines in what comorbidities are considered significant. For example, only two of the five guidelines list gastroesophageal reflux disease as a significant comorbidity. Four guidelines (AACD/OS/ASMBS, ICSI, NHMRC, NICE) recommend bariatric surgery be considered for individuals with a BMI of greater than 30 kg/m^2 who have severe comorbidities such as diabetes, and NICE recommends bariatric surgery for individuals of Asian descent with recent-onset diabetes who may have a lower BMI than other populations. The VA determined that there was insufficient evidence to recommend the use of bariatric surgery for individuals with a BMI less than 35 kg/m^2.

The AACD/OS/ASMBS and NICE guidelines recommend individuals have pre-surgical comprehensive medical and psychological evaluations. The use of multidisciplinary teams consisting of surgical, medical, nutrition, and psychological expertise is recommended by NICE and NHMRC.

Children

The ICSI (Fitch et al., 2013b) (good quality), the Australian NHMRC (NHMRC, 2013), and NICE (NICE, 2014) provide recommendations on indications for bariatric surgery in the pediatric population. Both the ICSI and NHMRC guidelines recommend bariatric surgery as an option for adolescents with a BMI greater than 40, or greater than 35 with severe comorbidities. The NHMRC specifies that only laparoscopic gastric banding performed by a specialist bariatric/pediatric surgical team is recommended for adolescents. The guideline from ICSI is the most comprehensive and recommends detailed pre-surgical evaluations, failed attempts at weight loss through formal weight loss programs, and the use of multidisciplinary team at regional bariatric centers of excellence. ICSI further recommends that children have attained Tanner stage 4 or 5 or have bone age of ≥13 years in girls or ≥15 years in boys before considering bariatric surgery. Pediatric bariatric surgery is not recommended by NICE except in the case of exceptional circumstances.

Assessment of congruence between guidelines and evidence

In general, the clinical practice guideline recommendations for adults are supported by the available evidence. Patients with BMI ≥40 kg/m^2 or with BMI 35 to 39.9 with obesity-related comorbid conditions have been well studied in the literature, and the clinical practice guidelines reflect this stronger evidence base. The divergence in the recommendations for patients with BMI 30 to 34.9 probably reflects the smaller number of studies that specifically address this population and the shorter follow-up periods reported in these studies. Recommendations regarding pre-surgical evaluations may reflect expert practice tips, but are not directly supported by the summary literature. Similarly, recommendations regarding preoperative weight loss are based on expert opinion and are not directly supported by the summary literature.

The wider variation in the recommendations for bariatric surgery in children reflects greater uncertainty about both the effectiveness and the adverse effects of surgery. When surgery is recommended for children, there is general agreement based on expert opinion that this should be performed at regional centers of excellence.

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APPENDIX A. METHODS

Scope Statement

Populations

Obese individuals who are being considered for bariatric or metabolic surgery

Population scoping notes: *Include <18. Exclude overweight (BMI<30)*

Interventions

Bariatric or metabolic surgery (Adjustable gastric banding, Roux-en-y gastric bypass, biliopancreatic diversion, duodenal switch, vertical sleeve gastrectomy)

Intervention exclusions: *Gastric balloon (not FDA approved)*

Comparators

Nonsurgical treatment (medical management, pharmacotherapy, intensive multicomponent behavioral interventions, behavioral counseling, structured weight management programs (e.g. Weight Watchers)

Outcomes

Critical: All-cause mortality, Major Cardiac Events (MACE)

Important**:** Resolution of hypertension, weight loss, resolution of type 2 diabetes

Considered but not selected for the GRADE table: Hyperlipidemia, arthritis, sleep apnea, CPAP use, medication use

Key Questions

1. Should coverage be recommended for bariatric surgery in each of the scenarios in the table below? (Note that the "resolution of diabetes" would not be an applicable outcome in scenarios 4-9)

	BMI 30-34.9	BMI 35-39.9	BMI>=40
With DM2	Scenario 1	Scenario 2	Scenario 3
W/o DM2 nor other comorbidities	Scenario 4*	Scenario 5*	Scenario 6*
w/o DM2 but with other comorbidities	Scenario 7*	Scenario 8*	Scenario 9*

*Resolution of type 2 diabetes isn't a relevant outcome for this population

2. What is the appropriate minimum age for bariatric surgery?

3. What components and systems of care are associated with improved health outcomes? (e.g., centers of excellence, surgeon's experience, etc.)
4. What preoperative assessments or requirements for preoperative weight loss should be recommended in patients being considered for bariatric surgery?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using the terms "bariatric." Searches of core sources were limited to citations published after 2004 with one exception (see inclusion criteria).

The core sources searched included:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Health Technology Assessment (HTA) program
BMJ Clinical Evidence
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Interscience)
Hayes, Inc.
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program (WA HTA)

A recent technology assessment from the WA HTA program was identified as the most comprehensive review identified (WA HTA, 2015). A MEDLINE® (Ovid) search was then conducted to identify systematic reviews, meta-analyses, and technology assessments published after the search dates of the WA HTA report. The search was limited to publications in English published after 2014 (the end search date for the WA HTA systematic review).

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice guidelines was also conducted, using the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Centers for Disease Control and Prevention (CDC) – Community Preventive Services
Choosing Wisely
Institute for Clinical Systems Improvement (ICSI)
National Guidelines Clearinghouse
New Zealand Guidelines Group
NICE
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DOD)

Inclusion/Exclusion Criteria

Due to the volume of available literature related to the effectiveness of bariatric surgery in adults (Key Question #1), reviews were limited to those published after 2013. Center staff dual quality assessed the identified reviews and only included those that were rated as good quality.

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, or clinical practice guidelines. The following systematic review was excluded because it only included studies that were found in the other systematic reviews:

Ashrafian, H., Toma, T., Rowland, S. P., Harling, L., Tan, A., Efthimiou, E., … Athanasiou, T. (2014). Bariatric surgery or non-surgical weight loss for obstructive sleep apnoea? A systematic review and comparison of meta-analyses. *Obesity Surgery, 25*(7), 1239-50. DOI: 10.1007/s11695-014-1533-2.

APPENDIX B. GRADE INFORMED FRAMEWORK - ELEMENT DESCRIPTIONS

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issue about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality or strength of evidence rating across studies for the treatment/outcome[1]

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

[1] Includes risk of bias, precision, directness, consistency and publication bias

***Low*:** The subcommittee's confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

***Very low*:** The subcommittee has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

APPENDIX C. GRADE EVIDENCE PROFILE

Quality Assessment (Confidence in Estimate of Effect) – Adults							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
All-cause Mortality[1]							
14	Cohort	Moderate	Consistent	Direct	No serious imprecision	Large effect size	Low confidence in estimate of effect ●●○○
Major Adverse Cardiovascular Events[1]							
4	Cohort	Moderate	Consistent	Direct	No serious imprecision	Large effect size	Low confidence in estimate of effect ●●○○
Type 2 DM Remission/Resolution[2]							
60	15 RCTs; 45 observational studies	Moderate to High	Consistent	Direct	Imprecise	None	Moderate confidence in estimate of effect ●●●○
Hypertension Remission/Resolution[2]							
52	13 RCTs; 39 observational studies	Moderate	Consistent	Direct	Imprecise	None	Moderate confidence in estimate of

Quality Assessment (Confidence in Estimate of Effect) – Adults							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
							effect ●●●○
Change in BMI[2]							
101	28 RCTs; 73 observational studies	Moderate to High	Consistent	Direct	Imprecise	None	Moderate confidence in estimate of effect ●●●○

[1] Studies from Tables 1 and 2(Kwok, 2014). Strength of evidence assessment based on Table 2 in Kwok (2014).

[2]Studies and strength of evidence assessment based on Figure 2 of Colquitt (2014), Supplemental Table 1 of Muller-Stich (2015), and the description of study quality from the WA HTA review (2015, p.27-28). Chang (2014) does not provide individual study risk of bias assessments.

Quality Assessment (Confidence in Estimate of Effect) – Children and Adolescents							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
All-cause Mortality							
0	NA	NA	NA	NA	NA	NA	Insufficient evidence
Major Adverse Cardiovascular Events							
0	NA	NA	NA	NA	NA	NA	Insufficient evidence

Quality Assessment (Confidence in Estimate of Effect) – Children and Adolescents							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Type 2 DM Remission/Resolution[1]							
13	13 observational studies	High	Consistent	Direct	Imprecise	None	Very low confidence in estimate of effect ●○○○
Hypertension Remission/Resolution[1]							
15	15 observational studies	High	Consistent	Direct	Imprecise	None	Very low confidence in estimate of effect ●○○○
Change in BMI[1]							
28	1 RCT; 27 observational studies	High	Consistent	Direct	Imprecise	None	Low confidence in estimate of effect ●●○○

[1] Studies from Black (2013) and Treadwell (2008).

Appendix D. Mortality Benefit Outcomes from Kwok (2014) Systematic Review and Meta-Analysis

Several large cohort studies with long-term follow-up comparing bariatric surgery patients to non-surgical controls have demonstrated a consistent reduction in all-cause mortality (as summarized in the meta-analysis in Kwok 2014). In the included cohort studies that performed direct subgroup analysis by BMI, the effects of bariatric surgery appear to be stronger in patients with higher BMI, though other cohorts that report proportional hazard ratios using BMI of 35-40 kg/m2 as the reference find increasing mortality in BMI groups >40. Only two of the cohorts reported outcomes by baseline comorbidities. In the Swedish Obese Subjects study (Sjostorm, 2012), patients with T2DM may have benefited more than those without T2DM, while patients with SBP <140 may have benefited more than hypertensive patients; however, in both scenarios the 95% confidence intervals overlap. It should be noted that Sjostrom reported on the incidence of cardiovascular events rather than mortality and that 70% of the patients received vertical banded gastroplasty, a procedure that is no longer used in the United States. Scott (2013) reports on a cohort of bariatric patients compared to matched controls undergoing either orthopedic or gastrointestinal procedures. There were no significant differences based on the presence of HTN in either group or T2DM in the bariatric-orthopedic comparison; among T2DM patients in the bariatric-GI comparison, there was a slight increase in the proportional hazard of mortality. Two other cohort studies (Arterburn, 2013 and Johnson, 2013) only included patients with T2DM at baseline.

Caution should be exercised in interpreting subgroup analyses from these cohorts given the potentially small number of patients involved. Individual studies with pre-specified inclusion criteria based on comorbidities are more likely to provide accurate estimates of the effects in these groups. On balance, there is insufficient evidence from these cohort studies to conclude that the effects of bariatric surgery on long-term mortality vary based on pre-operative BMI or the presence of comorbid conditions.

Studies in the table below were reviewed in the following article: Kwok, C. S., Pradhan, A., Khan, M. A., Anderson, S. G., Keavney, B. D., Myint, P. K., … Loke, Y. K. (2014). Bariatric surgery and its impact on cardiovascular disease and mortality: a systematic review and meta-analysis. International Journal of Cardiology, 173(1), 20-28. DOI: 10.1016/j.ijcard.2014.02.026

Study	Population (surgical group)	Overall effect of surgery on mortality (95% CI)	Effect of surgery on mortality by BMI (95% CI)	Mortality effect by comorbidities (95% CI)
Adams (2007) Matched retrospective cohort	9,949 adults RYGB Avg BMI 44.9	HR 0.63 (0.53 to 0.74) (all subjects) HR 0.60 (0.45 to 0.67) (matched subjects)	BMI<45 HR 0.72 (0.53 to 0.99) BMI >45 HR 0.56 (0.43 to 0.74)	NR
Arterburn (2013) Retrospective cohort	1,395 adults 80% RYGB BMI>35 and T2DM	HR 0.54 (0.22 to 1.30)	NR	NR
Busetto (2007) Matched cohort	821 adults LAGB BMI>40	RR 0.36 (0.16 to 0.79)	BMI 40-49 RR 0.67 (0.23 to 1.94) BMI>50 RR 0.21 (0.21 to 0.75)	NR
Christou (2004) Retrospective cohort	1,035 adults RYGB Mean BMI 50.0	RR 0.11 (0.04 to 0.27)	NR	NR
Flum (2004) Retrospective cohort	3,328 adults Any gastric bypass "Morbidly obese" (by ICD codes) 13% T2DM	HR 0.67 (0.54 to 0.85)	NR	NR
Gentileschi (2012) Prospective cohort	208 adults RYGB, VSG, AGB Avg BMI 46.6 31% T2DM, 48% HTN	1/208[i] (surgical group) 4/81 (non-surgical group)	NR	NR
Johnson (2013) Retrospective cohort	2,580 adults with T2DM Any bariatric surgery Avg BMI 47 82% HTN, 8.6% CAD	41/2580[ii] (surgical group) 985/13,371 (non-surgical group)	NR	NR

Maciejewski (2011) Retrospective cohort	850 adults (Vets) RYGB Avg BMI 47	HR 0.64[iii] (0.51 to 0.80)	BMI 35-39 HR 1.0 (reference)[iv] BMI 40-49 HR 1.22 (1.16 to 1.27) BMI >50 HR 1.71 (1.59 to 1.85)	NR
Miranda (2012) Retrospective cohort	2,020 adults 95% RYGB Avg BMI 49	HR 0.76 (0.60 to 0.96)	NR	NR
Peeters (2007) Prospective cohort	966 adults LAGB Avg BMI 45	HR 0.28 (0.10 to 0.85)	BMI <40 HR 0.89 BMI >40 HR 0.16	NR
Scott (2013) Retrospective Cohort	4,747 adults Any bariatric surgery "Morbid obesity" (by ICD codes) 41% T2DM, 71% HTN, 5% CAD	HR 0.72 compared to matched ortho surgery pts (0.58 to 0.89) HR 0.48 compared to matched GI surgery pts (0.39 to 0.61)	NR	Bariatric-ortho[v] HTN HR 1.02 (0.8 to 1.4) T2DM HR 1.14 (0.9 to 1.5) Bariatric-GI HTN HR 0.79 (0.6 to 1.1) T2DM HR 1.49 (1.1 to 2.0)
Sjostrom (2012) Prospective cohort	2,010 adults 70% gastroplasty	HR 0.83[vi] (0.69 to 1.00)	BMI <40.8 HR 0.91 (0.70 to 1.18) BMI >40.8 HR 0.8 (0.60 to 1.06)	T2DM HR 0.63 (0.45 to 0.90) No TD2M HR 0.84 (0.67 to 1.06) SBP<140 HR 0.63 (0.46 to 0.86) SBP>140 HR 0.82 (0.64 to 1.04)

Sowemimo (2007) Retrospective cohort	908 adults Nearly all RYGB BMI>40 or >35 with comorbidities Mean BMI 54	HR 0.18 (0.09 to 0.35)	NR	NR

BMI=Body mass index (reported in kg/m^2), CAD=Coronary artery disease, HR=Hazard ratio, HTN=Hypertension, LAGB=Laparoscopic Adjustable gastric banding, NR=Not reported, RR=Relative risk, RYGB=Roux-en-Y gastric bypass, SBP=Systolic blood pressure (reported in mmHg), T2DM=Type 2 diabetes mellitus, VSG=Vertical sleeve gastrectomy

[i] Reported as crude event rates

[ii] Reported as crude event rates

[iii] Reported after unadjusted Cox regression; after adjustment for covariates, the HR was 0.80 (95% CI 0.63 to 0.995). An analysis of propensity matched patients resulted in a HR of 0.83 (95% CI 0.61 to 1.14).

[iv] Reported as adjusted Cox proportional hazards

[v] Reported as Cox proportional hazards

[vi] Primary outcome in Sjostrom was not mortality but incidence of CV events (included here because of its analysis by comorbidity)

[vii] Reported as adjusted Cox proportional hazards

APPENDIX E. BARIATRIC SURGERY COVERAGE

Table E1. Bariatric Surgery Coverage – Adults

Coverage criteria	Payer				
	Washington Medicaid	Aetna[1]	Cigna[2]	Regence BCBS[3]	Moda
Patient Characteristics					
Age	18 – 20 yrs (LAGB obly) 21 – 59 yrs (all procedures)	≥ 18 yrs	≥ 18 yrs	≥ 18 yrs	≥ 18 yrs
BMI	≥ 35 with comorbidities 30-34.9 with DM2 (*see below*)	> 40 > 35 with comorbidities (*see below*)	≥ 40 ≥ 35 with comorbidities (*see below*)	≥ 40 ≥ 35 with DM2 or at least two other comorbidities (*see below*)	≥ 40 ≥ 35 with comorbidities (*see below*)
Not pregnant	√	---	---	---	---
Comorbidities					
Coronary heart disease	---	√	√	√	√
Diabetes	√	√	√	√	√
Dyslipidemia	---	---	√	√	---
Hypertension	---	√	√ (poorly controlled or pulmonary)	√	√
Lower extremity lymphatic or venous obstruction	---	---	√	---	---
Mechanical arthopathy in major weight bearing joint	√	---	√	---	√
Rare comorbid conditions (e.g., pseudo tumor cerebri)	√[4]	---	---	---	---
Sleep apnea	---	√	√	√	√
Absence of other medical conditions (e.g., multiple sclerosis)	√	---	---	---	√

Key: √ – required; --- – not in policy description

Abbreviations: BCBS – Blue Cross Blue Shield; BMI – body mass index; LAGB – laparoscopic adjustable gastric banding; yrs – years

Notes:

1. Specific to open or laparoscopic Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable silicone gastric banding (LASGB), open or laparoscopic sleeve gastrectomy, open or laparoscopic biliopancreatic diversion (BPD), and duodenal switch (DS).
2. Specific to open or laparoscopic Roux-en-Y gastric bypass, open or laparoscopic adjustable silicone gastric banding (LAP-BAND®, REALIZE™), open or laparoscopic biliopancreatic diversity with duodenal switch (BPD/DS) for individuals with a BMI >50, open or laparoscopic sleeve gastrectomy, open or laparoscopic vertical banded gastroplasty
3. Roux-en-Y with an alimentary limb of 150 cm or less, sleeve gastrectomy as a stand-alone procedure, or adjustable gastric banding
4. Must be medical evidence that bariatric surgery is medically necessary and that the benefits of bariatric surgery outweigh the risk of surgical mortality

Table E2. Bariatric Surgery Coverage – Children

Coverage criteria	Payer	
	Aetna[1]	Cigna[2]
Patient Characteristics		
Age	Adolescents who have completed bone growth (~13 yrs in girls, ~15 yrs in boys)	Reached full expected skeletal growth
BMI	> 40 with serious comorbidities > 50 with less serious comorbidities	≥ 40 ≥ 35 with comorbidities
Comorbidities		
Coronary artery disease	---	√
Diabetes	√ (>40 BMI)	√
Dislipidemias	√ (> 50 BMI)	√
Gastroesophageal reflux disease	√ (> 50 BMI)	---
Hypertension	√ (> 50 BMI)	√ (poorly controlled or pulmonary)
Intertriginous soft-tissue infection	√ (> 50 BMI)	---
Mechanical arthropathy in a major weight bearing joint	√ (> 50 BMI)	√
Nonalcoholic steatohepatitis	√ (> 50 BMI)	---
Obesity-related psychosocial distress	√ (> 50 BMI)	---
Rare comorbid conditions (e.g., pseudo tumor cerebri)	√ (>40 BMI)	---
Significant impairments in daily living	√ (> 50 BMI)	---
Sleep apnea	√ (>40 BMI)	√
Stress urinary incontinence	√ (> 50 BMI)	---
Venous stasis disease	√ (> 50 BMI)	√

Key: √ – required; --- – not in policy description Abbreviations; BMI – body mass index; yrs - years

Notes:

1. Specific to open or laparoscopic Roun-en-Y gastric bypass (RYGB), laparoscopic adjustable silicone gastric banding (LASGB), open or laparoscopic sleeve gastrectomy, open or laparoscopic biliopancreatic diversion (BPD), and duodenal switch (DS)

2. Specific to open or laparoscopic Roux-en-Y gastric bypass, open or laparoscopic adjustable silicone gastric banding (LAP-BAND®, REALIZE™), open or laparoscopic biliopancreatic diversity with duodenal switch (BPD/DS) for individuals with a BMI >50, open or laparoscopic sleeve gastrectomy, open or laparoscopic vertical banded gastroplasty

Table E3. Pre-Surgical Requirements

Coverage criteria	Payer				
	Washington Medicaid	Aetna[1]	Cigna[4]	Regence BCBS	Moda
Patient Evaluation					
Comprehensive psychosocial evaluation	√[2]	√[3]	√	√	√
Internal medicine evaluation	√	---	√	---	√
Surgical evaluation	√	---	√	---	---
Nutrition evaluation	---	---	√	---	√
Weight Loss Program					
Required	√	√ (physician-supervised *or* multi-disciplinary surgical prep regimen)	√ (physician- or registered dietician-supervised)	√ (physician-supervised)	√
Timing	Within 180 days of surgery	Within 2 years of surgery (physician-supervised) Within 6 months of surgery (surgical prep regimen)	Within 1 year of surgery	Within 2 years of surgery	Within 2 years of surgery
Duration	≥ 6 months	Cumulative total ≥ 6 months, one program ≥ 3 months (physician-supervised) ≥ 3 months (surgical prep regimen)	≥ 3 months	≥ 6 months	≥ 6 months
Required weight loss	5% of initial body weight	No net weight gain during program	---	----	5% of initial body weight over 6 months
Program Components	Supervised by licensed provider;	Physician-supervised: medical record documentation with	---	Three visits for medical supervision (no	Hypocaloric diet changes, nutritional

Coverage criteria	Payer				
	Washington Medicaid	Aetna[1]	Cigna[4]	Regence BCBS	Moda
	monthly provider visits; 2x/month counseling by a registered dietitian; patient journal of participation	program compliance record; supervised nutrition and exercise program must have face-to-face component Surgical Prep Regimen: Behavior modification program; dietician or nutritionist consultation; medical record documentation; supervised exercise regimen; substantial face-to-face component; reduced-calorie diet supervised by a dietitian or nutritionist		more than 4 months apart); provided by MD, DO, NP, PA, or RD under supervision of MD, DO, NP or PA; assessment and counseling on weight, diet, exercise and behavior modification; clinical documentation of willingness to comply with pre- and post-operative treatment plan	education, physical activity, behavior change strategies; three or more primary care visits; completion of a 8-week health education, weight management program

Key: √ – required; --- – not in policy description

Abbreviations: DO – doctor of osteopathy; MD – medical doctor; NP – nurse practitioner; PA – physician assistant; RD – registered dietician

Notes:

1. Specific to open or laparoscopic Roun-en-Y gastric bypass (RYGB), laparoscopic adjustable silicone gastric banding (LASGB), open or laparoscopic sleeve gastrectomy, open or laparoscopic biliopancreatic diversion (BPD), and duodenal switch (DS)
2. Provider must be a psychiatrist, licensed psychiatric ARNP, or licensed independent social worker with a minimum of two years postmasters' experience in a mental health setting
3. For members who have a history of severe psychiatric disturbance (schizophrenia, borderline personality disorder, suicidal ideation, severe depression) or who are currently under the care of a psychologist/psychiatrist or who are on psychotropic medications
4. Specific to open or laparoscopic Roux-en-Y gastric bypass, open or laparoscopic adjustable silicone gastric banding (LAP-BAND®, REALIZE™), open or laparoscopic biliopancreatic diversity with duodenal switch (BPD/DS) for individuals with a BMI >50, open or laparoscopic sleeve gastrectomy, open or laparoscopic vertical banded gastroplasty

Table E4. Facility Requirements

Approved Facility Requirements	Payers Washington Medicaid
Minimum number of bariatric surgical procedures performed	100
Direction	Experience board-certified surgeon
Time in operation	≥ 5 years
Mortality rate	≤ 2%
Morbidity rate	≤ 15%
Patient follow-up	≥ 5 years
Average patient weight loss at 5 years	≥ 50%
Reoperation/revision rate	≤ 5%

Table E5. Repeat Surgery Coverage

Circumstances	Payers		
	Aetna	Cigna	Regence BCBS
Adjustment of silicone gastric band	---	√	---
Removal of gastric band	√	---	---
Correct complications	√	√	√
Conversion to sleeve gastrectomy, RYGB or BPD/DS	√[1, 2, 3]	√[2]	√
Failed dilation of gastric pouch after primary surgery	√[1] (if primary surgery was successful in inducing weight loss)	√	---
Replacement of adjustable band	√ (for complications)	---	---

Key: √ – covered; --- – not in policy description

Abbreviations: BPD – biliopancreatic diversion; DS – duodenal switch RYGB – Roux-en-Y gastric bypass;

Notes:

1. If patient has been compliant with a prescribed nutrition and exercise program following the procedure
2. For members who have not lost > 50% of body weight 2 years following primary surgery
3. Conversion from adjustable band to sleeve gastrectomy, RYGB or BPD/DS, for complications that cannot be corrected with band manipulation, adjustments or replacement

Table E6. Non-Covered Conditions and Procedures

	Payers		
	Aetna	**Cigna**	**Regence BCBS**
Conditions			
Idiopathic intracranial hypertension	X	---	---
Infertility	X	---	---
DM2 w/BMI <35	X	X[1]	
Gastroesophageal reflux in non-obese persons	X	---	X
Gastroparesis	X	---	---
Procedures			
Band over bypass	X	---	X
Band over sleeve	X	---	X
Roux-en-Y gastric bypass combined with simultaneous BPD without DS	---	X	---
Gastrointestinal liners (EndoBarrier™)	X	X	---
Gastroplasty ("stomach stapling")	X	X	X
Intragastric balloon	X	X	
Laparoscopic gastric plication	X	X	X
Loop gastric bypass	X	X	
Mini gastric bypass	X	X	X
Sclerotherapy for the treatment of dilated gastrojejunostomy following bariatric surgery	X	---	X
Silastic ring vertical gastric bypass (Fobi pouch)	X	X	---
Transoral endoscopic surgery (OverStitch suturing device or StomaphyX™ device)	X	X (including TOGA®)	X
Vagus nerve blocking	X	X	---
Gastric electrical stimulation or gastric pacing	---	X	---
Intestinal bypass (jejunoileal bypass)	---	X	X
restorative obesity surgery, endoluminal (ROSE)	---	X	X
Vagus nerve stimulation	---	X	---
Distal gastric bypass (long limb gastric bypass, >150 cm)	---	---	X
Biliopancreatic bypass (Scopinaro procedure)	---	---	X

Biliopancreatic bypass with duodenal switch	---	---	X
Two-stage procedures	---	---	X
Vertical banded gastroplasty	---	---	X
EndoCinch™	---	---	X

Key: √ – covered; X – not covered; --- – not in policy description

Notes:

1. Not covered when performed solely for treatment of diabetes mellitus
2. Specific requirements for vertical banded gastroplasty (members who are at increased risk of adverse consequences from Roux-en-Y Gastric bypass due to the presence of:
    - Demonstrated complications from extensive adhesions involving the intestines from prior major abdominal surgery, multiple minor surgeries, or major trauma
    - Hepatic cirrhosis with elevated liver function tests
    - Inflammatory bowel disease (Crohn's disease or ulcerative colitis)
    - Poorly controlled systemic disease
    - Radiation enteritis.

APPENDIX F. APPLICABLE CODES

CODES	DESCRIPTION
ICD-10	
E11.0 – E11.9	Diabetes, type 2
E66.01-E66.9	Overweight, Obesity and Morbid Obesity
G47.30 – G47.39	Sleep apnea
I10	Essential hypertension
ICD-9-CM Volume I Codes	
250.00, 250.02; 250.10, 250.12, 250.20, 250.22, 250.30, 250.32, 250.40, 250.42, 250.50, 250.52, 250.60, 250.62, 250.70, 250.72, 250.80, 250.82, 250.90, 250.92	Diabetes, Type II
278.00 – 278.03	Overweight, Obesity, and Morbid Obesity
327.20 – 327.29; 780.57	Sleep apnea
401.0 – 401.9	Hypertension
ICD-9-CM Volume III Codes	
43.82	Laparoscopic vertical (sleeve) gastrectomy
43.89	Open and other partial gastrectomy
44.31	High gastric bypass
44.38	Laparoscopic gastroenterostomy
44.5	Revision of gastric anastomosis
44.68	Laparoscopic gastroplasty
44.69	Other repair of stomach
44.95	Laparoscopic gastric restrictive procedure
44.96	Laparoscopic revision of gastric restrictive procedure
44.97	Laparoscopic removal of gastric restrictive device(s)
44.98	Laparoscopic) adjustment of size of adjustable gastric restrictive device
45.51	Isolation of segment of small intestine
45.91	Small-to-small intestinal anastomosis

CPT Codes	
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
HCPCS Level II Codes	
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Note: Inclusion on this list does not guarantee coverage

APPENDIX G. OUTCOMES BY BASELINE MEAN BMI FROM THE WA HTA REPORT (P. 64-65)

Baseline Mean BMI Category									
		30-34.99		35-39.99		40-49.99		>50	
		Median	Range	Median	Range	Median	Range	Median	Range
% Decrease BMI	RYGB	25.4	(19.6-34.3)	26.0	(24.1-33.1)	32.2	(7.5-52.3)	34	(10.1-46.7)
	VSG	21.3	(21.3-21.3)	22.0	(19.1-22.5)	28.4	(15.0-37.1)	30.1	(11.0-39.4)
	LAGB	16.8	(11.8-21.7)	16.8	(13.0-17.5)	20.4	(6.0-46.8)	17.7	(1.0-31.8)
	BPD/DS	31.8	(17.3-46.3)			32.6	(15.9-50.8)	43.4	(39.2-47.7)
	Follow-up (months)	12.0	(3.0-45.2)	15.3	(12.0-60.0)	12.0	(0.5-120.0)	22.6	(1.2-84.0)
	No. Studies	7		6		79		22	
	Good/Fair/Poor	2/3/2		3/1/2		9/34/36		4/10/8	
% EWL	RYGB	70.0		77.0	(61.0-92.9)	67.0	(27.1-88.0)	61.8	(43.8-72.3)
	VSG			58.5	(51.0-66.0)	59.2	(30.7-83.0)	47.5	(25.4-75.0)
	LAGB	87.2		50.1	(34.0-62.5)	43.5	(18.2-78.8)	45.9	(31.0-73.0)
	BPD/DS					52.7	(34.9-70.4)	73.4	63.0-84.0)
	Follow-up (months)	18.0	(12.0-24.0)	30.0	(18.7-60.0)	24.0	(0.47-120)	24.0	(12.0-84.0)
	No. Studies	2		4		57		15	
	Good/Fair/Poor	1/0/1		1/1/2		6/27/24		1/8/6	
% Improvement Hypertension	RYGB			90.0		71.0	(22.0-100.0)	62.6	(60.7-69.2)
	VSG					64.3	(23.5-100.0)		
	LAGB			40.0		57.5	(18.0-100.0)	54.3	(33.3-66.7)
	BPD/DS	67.0				81.4	(68.6-87.0)	68.3	(66.7-69.9)
	Follow-up (months)	36.0		60.0		21.0	(3.5-84.0)	24.0	(12.0-50.4)
	No. Studies	1		1		29		5	
	Good/Fair/Poor	0/1/0		0/0/1		4/12/13		1/3/1	

Baseline Mean BMI Category									
		30-34.99		35-39.99		40-49.99		>50	
		Median	Range	Median	Range	Median	Range	Median	Range
% Improvement T2DM	RYGB	51.1	(33.0-92.3)	73.4	(66.7-80.0)	79.0	(33.0-100.0)	77.1	(40.0-100.0)
	VSG	50.0	(50.0-50.0)			77.3	(36.0-100.0)	88.9	(88.9-88.9)
	LAGB	33.0	(21.1-100.0)	50.0	(25.0-73.0)	50.0	(17.0-100.0)	52.3	(36.4-66.7)
	BPD/DS	84.8	(83.0-84.8)			87.1	(81.5-92.7)	91.4	(82.7-100.0)
	Follow-up (months)	12.0	(3.0-45.2)	24.0	(12.0-60.0)	16.0	(1.0-62.7)	24.0	(1.5-50.4)
	No. Studies	6		3		35		7	
	Good/Fair/Poor	0/3/3		2/0/1		3/14/18		1/4/2	
% Improvement Sleep Apnea	RYGB	89.0				70.5	(10.0-100.0)	56.7	(49.3-88.0)
	VSG					62.0	(6.0-99.0)		
	LAGB					29.0	(3.0-55.0)	46.2	(39.3-66.7)
	BPD/DS	90.0						79.5	(78.9-80.0)
	Follow-up (months)	45.15				21.6	(12.0-36.0)	20.1	(12.0-20.1)
	No. Studies	1		0		11		4	
	Good/Fair/Poor	0/0/1				2/5/4		1/3/0	
% Improvement Dyslipidemia	RYGB			100.0		64.5	(6.0-100.0)	52.9	(27.3-58.8)
	VSG					67.5	(35.0-67.5)		
	LAGB			38.0		36.5	(0.0-36.5)	34.4	(23.3-45.5)
	BPD/DS					90.0	(90.0-90.0)		
	Follow-up (months)			60.0		24.0	(12.0-62.7)	16.2	(12.0-50.4)
	No. Studies	0		1		18		3	
	Good/Fair/Poor	0		0/0/1		2/9/7		1/1/1	

APPENDIX H. COST-EFFECTIVENESS ESTIMATES FROM THE WA HTA REPORT (P. 80)

BMI Level/ Procedure	Cost ($)	Effectiveness (QALYs)	Cost-effectiveness ($/QALY gained)	
			Vs. SC	Vs. RYGB
BMI≥30				
Standard care	$34,923	7.5680	NA	NA
RYGB	$54,110	8.0807	$37,423	NA
VSG	$48,702	8.0417	$29,087	Less expensive & less effective
LAGB	$47,668	7.9252	$35,680	Less expensive & less effective
BPD/DS	$65,741	8.2307	$46,508	$77,574
BMI 30-34.9				
Standard care	$27,943	7.9418	NA	NA
RYGB	$49,735	8.3529	$53,021	NA
VSG	$44,298	8.3211	$43,122	Less expensive & less effective
LAGB	$42,738	8.2273	$51,826	Less expensive & less effective
BPD/DS	$61,410	8.4730	$63,011	$97,194
BMI 35-39.9				
Standard care	$32,538	7.6567	NA	NA
RYGB	$52,886	8.1351	$42,534	NA
VSG	$47,468	8.0986	$33,789	Less expensive & less effective
LAGB	$46,217	7.9898	$41,073	Less expensive & less effective
BPD/DS	$64,533	8.2751	$51,743	$83,224
BMI≥40				
Standard care	$40,329	7.2846	NA	NA
RYGB	$58,257	7.8630	$30,995	NA
VSG	$53,047	7.8194	$23,784	Less expensive & less effective
LAGB	$52,255	7.6882	$29,552	Less expensive & less effective
BPD/DS	$69,329	8.0322	$38,790	$65,431

BPD = biliopancreatic diversion; ICER = incremental cost-effectiveness ratio; LAGB = laparoscopic adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; VSG = vertical sleeve gastrectomy.

NOTE: Because of rounding, performing calculations may not produce the exact results shown.

[i] Reported as crude event rates

[ii] Reported as crude event rates

[iii] Reported after unadjusted Cox regression; after adjustment for covariates, the HR was 0.80 (95% CI 0.63 to 0.995). An analysis of propensity matched patients resulted in a HR of 0.83 (95% CI 0.61 to 1.14).

[iv] Reported as adjusted Cox proportional hazards

[v] Reported as Cox proportional hazards

[vi] Primary outcome in Sjostrom was not mortality but incidence of CV events (included here because of its analysis by comorbidity)

Bariatric/Metabolic Surgery for Obesity

Issue: The HERC is reviewing treatments for obesity as part of its biennial review. The Health Technology Assessment Subcommittee (HTAS) has performed a detailed assessment of the evidence and developed a Coverage Guidance on bariatric surgery for obesity. The Obesity Task Force met on 3/3/16 and 3/17/16 to discuss clinical interventions for obesity including bariatric/metabolic surgery. They reviewed the draft HTAS Coverage Guidance recommendations and made recommendations to VbBS on changes to the Prioritized List of Health Services.

Current Prioritized List Status:

Line: 30

Condition: TYPE 2 DIABETES MELLITUS (See Coding Specification Below) (See Guideline Notes 8,62,64,65)
Treatment: MEDICAL THERAPY, BARIATRIC SURGERY WITH BMI >= 35
ICD-10: E08.00-E08.29,E08.311-E08.9,E09.00-E09.29,E09.311-E09.9,E11.00-E11.29,E11.311-E11.9,E13.00-E13.29,E13.311-E13.9,E16.1,Z46.51
CPT: 43644,43645,43770-43775,43846-43848,48155,64505-64530,90935-90947,90989-90997,92002-92014,92227,96150-96154,97605-97608,97802-97804,98960-98969,99051,99060, 99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607
HCPCS: G0108,G0109,G0245,G0246,G0270,G0271,G0396,G0397,G0406-G0408,G0425-G0427,G0458,G0463,G0466,G0467,S2083,S9140-S9145,S9353,S9537

CPT codes 43644-43645 and 43846-43848 (Roux-En-Y gastric bypass) and 43770-43775 (laparoscopic adjustable gastric banding and sleeve gastrectomy) are only included on this line as treatment according to the requirements in Guideline Note 8 when paired with:

1) a primary diagnosis of E11 (Type II Diabetes with or without complication);
2) a secondary diagnosis of E66.01, E66.09, E66.2, E66.8 or E66.9 (Obesity); AND,
3) a tertiary diagnosis code of Z68.35-Z68.39 or Z68.4.

Line: 325

Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes 5,64,65)
Treatment: INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS
ICD-10: E66.01-E66.9,Z68.30-Z68.45,Z68.54
CPT: 96150-96154,97802-97804,98966-98969,99051,99060,99070,99078,99201-99215,99281-99285,99341-99355,99358-99378,99381-99404,99408-99416,99429-99449,99487-99498
HCPCS: G0396,G0397,G0447,G0463,G0466,G0467,G0473

Line: 589

Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes 8,64,65)
Treatment: NON-INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS; BARIATRIC SURGERY FOR OBESITY WITH A SIGNIFICANT COMORBIDITY OTHER THAN TYPE II DIABETES & BMI >=35 OR BMI>=40 WITHOUT A SIGNIFICANT COMORBIDITY
ICD-10: E66.01-E66.9,Z68.30-Z68.45,Z68.54,Z71.3
CPT: 43644,43645,43770-43775,43846-43848,98966-98969,99051,99060,99070,99078,99201-99215,99281-99285,99341-99355,99358-99378,99381-99404,99408-99416,99429-99449, 99487-99498,99605-99607
HCPCS: G0396,G0397,G0447,G0463,G0466,G0467,G0473

Bariatric/Metabolic Surgery for Obesity

GUIDELINE NOTE 8, BARIATRIC SURGERY

Lines 30,589

Bariatric surgery is included under the following criteria:

A) Age ≥ 18
B) The patient has
   1) a BMI ≥ 35 with co-morbid type II diabetes for inclusion on Line 30 TYPE 2 DIABETES MELLITUS; OR
   2) BMI >=35 with at least one significant co-morbidity other than type II diabetes (e.g., obstructive sleep apnea, hyperlipidemia, hypertension) or BMI >= 40 without a significant co-morbidity for inclusion on Line 589
C) No prior history of Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding, unless they resulted in failure due to complications of the original surgery.
D) Participate in the following four evaluations and meet criteria as described.
   1) Psychosocial evaluation: (Conducted by a licensed mental health professional)
      a) Evaluation to assess potential compliance with post-operative requirements.
      b) Must remain free of abuse of or dependence on alcohol during the six-month period immediately preceding surgery. No current use of nicotine or illicit drugs and must remain abstinent from their use during the six-month observation period. Testing will, at a minimum, be conducted within one month of the surgery to confirm abstinence from nicotine and illicit drugs.
      c) No mental or behavioral disorder that may interfere with postoperative outcomes[1].
      d) Patient with previous psychiatric illness must be stable for at least 6 months.
   2) Medical evaluation: (Conducted by OHP primary care provider)
      a) Pre-operative physical condition and mortality risk assessed with patient found to be an appropriate candidate.
      b) Optimize medical control of diabetes, hypertension, or other co-morbid conditions.
      c) Female patient not currently pregnant with no plans for pregnancy for at least 2 years post-surgery. Contraception methods reviewed with patient agreement to use effective contraception through 2nd year post-surgery.
   3) Surgical evaluation: (Conducted by a licensed bariatric surgeon associated with program[2])
      a) Patient found to be an appropriate candidate for surgery at initial evaluation and throughout period leading to surgery while continuously enrolled on OHP.
      b) Received counseling by a credentialed expert on the team regarding the risks and benefits of the procedure[3] and understands the many potential complications of the surgery (including death) and the realistic expectations of post-surgical outcomes.
   4) Dietician evaluation: (Conducted by licensed dietician)
      a) Evaluation of adequacy of prior dietary efforts to lose weight. If no or inadequate prior dietary effort to lose weight, must undergo six-month medically supervised weight reduction program.
      b) Counseling in dietary lifestyle changes

E) Participate in additional evaluations:
   1) Post-surgical attention to lifestyle, an exercise program and dietary changes and understands the need for post-surgical follow-up with all applicable professionals (e.g. nutritionist, psychologist/psychiatrist, exercise physiologist or physical therapist, support group participation, regularly scheduled physician follow-up visits).

[1] Many patients (>50%) have depression as a co-morbid diagnosis that, if treated, would not preclude their participation in the bariatric surgery program.

[2] All surgical services must be provided by a program with current certification by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), or in active pursuit of such certification with all of the following: a dedicated, comprehensive, multidisciplinary, pathway-directed bariatric program in place; hospital to have performed bariatrics > 1 year and > 25 cases the previous 12 months; trained and credentialed bariatric surgeon performing at least 50 cases in past 24 months; qualified bariatric call coverage 24/7/365;appropriate bariatric-grade equipment in outpatient and inpatient facilities; appropriate medical specialty services to complement surgeons' care for patients; and quality improvement program with prospective documentation of surgical outcomes. If the program is still pursuing (MBSAQIP) certification, it must also restrict care to lower-risk OHP patients including: age < 65 years; BMI < 70; no major elective revisional surgery; and, no extreme medical comorbidities (such as wheel-chair bound, severe cardiopulmonary compromise, or other excessive risk). All programs must agree to yearly submission of outcomes data to Division of Medicaid Assistance Programs (DMAP).

[3] Only Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding and sleeve gastrectomy are approved for inclusion.

Evidence summary (GRADE table from HTAS Coverage Guidance):

Coverage question: Should bariatric surgery be recommended for coverage in adults?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
All-cause mortality (*Critical outcome)*	Odds ratio: 0.48 (95% CI 0.35 to 0.64) Crude event rates 3.6% with surgery and 11.4% without surgery Number needed to treat = 13 ●●○○ *(low certainty based on consistent but indirect observational studies)*	Bariatric surgery costs tens of thousands of dollars per surgery, but has been shown to be cost effective across BMI thresholds and surgery types.	Patients would balance surgery and its risks with risks of living with morbid obesity. Many patients who have failed conservative attempts at weight loss may elect	The greatest benefit may be with BMI ≥ 40 but otherwise specific subpopulations which would benefit the most from bariatric surgery are not well characterized.

Bariatric/Metabolic Surgery for Obesity

Coverage question: Should bariatric surgery be recommended for coverage in adults?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Major adverse cardiovascular events (*Critical outcome*)	Odds ratio: 0.54 (95% CI 0.41 to 0.70) Crude event rates 2.4% with surgery and 4.0% without surgery Number needed to treat = 62 ●●○○ (*low certainty based on consistent but indirect observational studies)*		surgery. The benefits of decreased mortality, dramatic weight loss, and regression of diabetes are important outcomes that patients and society would strongly value. However, there would still be moderate variability because of the risks and costs associated with surgery, as well as the intensive peri- and post-operative follow up.	The pre-operative requirements for achieving optimal outcomes are unclear. Given the rate of complications and need for reoperation reported in the summary literature, benefit plans may wish to consider alternative payment methodologies like bundled payments or a pay-for-outcomes approach. Surgeon case volume, and to a lesser extent hospital case volume, appear to affect outcomes for patients undergoing bariatric surgery and requirements regarding surgeon or facility volume may be reasonable.
Type 2 DM remission/resolution (*Important outcome*)	Odds ratio: 3.6 to 52.4 (favoring surgery) Number needed to treat: 1 to 5 ●●●○ *(moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects)*			
Hypertension remission/ resolution (*Important outcome*)	Odds ratio: 2.99 to 3.12 (favoring surgery) Number needed to treat: 4 ●●●○ *(moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects)*			
Change in BMI (*Important outcome*)	Mean difference at 1 year: -5.5 to -33.35 kg/m^2 (favoring surgery) Pooled mean difference: -7.4 kg/m^2 (favoring surgery) ●●●○ *(moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects)*			

Bariatric/Metabolic Surgery for Obesity

Coverage question: Should bariatric surgery be recommended for coverage in adults?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Rationale: Bariatric surgery appears to lower all-cause mortality and major adverse cardiovascular events in obese adults (low certainty), and significantly reduces BMI, and results in resolution of type 2 diabetes and hypertension. The greatest benefit appears to be with BMI ≥ 40. Though bariatric surgery is costly and carries significant perioperative risks, the clear long-term positive health benefits leads to a recommendation for coverage. The strength of the recommendation is based on the fact that there is a strong benefit on critical outcomes (particularly in diabetics), and patients desiring surgery would strongly prefer this intervention. For those without diabetes, and other comorbidities are present, the evidence is less clear, leading to a weak recommendation.				

Recommendation:
Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass, gastric banding, and sleeve gastrectomy) is recommended for:
• Adult obese patients (BMI ≥ 35 and <40) with:
  ○ Type 2 diabetes *(strong recommendation)* OR
  ○ at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea *(weak recommendation)*
• Adult obese patients (BMI ≥ 40) *(strong recommendation)*
 	
Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program *(weak recommendation).*
Metabolic and bariatric surgery is not recommended for coverage in:
• Patients with BMI <35, or 35-40 without the defined comorbid conditions above *(weak recommendation)*				

Note: GRADE framework elements are described in Appendix B. A GRADE evidence profile is provided in Appendix C.

Coverage question: Should bariatric surgery be recommended for coverage in children and adolescents?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
All-cause mortality (*Critical outcome*)	Insufficient evidence in this population *Insufficient evidence*	High cost (tens of thousands of dollars) but may be cost effective especially given the long	High variability. If conservative treatments have failed, children, adolescents and their	Parental involvement in weight management plans is likely necessary to assist the

Bariatric/Metabolic Surgery for Obesity

Coverage question: Should bariatric surgery be recommended for coverage in children and adolescents?				
Major adverse cardiovascular events (*Critical outcome*)	Insufficient evidence in this population *Insufficient evidence*	time horizon if weight loss is maintained. However, uncertainty about the long-term balance of benefits and harms could significantly alter estimates of cost-effectiveness.	parents would be highly motivated to find an effective alternative intervention. Children may have a significant fear of surgery, but the profound social and emotional impact of obesity may override their concerns. Parents are likely to be more concerned about the long term health impacts of obesity than children, and may be concerned about the uncertainty about the long term benefits.	effectiveness of obesity treatments (based on expert opinion). Pediatric bariatric surgery is likely to be available at only a few highly specialized centers. The American Academy of Pediatrics has 10 criteria that pediatric bariatric surgery programs should meet.
Type 2 DM remission/resolution (*Important outcome*)	Rates of remission of T2DM ranged from 50 to 100% ●○○○ *(very low certainty based on mostly small observational trials with imprecise effects)*			
Hypertension remission/ resolution (*Important outcome*)	Rates of remission of hypertension ranged from 50 to 100% ●○○○ (*very low certainty based on mostly small observational trials with imprecise effects)*			
Change in BMI (*Important outcome*)	Mean weighted difference in BMI at 1 year (from baseline): -10.5 to -17.2 kg/m^2 ●●○○ *(low certainty based on mostly small observational trials)*			
Rationale: Bariatric surgery likely results in significant reductions in BMI (low certainty) and is associated with remission of type 2 diabetes and hypertension (very low certainty). However, coverage is not recommended because of the limited evidence about overall long-term benefits and harms of bariatric surgery in this population as well as the high variability in values and preferences.				
Recommendation: Bariatric surgery is not recommended for coverage in children and adolescents *(weak recommendation).*				

Note: GRADE framework elements are described in Appendix B. A GRADE evidence profile is provided in Appendix C.

Bariatric/Metabolic Surgery for Obesity

Coverage question: Should reoperative bariatric surgery for inadequate weight loss be recommended for coverage?					
Outcomes		**Estimate of Effect for Outcome** **Confidence in Estimate of Effect**	**Resource allocation**	**Values and Preferences**	**Other considerations**
Critical outcomes	All-cause mortality	Insufficient evidence in this population *Insufficient evidence*	A second high cost procedure (tens of thousands of dollars), with a history of prior failure may be more costly in total and less effective, however, the cost – effectiveness in this group is unknown.	There would be high variability in patient preferences. With a prior failure of a bariatric procedure, some patients would be hesitant to try an additional procedure given the burdens of surgery and prior ineffectiveness. Others would be motivated to try a different procedure in hopes that it would work better. Patients seeking reoperation have likely no other good potential option given failure of multiple previous alternatives (e.g. clinical, pharmacological, nutritional, physical activity, and surgical).	There is evidence of greater complications rates with reoperation. There is insufficient evidence in the reoperation group to know if their outcomes would be substantially different that those undergoing their first operation. A significant proportion of these patients would be going from a band to a RYGB (from a procedure with a higher failure rate to a lower failure rate).
	Major adverse cardiovascular events	Insufficient evidence in this population *Insufficient evidence*			
Important outcomes	Type 2 DM remission / resolution	Insufficient evidence in this population *Insufficient evidence*			
	Hypertension remission/ resolution	Insufficient evidence in this population *Insufficient evidence*			
	Change in BMI	Mean change in BMI (from baseline): +2.4 kg/m^2 to -17.2 kg/m^2 (follow-up ranging from 8 to 48 months) ●○○○ *(very low certainty based on small case series)*			
Rationale: Reoperation is associated with higher complication rates but also effective weight loss (based on very low quality evidence). While there are not long term health outcomes available, there is no reason to believe that significant weight loss in the reoperation group would be associated with less future health benefits. Therefore, the subcommittee makes no recommendation that the coverage criteria should be different between reoperation and primary surgery. Surgeons will also evaluate their patients and consider reasons for failure when deciding if the patient is a good candidate for reoperation.					
Recommendation: No recommendation that coverage criteria for re-operation should be different than for primary surgery.					

Note: GRADE framework elements are described in Appendix B GRADE evidence profile is provided in Appendix C

Bariatric/metabolic surgery for obesity

HTAS Coverage Recommendations

Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass, gastric banding, and sleeve gastrectomy) is recommended for:

- Adult obese patients (BMI ≥ 35) with
    - Type 2 diabetes *(strong recommendation)* OR
    - at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea *(weak recommendation)*
- Adult obese patients (BMI ≥ 40) *(strong recommendation)*

Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program *(weak recommendation).*

Metabolic and bariatric surgery is not recommended for coverage in:

- Patients with BMI <35, or 35-40 without the defined comorbid conditions above *(weak recommendation)*

Children and adolescents *(weak recommendation)*

HERC Staff Assessment:

Currently, bariatric surgery only pairs in the funded region of the Prioritized List with diabetes. The Coverage Guidance suggests that coverage should be expanded to those with diabetes or other comorbidities. Therefore, changing the primary indication for bariatric surgery on the List to be for obesity rather than diabetes makes sense and consolidating the bariatric surgery codes to the Obesity line is indicated. Having bariatric surgery codes on the lower obesity line (589) is confusing because of the comorbidity rule, when there are clearly defined comorbidities in the new proposed guideline note language. Because the weight loss is less, consider not covering gastric banding as a preferred surgical treatment.

Obesity Task Force Phase 1 Recommendations *(reflecting 3/3/16 and 3/17/16 task force discussions)*:

1) Add bariatric surgery to Line 325
    a. Change the Treatment title
    b. Add bariatric surgery codes (see Code Movement Table)
2) Remove bariatric surgery from Line 30, Type 2 Diabetes
    a. Change title of the Treatment to not include bariatric surgery
    b. Remove bariatric surgery codes from line 30 (see Code Movement Table)
    c. Remove coding specification about bariatric surgery
    d. Remove reference to Guideline Note 8
3) Remove bariatric surgery from Line 589
    a. Change the Treatment title

   b. Remove bariatric surgery codes from Line 589 (see Code Movement Table)

4) Revise Guideline Note 8
   a. Expand to BMI >40 without comorbidities, and 35 with specific comorbidities
   b. Continue to not cover surgery for children and adolescents
   c. Allow reoperations
   d. Discuss whether gastric banding should be covered only when there are contraindications or also in women of reproductive age with intent to conceive
   e. Add freedom from marijuana dependence/abuse to the 6 month contraindications
   f. Change language around the certification/accreditation requirements from the MBSAQIP
   g. Make other minor guideline changes

Line: 30
Condition: TYPE 2 DIABETES MELLITUS (See Coding Specification Below) (See Guideline Notes ~~8,~~62,64,65)
Treatment: MEDICAL THERAPY~~, BARIATRIC SURGERY WITH BMI >= 35~~
ICD-10: E08.00-E08.29,E08.311-E08.9,E09.00-E09.29,E09.311-E09.9,E11.00-E11.29,E11.311-E11.9,E13.00-E13.29,E13.311-E13.9, E16.1,Z46.51
CPT: 43644,43645,43770-43775,43846-43848,48155,64505-64530,90935-90947,90989-90997,92002-92014,92227,96150-96154, 97605-97608,97802-97804,98960-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607
HCPCS: G0108,G0109,G0245,G0246,G0270,G0271,G0396,G0397,G0406-G0408,G0425-G0427,G0458,G0463,G0466,G0467,S2083, S9140-S9145,S9353,S9537

~~CPT codes 43644-43645 and 43846-43848 (Roux-En-Y gastric bypass) and 43770-43775 (laparoscopic adjustable gastric banding and sleeve gastrectomy) are only included on this line as treatment according to the requirements in Guideline Note 8 when paired with:~~
~~1) a primary diagnosis of E11 (Type II Diabetes with or without complication);~~
~~2) a secondary diagnosis of E66.01, E66.09, E66.2, E66.8 or E66.9 (Obesity); AND,~~
~~3) a tertiary diagnosis code of Z68.35-Z68.39 or Z68.4.~~

Line: 325
Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes 5,8, 64,65)
Treatment: INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS, BARIATRIC SURGERY
ICD-10: E66.01-E66.9, Z68.30-Z68.45,Z68.54
CPT: 96150-96154,97802-97804,98966-98969,99051,99060,99070,99078,99201-99215,99281-99285,99341-99355,99358-99378, 99381-99404,99408-99416,99429-99449,99487-99498
HCPCS: G0396,G0397,G0447,G0463,G0466,G0467,G0473

Line: 589 ***(Note: This line is recommended for deletion under a separate issue)***
Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes ~~8,~~64,65)
Treatment: NON-INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS~~; BARIATRIC SURGERY FOR OBESITY WITH A SIGNIFICANT COMORBIDITY OTHER THAN TYPE II DIABETES & BMI >=35 OR BMI>=40 WITHOUT A SIGNIFICANT COMORBIDITY~~
ICD-10: E66.01-E66.9,Z68.30-Z68.45,Z68.54,Z71.3
CPT: 43644,43645,43770-43775,43846-43848,98966-98969,99051,99060,99070,99078,99201-99215,99281-99285,99341-99355, 99358-99378,99381-99404,99408-99416,99429-99449,99487-99498,99605-99607
HCPCS: G0396,G0397,G0447,G0463,G0466,G0467,G0473

GUIDELINE NOTE 8, BARIATRIC SURGERY

Line~~s~~ ~~30,589~~ 325

Bariatric/metabolic surgery (limited to Roux-en-Y gastric bypass, gastric banding[1], and sleeve gastrectomy) is included on Line 325~~under~~ when the following criteria are met:

A) Age ≥ 18

B) The patient has obesity with a:

~~1) a BMI ≥ 35 with co-morbid type II diabetes for inclusion on Line 30 TYPE 2 DIABETES MELLITUS; OR~~

~~2) BMI >=35 with at least one significant co-morbidity other than type II diabetes (e.g., obstructive sleep apnea, hyperlipidemia, hypertension) or BMI >= 40 without a significant co-morbidity for inclusion on Line 589~~

1) BMI ≥ 40 OR
2) BMI ≥ 35 with:
   a) Type 2 diabetes, OR
   b) at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea

B) ~~No prior history of Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding, or repeat gastric banding or unless they resulted in failure due to complications of the original surgery.~~ Repeat bariatric surgery is included when it is a conversion from a less intensive (such as gastric band or sleeve gastrectomy) to a more intensive surgery (e.g. Roux-en-Y). Repair of surgical complications (excluding failure to lose sufficient weight) are also included on this and other lines. Reversal of surgical procedures and devices is included on this line when benefits of reversal outweigh harms.

C) Participate in the following four evaluations and meet criteria as described.
1) Psychosocial evaluation: (Conducted by a licensed mental health professional)
   a) Evaluation to assess potential compliance with post-operative requirements.
   b) Must remain free of abuse of or dependence on alcohol or marijuana during the six-month period immediately preceding surgery. No current use of nicotine or illicit drugs and must remain abstinent from their use during the six-month observation period. Testing will, at a minimum, be conducted within one month of the quit date and within 1 month of the surgery to confirm abstinence from nicotine and illicit drugs.
   c) No mental or behavioral disorder that may interfere with postoperative outcomes[2].
   d) Patient with ~~previous~~ psychiatric illness must be stable for at least 6 months.
2) Medical evaluation: (Conducted by OHP primary care provider)
   a) Pre-operative physical condition and mortality risk assessed with patient found to be an appropriate candidate.
   b) Optimize medical control of diabetes, hypertension, or other co-morbid conditions.
   c) Female patient not currently pregnant with no plans for pregnancy for at least 2 years post-surgery. Contraception methods reviewed with patient agreement to use effective contraception through 2nd year post-surgery.
3) Surgical evaluation: (Conducted by a licensed bariatric surgeon associated with program[~~2~~3])
   a) Patient found to be an appropriate candidate for surgery at initial evaluation and throughout period leading to surgery ~~while continuously enrolled on OHP~~.

b) Received counseling by a credentialed expert on the team regarding the risks and benefits of the procedure~~3~~ and understands the many potential complications of the surgery (including death) and the realistic expectations of post-surgical outcomes.

4) Dietician evaluation: (Conducted by licensed dietician)
   a) Evaluation of adequacy of prior dietary efforts to lose weight. If no or inadequate prior dietary effort to lose weight, must undergo six-month ~~medically~~ clinically supervised weight reduction program (including intensive nutrition and physical activity counseling as defined by the USPSTF).
   b) Counseling in dietary lifestyle changes

D) Participate in additional evaluations:
   1) Post-surgical attention to lifestyle, an exercise program and dietary changes and understands the need for post-surgical follow-up with all applicable professionals (e.g. nutritionist, psychologist/psychiatrist, exercise physiologist or physical therapist, support group participation, regularly scheduled physician follow-up visits).

Option 1: [1] Banding is only included when sleeve gastrectomy or Roux-en-Y are contraindicated OR

Option 2: [1] Banding is only included when sleeve gastrectomy or Roux-en-Y are contraindicated, or for a woman of reproductive age with intent to conceive a pregnancy who prefers a less intensive surgical treatment.

[2] Many patients (>50%) have depression as a co-morbid diagnosis that, if treated, would not preclude their participation in the bariatric surgery program.

[3] All surgical services must be provided by a program with current ~~certification~~ accreditation (as a comprehensive center or low acuity center) by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). ~~, or in active pursuit of such certification with all of the following: a dedicated, comprehensive, multidisciplinary, pathway-directed bariatric program in place; hospital to have performed bariatrics > 1 year and > 25 cases the previous 12 months; trained and credentialed bariatric surgeon performing at least 50 cases in past 24 months; qualified bariatric call coverage 24/7/365;appropriate bariatric-grade equipment in outpatient and inpatient facilities; appropriate medical specialty services to complement surgeons' care for patients; and quality improvement program with prospective documentation of surgical outcomes. If the program is still pursuing (MBSAQIP) certification, it must also restrict care to lower-risk OHP patients including: age < 65 years; BMI < 70; no major elective revisional surgery; and, no extreme medical comorbidities (such as wheel-chair bound, severe cardiopulmonary compromise, or other excessive risk). All programs must agree to yearly submission of outcomes data to Division of Medicaid Assistance Programs (DMAP).~~

~~3 Only Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding and sleeve gastrectomy are approved for inclusion.~~

Bariatric/metabolic surgery for obesity

Code Movement Table

Code	Code Description	Staff Recommendation
Z46.51	Encounter for fitting and adjustment of gastric lap band	Remove from Line 30, and place on Line 325 only
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)	Remove from Line 30 and 589, and place on Line 325 only
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption	Remove from Line 30 and 589, and place on Line 325 only
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	Remove from Line 30 and 589, and place on Line 325 only
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only	Remove from Line 30 and 589, and place on Line 325 only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	Remove from Line 30 and 589, and place on Line 325 only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	Remove from Line 30 and 589, and place on Line 325 only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	Remove from Line 30 and 589, and place on Line 325 only
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)	Remove from Line 30 and 589, and place on Line 325 only
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy	Remove from Line 30 and 589, and place on Line 325 only
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption	Remove from Line 30 and 589, and place on Line 325 only
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)	Remove from Line 30 and 589, and place on Line 325 only
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline	Remove from Line 30, place on Line 325

Bariatric Surgery utilization analysis

Comparing commercial and Medicaid populations

Health Evidence Review Commission and
Center for Health Systems Effectiveness

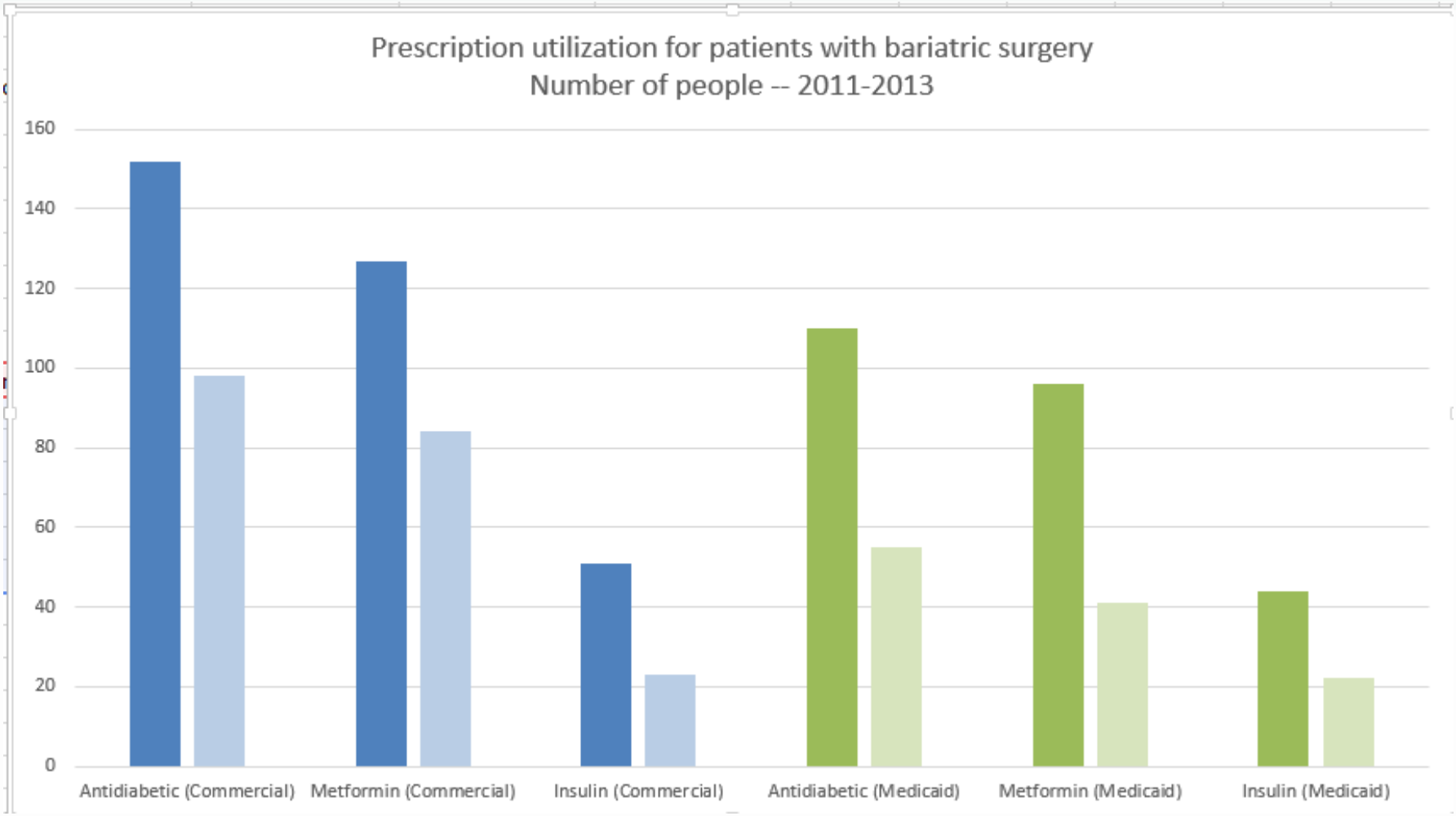
Oregon Health Authority

Claims analysis

- Source: All Payer All Claims database, services received in calendar years 2011-2013 (2014 data was incomplete)
- Commercial and OHP data for people who had bariatric surgery
- (additional selection criteria)
- Established index surgery date then tracked use of medications, insulin before surgery and 30+ days after surgery
- Counted number of people filling at least one prescription in either period

Overall summary

- Commercial insured data showed 1,018 surgeries over the three years
- Medicaid showed 240 surgeries
- Compared claims 1 year pre-surgery with whatever post surgical prescription claims we had (whether 1 month or 2 years); filled prescriptions only
- Some underreporting possible because of unfilled prescriptions or prescriptions purchased without use of insurance
- For Medicaid, surgery was only available for patients with diabetes, and wait lists were common in some areas



Darker bars represent patients using the medication during the year prior to surgery; lighter bars represent patients using the medication at any point after surgery.

1,018 total surgeries in commercial;
240 in Medicaid

Oregon Health Authority

HERC Coverage Guidance – Metabolic and Bariatric Surgery
Disposition of Public Comments

Table of Contents

Commenters

Identification	Stakeholder
A	Oregon Chapter of the American Society for Metabolic and Bariatric Surgery *[Submitted January 18, 2016]*

Public Comments

ID/#	Comment	Disposition
A1	"[W]e would like to applaud the efforts to update the current policy on metabolic and bariatric surgery. We agreed with standardizing the indications for surgery to come in line with current clinical practice throughout the United States. We agree the information in the areas of adolescent surgery and surgical treatment of BMI less than 35 is incomplete and rapidly evolving. We believe these two areas should be reassessed in two years."	Thank you for your comment. The Oregon HERC assesses any new evidence every two years to determine if a new coverage guidance is needed.

Accreditation issue in bariatric surgery

Question: Should the guideline note on bariatric surgery continue to require accreditation through the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)?

Relevant history

Prioritized List

When bariatric surgery was first covered on the Prioritized List, there was a strong interest in ensuring quality outcomes. The current guideline note required that the hospitals either be certified by MBSAQIP or in pursuit of certification. It also requires bariatric surgery programs to provide yearly data to DMAP. The required regular reporting of outcomes to DMAP never occurred. Here is the current Guideline Note 8 Bariatric Surgery excerpt:

> All surgical services must be provided by a program with current certification by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), or in active pursuit of such certification with all of the following: a dedicated, comprehensive, multidisciplinary, pathway-directed bariatric program in place; hospital to have performed bariatrics > 1 year and > 25 cases the previous 12 months; trained and credentialed bariatric surgeon performing at least 50 cases in past 24 months; qualified bariatric call coverage 24/7/365;appropriate bariatric-grade equipment in outpatient and inpatient facilities; appropriate medical specialty services to complement surgeons' care for patients; and quality improvement program with prospective documentation of surgical outcomes. If the program is still pursuing (MBSAQIP) certification, it must also restrict care to lower-risk OHP patients including: age < 65 years; BMI < 70; no major elective revisional surgery; and, no extreme medical comorbidities (such as wheel-chair bound, severe cardiopulmonary compromise, or other excessive risk). All programs must agree to yearly submission of outcomes data to Division of Medicaid Assistance Programs (DMAP).

HTAS Coverage Guidance

HTAS developed a Coverage Guidance on bariatric surgery. They asked a Key Question:

> What components and systems of care are associated with improved health outcomes (e.g., centers of excellence, surgeon's experience, etc.)?

The Coverage Guidance includes one systematic review on systems of care (Zevin, 2012) evaluating surgeon and hospital volume. The Coverage Guidance concludes that "there is low certainty evidence that surgeon experience is associated with improved outcomes and very low certainty evidence that hospital bariatric surgical volume is associated with improved outcomes."

The Washington HTA found limited evidence of post-operative support groups.

Accreditation issue in bariatric surgery

The draft Coverage Guidance box language about accreditation is as follows:

> Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program *(weak recommendation).*

Obesity Task Force Phase I

The obesity task force used the HTAS Draft Coverage Guidance as the basis for developing recommended changes to the Prioritized List. They became aware through expert testimony that there were two types of accreditation (comprehensive center or low acuity center) and thus recommended language limiting surgery to one of these two centers. It was understood at that time that this would include all of the bariatric surgery centers in the state.

They suggested editing that section as follows:

> All surgical services must be provided by a program with current ~~certification~~ accreditation (as a comprehensive center or low acuity center) by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). ~~, or in active pursuit of such certification with all of the following: a dedicated, comprehensive, multidisciplinary, pathway-directed bariatric program in place; hospital to have performed bariatrics > 1 year and > 25 cases the previous 12 months; trained and credentialed bariatric surgeon performing at least 50 cases in past 24 months; qualified bariatric call coverage 24/7/365;appropriate bariatric-grade equipment in outpatient and inpatient facilities; appropriate medical specialty services to complement surgeons' care for patients; and quality improvement program with prospective documentation of surgical outcomes. If the program is still pursuing (MBSAQIP) certification, it must also restrict care to lower risk OHP patients including: age < 65 years; BMI < 70; no major elective revisional surgery; and, no extreme medical comorbidities (such as wheel-chair bound, severe cardiopulmonary compromise, or other excessive risk). All programs must agree to yearly submission of outcomes data to Division of Medicaid Assistance Programs (DMAP).~~

Interim update - Kaiser

HERC staff became aware that Kaiser does bariatric surgery through a query raised through HealthShare, Helen Bellanca and Joyce Caramella.

From Joyce Caramella, RN, Quality Improvement Coordinator, HealthShare

> This proposed wording further restricts where OHP members can have this surgery. Currently there are 9 centers in Oregon that qualify, two in Portland that are comprehensive centers (OHSU and Legacy Good Samaritan and one that is a low acuity center. Last case I had regarding this surgery, the member was on a 3 year wait list for his approved surgery at OHSU.

We had hoped that Kaiser might be considered for approval, they now can do these surgeries on their members and Medicare members, but not OHP members.

This is a lifesaving procedure for these members, and it feel cruel to deny them an approved service for such a long timeframe.

From Helen Bellanca, MD, MPH, HealthShare

Kaiser is not seeking MBSAQIP certification for several reasons:

1. Having that certification would obligate them to be open to anyone in the community seeking the surgery. Because Kaiser is a closed system, they didn't feel they could meet that obligation
2. Standards in bariatric surgery have shifted. It used to be thought that high-volume centers provided the best care, and so these certifications are based on volume. However, that standard was only true when the surgery was new and there weren't that many people doing it. Now that there is way more experience in the field, quality can be determined by outcomes (data on complication rates) rather than volume, which is what Kaiser does.
3. It is prohibitively expensive to be certified. Not only are there direct costs to the certification itself, but there are indirect costs to use their specific data system, hire more nurses, require the surgeons to alter their call schedule, etc.

It was the feeling at Kaiser that the only people who push for certification are the institutions who are already certified, but that their quality data is actually not as good as Kaiser's. Kaiser has no internal incentive to seek this certification and they don't feel it reflects the quality of the care they provide.

In terms of solutions, they offered this one:

They told me that a recent standard for Medicare/Medicaid elsewhere was for patients to be notified that they have a right to receive the surgery at an MBSAQIP-certified center, that Kaiser was not such a center, but that they could waive this right and have the surgery at Kaiser if they chose. They recommend including that language in the HERC guidance. Something like:

Patients must be notified of their right to have all surgical services ~~must be~~ provided by a program with current ~~certification~~ accreditation (as a comprehensive center or low acuity center) by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). Patients may waive this right if they choose, but must sign a consent form indicating that they understand that they are waiving that right in order to get the care at the institution of their choice.

Accreditation issue in bariatric surgery

*From Dr. Bruce Wolfe, MD (*HERC appointed expert on the Bariatric Surgery Coverage Guidance

> The systematic review by Drs. Azagury and Morton identified 13 papers that met inclusion criteria. 10 of the 13 found accreditation improved outcomes while 3 did not. The author of one of these and co-author of another, John Birkmeyer, requested a review of the accreditation requirements by CMS, a request that was granted as you know. Given the lack of unanimity of the reported analyses and the withdrawal of the accreditation required by CMS, Oregon would be justified in not requiring MBSAQIP accreditation for participation in the care of bariatric surgery patients covered by Medicaid. The question at the committee meeting addressed by Dr. Halpin and myself was how can administrators of Oregon Medicaid be assured that each provider of bariatric surgical services is performing at an acceptable level? Our answer to that question is MBSAQIP accreditation. The key to the accreditation is the accumulation of outcomes among all patients undergoing bariatric surgery at the center and with reporting of the risk-adjusted outcomes in relation to the total MBSAQIP database. In this way, the centers receive analyses indicating what areas of their program require improvement. As reported by Birkmeyer, it is certainly possible for a given center to be performing at a level equivalent to others in the state or nation without necessarily being a part of the accreditation system with data analysis and reporting. Conversely, it is also possible for a given center to not be performing at such a level.
>
> Dr. Halpin and I have discussed the matter and have no objection to whatever decision you may make as, indicated above, that decision would be supportable by selected evidence.

<u>Background about the controversy</u>

Blackstone, 2014

1. Commentary, pro/con article that explains history of accreditation and arguments
2. Accreditation started in 2004, and in 2012, the two national accreditation programs ASMBS Centers of Excellence and ACS Bariatric Surgery Center Network merged into the the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program(MBSAQIP). Univ of Michigan/BCBS collaborative created new model that was adopted.
3. CMS convened an expert panel and decided in 2013 to drop the accreditation requirement. Medical specialty societies were opposed.
4. Argument against accreditation –

   a. Concentrating medicare patients into centers of excellence did not improve outcomes
   b. Disadvantages minority patients. 17% decline in access to care among minority Medicare patients
5. Argument for accreditation –
   a. Articles arguing that COE are no better than non-COE have numerous limitations, including other 1) simultaneous initiatives in Michigan that would improve outcomes despite non-COE; 2) new adoption of accreditation caused misclassification
   b. 2 studies found increased mortality in non-COE hospitals
   c. Studies saying that differential access are self-contradictory

Blondet, 2015

1. Summary of historical process and data supporting accreditation
2. No specific methodology identified
3. Strong recommends accreditation based on improved outcomes. Discredits the studies that demonstrate no improvement in morbidity/mortality.

<u>Evidence summary</u>

Morton, 2014

1. 2010 National wide inpatient sample of 117,478 weighted bariatric patient discharges corresponding to 235 unique hospitals. A total of 72,615 (61.8%) weighted discharges, corresponding to 145 (61.7%) named or AHA identifiable hospitals were included.
2. Among the 145 hospitals, 66 (45.5%) were unaccredited and 79 (54.5%) accredited.
3. Baseline characteristics between accredited and unaccredited hospitals are significant:

TABLE 1. Hospital Characteristics by Accreditation Status, 2010

	Unaccredited	Accredited	*P*
Hospitals, no. (%)	66 (45.5)	79 (54.5)	
Mean volume	279	265	0.909
HVC, %	52.8	80.8	<0.0001
Teaching hospital, %	66.2	58.1	<0.0001

4. Patient characteristics also vary significantly between unaccredited and accredited hospitals:
   a. Procedures
   b. Race
   c. Age
   d. Insurance

   e. Charleston combordity index
5. Results:
   a. Compared with accredited centers, unaccredited centers had a higher:
      i. Mean LOS (2.25 vs 1.99 days, *P* < 0.0001)
      ii. Total charges ($51,189 vs $42,212, *P* < 0.0001)
      iii. Incidence of any complication (12.3% vs 11.3%, *P* = 0.001)
      iv. Mortality (0.13% vs 0.07%, *P* = 0.019)
      v. Failure to rescue (0.97% vs 0.55%, *P* = 0.046).
   b. Accredited centers had higher rates of:
      i. Deep venous thrombosis (1.43 v 2.12, P <0.0001)
      ii. Cardiac arrhythmia (2.81 v 3.79, P<0.0001)
   c. Multivariable logistic regression analysis identified unaccredited status as a positive predictor of incidence of complication [odds ratio (OR) = 1.08, *P* < 0.0001], as well as mortality (OR = 2.13, *P* = 0.013).
   d. Teaching hospitals also increased risk of any in-hospital complication OR 1.32 (95% CI 1.26-1.39, P<0.0001)

TABLE 6. OR for Any In-Hospital Complication, 2010

	OR	95% CI	*P*
Unaccredited	1.09	1.03–1.16	0.005
HVC	0.82	0.77–0.86	<0.0001
Teaching hospital	1.32	1.26–1.39	<0.0001
Age ≥ 50	1.59	1.52–1.67	<0.0001
Male	1.25	1.18–1.32	<0.0001
White	1.02	0.97–1.07	0.459
Private insurance	0.91	0.85–0.97	0.004
Medicare insurance	1.69	1.56–1.83	<0.0001
Charlson comorbidity			
0 (reference)	-		
1	1.03	0.98–1.09	0.286
2	1.50	1.40–1.61	<0.0001
≥3	2.68	2.40–2.99	<0.0001

   e.

TABLE 7. OR for In-Hospital Mortality, 2010

	OR	95% CI	*P*
Unaccredited	2.26	1.24–4.10	0.007
HVC	0.82	0.44–1.52	0.524
Teaching hospital	1.58	0.86–2.89	0.140
Age ≥ 50	0.61	0.33–1.11	0.106
Male	1.35	0.75–2.42	0.322
White	1.07	0.62–1.85	0.808
Private insurance	0.22	0.11–0.43	<0.0001
Medicare insurance	1.46	0.74–2.87	0.271
Charlson comorbidity			
0 (reference)	—		
1	0.86	0.44–1.67	0.648
2	1.63	0.75–3.52	0.217
≥3	7.50	3.36–16.7	<0.0001

f.

6. **Author Conclusions:** Hospital accreditation status is associated with safer outcomes, shorter LOS, and lower total charges after bariatric surgery.
7. **Staff conclusions:** The study does suggest that outcomes are better at accredited hospitals. However, there are significant differences between baseline characteristics of patients and hospitals between unaccredited and accredited that make conclusions more challenging to interpret. For mortality, the highest risk predictor is being unaccredited. For any complication, the highest system level risk predictors are Medicare insurance (OR 1.69), teaching hospital (OR 1.32) then unaccredited (OR 1.09). High volume centers and private insurance are both protective against complications. For mortality, having private insurance is highly protective (OR 0.22).

Zevin, 2012 (from the CG)

1. Systematic review of volume-outcome associations in bariatric surgery; good quality
2. 24 observational studies comprising almost 460,000 patients.
3. Meta-analysis was not performed due to a high level of heterogeneity that resulted, in part, from differences in duration of follow-up and risk-adjustment.
4. 13 studies addressed the relationship between annual surgeon case volume and patient outcomes. Across the 5 cohort studies that were included, there was consistent evidence of improved outcomes with increasing surgeon volume. The results of lower quality studies (primarily retrospective cohorts) were mixed, but 6 of the 8 studies supported an association between surgeon volume and outcomes.
5. 17 studies addressed the association between hospital volume and outcomes. While the two case-control studies that were included did not support an association between facility volume and outcomes, the preponderance of retrospective case series (14/15 studies) that were included found an association between facility volume and outcomes.
6. Authors conclusions: There is strong evidence to support the association between surgeon volume and patient outcomes, and that weaker evidence supports the

association between hospital volume and outcomes. Overall, they conclude that the literature "supports the BSCOE accreditation and the bariatric surgery fellowship training programs" (Zevin et al., 2012, p. 70).

Other payer policies

CMS coverage

Effective for dates of service on and after February 21, 2006, these procedures are only covered when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (program standards and requirements in effect on February 15, 2006). **Effective for dates of service on and after September 24, 2013, facilities are no longer required to be certified.**

The Centers for Medicaid and Medicare have approved six facilities in Oregon to perform bariatric surgery: Bay Area Hospital, Legacy Good Samaritan Hospital and Medical Center, Oregon Health & Science University, Sacred Heart Medical Center, Salem Hospital, St. Charles Medical Center – Bend.

Moda

Bariatric surgery is only covered if provided by an approved facility, defined by Moda as a Center of Excellence.

Washington Medicaid

Bariatric surgery facilities approved by Washington Medicaid must have performed a minimum of 100 bariatric surgical procedures, be under the direction of an experienced board-certified surgeon, been in operation for at least five years, have a 2% or less mortality rate, have a 15% or less morbidity rate, have at least five years of patient follow-up data, have an average of at least 50% patient weight loss at five years, and have a reoperation/revision rate of 5% or less.

Aetna

No specific requirement

Cigna

No specific requirement

Regence BCBS

No specific requirement

HERC Staff Summary

Since the HTAS and Obesity Task Force Phase I reviewed the Bariatric Surgery Coverage Guidance, new information became available that differed from their understanding at the time. The new information is that there is a bariatric surgery program in Oregon that is not accredited. The understanding that all bariatric surgeons in Oregon were practicing at an accredited center was one (of many reasons) why ongoing accreditation was recommended to be required.

Historically, the Prioritized List guideline note dealing with bariatric surgery has required some element of proof of good outcomes from bariatric surgery programs. However, this requirement for data reporting has not been implemented and no guarantee of outcomes has been ascertained despite the fact that this requirement has been in place for many years. Studies generally support improved outcomes with accreditation (although there are a few contradictory studies). There are also a number of other variables associated with worse outcomes that are not excluded from coverage. CMS no longer requires accreditation. There is at least one system in Oregon (Kaiser) which is not accredited and does not plan to pursue accreditation, however, has OHSU fellowship-trained bariatric surgeons. Including proposed language about informing patients about patients' needing to be informed about their right to receive care at a MBSAQIP accredited center seems to be outside of typical Prioritized List territory. Requiring accreditation is not something the Prioritized List requires for other types of surgeries.

Given this, it is worth a brief discussion to determine whether requiring accreditation for inclusion on the Prioritized List is still appropriate.

HERC Staff Recommendation

Discuss whether to:

1. **Continue requiring accreditation** (one center in Oregon will be excluded)

   All surgical services must be provided by a program with current ~~certification~~ accreditation (as a comprehensive center or low acuity center) by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). ~~, or in active pursuit of such certification with all of the following: a dedicated, comprehensive, multidisciplinary, pathway-directed bariatric program in place; hospital to have performed bariatrics > 1 year and > 25 cases the previous 12 months; trained and credentialed bariatric surgeon performing at least 50 cases in past 24 months; qualified bariatric call coverage 24/7/365;appropriate bariatric-grade equipment in outpatient and inpatient facilities; appropriate medical specialty services to complement surgeons' care for patients; and quality improvement program with prospective documentation of surgical outcomes. If the program is still pursuing (MBSAQIP) certification, it must also~~

~~restrict care to lower-risk OHP patients including: age < 65 years; BMI < 70; no major elective revisional surgery; and, no extreme medical comorbidities (such as wheel-chair bound, severe cardiopulmonary compromise, or other excessive risk). All programs must agree to yearly submission of outcomes data to Division of Medicaid Assistance Programs (DMAP).~~

OR

2. **Adopt language similar to Washington, based on the Coverage Guidance finding that addresses the association between surgeon volume and outcomes:**
   All surgical services must be provided by a program with a minimum of 100 bariatric surgical procedures and be under the direction of an experienced board-certified surgeon.

OR

3. **Eliminate accreditation as part of the coverage requirement altogether.**

~~All surgical services must be provided by a program with current certification by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). , or in active pursuit of such certification with all of the following: a dedicated, comprehensive, multidisciplinary, pathway-directed bariatric program in place; hospital to have performed bariatrics > 1 year and > 25 cases the previous 12 months; trained and credentialed bariatric surgeon performing at least 50 cases in past 24 months; qualified bariatric call coverage 24/7/365;appropriate bariatric-grade equipment in outpatient and inpatient facilities; appropriate medical specialty services to complement surgeons' care for patients; and quality improvement program with prospective documentation of surgical outcomes. If the program is still pursuing (MBSAQIP) certification, it must also restrict care to lower-risk OHP patients including: age < 65 years; BMI < 70; no major elective revisional surgery; and, no extreme medical comorbidities (such as wheel-chair bound, severe cardiopulmonary compromise, or other excessive risk). All programs must agree to yearly submission of outcomes data to Division of Medicaid Assistance Programs (DMAP).~~

HERC Obesity Taskforce – Overall Summary

Question: Does the overall structure of the obesity lines and related guidelines make sense? How should they be modified as part of the HERC biennial review of this topic?

Question source: HERC staff, biennial review

Issue:

Obesity treatments, including pharmacologic, nutritional, behavioral, surgical, and multisector interventions are likely to have changed in the last few years. This topic is being addressed as part of the biennial review of the Prioritized List, to ensure that it is up to date. An Obesity Task Force was created to assist VbBS and HERC with this biennial review topic.

Phase I – Clinical interventions

Discussion scope:

1. Obesity and overweight, adult and pediatric
    a. Pharmacologic interventions
    b. Behavioral interventions
    c. Surgical
    d. Devices

Format:

2 meetings in MARCH 2016

Phase II – Multisector interventions

Discussion scope:

1. Evidence supporting multisector interventions to decrease obesity
    a. Paraclinical interventions
    b. Community based
    c. Regional policy interventions

HERC Obesity Taskforce – Overall Summary

Overall structure of Prioritized List:
The obesity lines are currently divided into funded and nonfunded lines. Bariatric surgery is only included on the Type 2 Diabetes line. Obesity was reprioritized during the ICD-10 process to mid-way down the Prioritized List based on limited efficacy.

The lower obesity line has non-intensive nutritional counseling and interventions, bariatric surgery for specific subgroups, and medication management. In practice, non-intensive nutritional counseling is more likely to be done and less easy to limit than the more effective intensive counseling. There are two groups of codes that are on the lower (unfunded) obesity line and not the higher (funded) line: bariatric surgery without diabetic comorbidity, and medication management codes (99605-99607).

The proposals include removing bariatric surgery from lower line and only placing on funded line (with a guideline) and continuing to not cover pharmacologic treatments of obesity. The loss of the lower obesity line would have minimal impact.

Obesity Task Force Recommendations:

1. Delete the lower obesity line, 589
2. Do not change current exclusion of pharmacologic treatments for obesity
3. Add exclusion of devices to the obesity guideline note to clarify intent
4. Move all obesity related interventions including bariatric surgery to the higher obesity line
5. Revise the bariatric surgery guideline to reflect the new HTAS Draft Coverage Guidance
6. Revise the obesity guideline note as it addresses behavioral interventions
7. Add statement on Multisector Interventions for obesity to the Prioritized List

Behavioral interventions for obesity

Question: Should current coverage on the Prioritized List of behavioral interventions for obesity be modified?

Issue: As part of the biennial review, OHP coverage of behavioral interventions are being reviewed and evidence updated. Currently, obesity and overweight guideline makes recommendations for intensive counseling on nutrition and physician activity. The Guideline Note language is based on USPSTF recommendations. Children are not currently discussed in the guideline. The Obesity Task Force Phase 1 addressed behavioral interventions for obesity.

Prioritized List Status:

Line: 325

Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes 5,64,65)
Treatment: INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS
ICD-10: E66.01-E66.9,Z68.30-Z68.45,Z68.54
CPT: 96150-96154,97802-97804,98966-98969,99051,99060,99070,99078,99201-99215, 99281-99285,99341-99355,99358-99378,99381-99404,99408-99416,99429-99449, 99487-99498
HCPCS: G0396,G0397,G0447,G0463,G0466,G0467,G0473

Line: 589

Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes 8,64,65)
Treatment: NON-INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS; BARIATRIC SURGERY FOR OBESITY WITH A SIGNIFICANT COMORBIDITY OTHER THAN TYPE II DIABETES & BMI >=35 OR BMI>=40 WITHOUT A SIGNIFICANT COMORBIDITY
ICD-10: E66.01-E66.9,Z68.30-Z68.45,Z68.54,Z71.3
CPT: 43644,43645,43770-43775,43846-43848,98966-98969,99051,99060,99070,99078, 99201-99215,99281-99285,99341-99355,99358-99378,99381-99404,99408-99416, 99429-99449,99487-99498,99605-99607
HCPCS: G0396,G0397,G0447,G0463,G0466,G0467,G0473

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT
Line 325
Medical treatment of overweight (with known cardiovascular risk factors) and obesity is limited to accepted intensive counseling on nutrition and physical activity, provided by health care professionals. Intensive counseling is defined as face-to-face contact more than monthly. Visits are not to exceed more than once per week. Intensive counseling visits (once every 1-2 weeks)

are included on this line for 6 months. Intensive counseling visits may continue for longer than 6 months as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention. Maintenance visits are included on this line no more than monthly after this intensive counseling period.

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome.

Pharmacological treatments are not intended to be included as services on this line.

Code	Description	Placement
96150	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment	167 lines
96151	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; re-assessment	167 lines
96152	Health and behavior intervention, each 15 minutes, face-to-face; individual	167 lines
96153	Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)	167 lines
96154	Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)	196 lines
96155	Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)	Ancillary File
97802	Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes	36 lines
97803	Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes	36 lines
97804	Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes	36 lines
98960	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient	1 Pregnancy 8 DM 1 30 DM 2
98961	Education and training for patient self-management by a qualified, nonphysician health care professional using a	1 Pregnancy 8 DM 1 30 DM 2

	standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients	
98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients	1 Pregnancy 8 DM 1 30 DM 2
99078	Physician or other qualified health care professional qualified by education, training, licensure/regulation (when applicable) educational services rendered to patients in a group setting (eg, prenatal, obesity, or diabetic instructions)	600+ lines
99401	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes	600+ lines
99402	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 30 minutes	600+ lines
99403	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 45 minutes	600+ lines
99404	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 60 minutes	600+ lines
99411	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes	600+ lines
99412	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 60 minutes	600+ lines
S0315	Disease management program; initial assessment and initiation of the program	Ancillary
S0316	Disease management program, follow-up/reassessment	Ancillary
S9445	Patient education, not otherwise classified, non-physician provider, individual, per session	Ancillary
S9446	Patient education, not otherwise classified, non-physician provider, group, per session	Ancillary
S9449	Weight management classes, non-physician provider, per session	Services recommended for non-coverage table
S9451	Exercise classes, non-physician provider, per session	Services recommended for non-coverage table

S9452	Nutrition classes, non-physician provider, per session	Services recommended for non-coverage table
S9470	Nutritional counseling, dietitian visit	Ancillary
Z71.3	Dietary counseling and surveillance	589,625

Evidence summary:

United States Preventive Services Task Force

Population	Recommendation	Grade	Year
All adults	The USPSTF recommends screening all adults for obesity. Clinicians should offer or refer patients with a body mass index (BMI) of 30 kg/m^2 or higher to intensive, multicomponent behavioral interventions.	B	2012, currently being updated
Children and Adolescents, Age 6-18 Years Old	The USPSTF recommends that clinicians screen children aged 6 years and older for obesity and offer them or refer them to comprehensive, intensive behavioral intervention to promote improvement in weight status.	B	2010, currently being updated
Adults who are overweight or obese and have additional CVD risk factors	The USPSTF recommends offering or referring adults who are overweight or obese and have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.	B	2014
General adult population without a known diagnosis of hypertension, diabetes, hyperlipidemia, or cardiovascular disease.	Although the correlation among healthful diet, physical activity, and the incidence of cardiovascular disease is strong, existing evidence indicates that the health benefit of initiating behavioral counseling in the primary care setting to promote a healthful diet and physical activity is small. Clinicians may choose to selectively counsel patients rather than incorporate counseling into the care of all adults in the general population.	C	2012, update in progress

Excerpted from summary by CEbP

LeBlanc, 2011

1. Systematic review and metanalysis
2. 58 trials, weight loss

   a. Behavioral interventions alone 38 trials (13,495 participants), weight change -3.01 kg (95% CI -4.02 to -2.01)
   b. Behavioral interventions plus orlistat with a weight change of -2.98 kg (95% CI -3.92 to -2.05)
   c. Behavioral interventions plus metformin with a weight change of -1.52 kg (95% CI -2.82 to -0.21).
   d. Intensive more effective than less intensive. Patients who participated in 12 to 26 intervention sessions in the first year generally lost 4 to 7 kg (8.8 to 15.4 lb) (6% of baseline weight) compared with 1.5 to 4 kg (3.3 to 8.8 lb) (2.8% of baseline weight) in those who participated in fewer than 12 sessions.
   e. Subset of trials (n=3) found that intensive behavioral interventions reduced incident diabetes by 50% at 2-3 year f/u
3. Conclusions: modest weight loss. More intensive more effective than less intensive. And diabetes may be prevented in high risk populations.

Dombrowski, 2014

1. Systematic review and metanalysis
2. 45 trials, more than 8000 patients
3. f/u 12 months
4. many different types of interventions by many providers
5. average 3.2 contacts with patients per month
6. behavioral interventions alone were associated with an average weight loss of 1.56 kg (95% CI -2.27 to -.086)

Hartmann-Boyce, et al, 2014b

1. Systematic review and metanalysis of pragmatic trials
2. 8 studies, over 3700 participants
3. Weight loss at 12 months
   a. Commercial programs with meal replacements were associated with an average weight loss of 6.83 kg (95% CI -8.39 to -5.26)
   b. Group based commercial programs without meal replacements were associated with an average weight loss of 2.21 kg (95% CI -2.89 to -1.54)
   c. Automated internet-based program were associated with an average weight loss of 0.7 kg (95% CI -1.37 to -0.03)
   d. Primary care-based programs were associated with an average weight loss of 0.45 kg (95% CI -1.34 to -0.43).
4. Weight loss at 24 months

Weight loss was attenuated in all groups, with only group-based commercial programs, with or without meal replacement, showing statistically significant differences in weight compared to control arms.

5. There was a high risk of bias of some of the studies

Balk, et al, 2015

1. Systematic review and metanalysis of behavioral interventions for people at high risk of diabetes
2. 53 studies included
3. Formed evidence for the Community Preventive Services Task Force
4. F/u period 1-23 years
5. Combined diet and physical activity promotion programs were associated with a relative risk of 0.59 (95% CI 0.52 to 0.66) for incident type 2 diabetes
6. Effectiveness did not appear to vary by setting, number of sessions, approach, duration, use of individual goals, or tailored diet plans. The authors concluded that programs with an individually tailored exercise plan may be more effective than those that did not.
7. More vs less intensive interventions
    a. 5 studies favored more intensive interventions (RR 0.28 for incident type 2 diabetes) over less intensive interventions (RR 0.56 for incident type 2 diabetes), though only one of the individual studies showed a statistically significant difference.
    b. More intensive programs were variably characterized by greater numbers of sessions, more intensive diet and exercise plans, goal setting, maintenance phases, individual contact, and use of an exercise physiologist.
8. There were no differences between group and individual interventions for the outcomes of body weight and incident diabetes. Group programs had a small benefit over individual programs for the outcome of fasting plasma glucose.
9. Long term studies found “no consistent pattern of results” for all cause or cardiovascular mortality. Limited evidence of no significant effects on cardiovascular events, nephropathy, or neuropathy.

Franz, et al, 2015

1. SR and MA in Type 2 diabetics
2. 11 RCTs (6,754 participants)
3. Behavioral interventions - including meal replacements, reduced energy intake plans, group behavioral weight management programs, intensive physical activity, and diets with various proportions of carbohydrates, fats, and protein
4. Weight loss at 1 year - 3% to 9% at 1 year.

5. The greatest % weight loss was in
    a. Intensive lifestyle intervention group (ILI, as described in the LookAHEAD trial) = 8.6%
    b. Mediterranean diet group = 7.2%
    c. For the programs with less than 5% weight loss at 12 months, there was no statistically significant change in hemoglobin A1c. The two programs that reported greater than 5% weight loss at 1 year (ILI, Mediterranean diet) were associated with statistically significant improvements in hemoglobin A1c of -0.6% and -1.2% respectively.
6. May not easily be adaptable to most health care settings

Hartmann-Boyce, et al, 2014a

1. SR, MA, and meta regression
2. 37 RCTs spanning over 13,000 participants
3. All behavioral interventions were associated with a mean weight loss of 2.84 kg at 12 months (95% CI -3.61 to -2.07) compared to controls
4. High heterogeneity
5. Greater weight loss associated with programs that had
    a. Calorie counting
    b. Contact with a dietician
    c. Behavioral techniques comparing participants' behavior with others
6. No other program characteristics were positively correlated with weight loss
    a. Supervised physical activity
    b. More frequent contact
    c. In person contact
    d. Individual vs group vs combined interventions

Johns, et al, 2014

1. SR and MA of behavioral interventions for either diet or exercise compared with combined behavioral weight management programs (BWMPs) in obese adults
2. 8 RCTs (spanning 1,022 participants)
3. 7 with moderate risk of bias
4. 3-6 months
    a. No difference in weight loss between diet-only and BWMPs at 3-6 months
    b. BWMPs were superior to exercise-only programs at 3-6 months (mean difference -5.33 kg, 95% CI -7.61 to -3.04),
5. 12 months

a. BWMPs were associated with greater weight loss than diet-only programs (mean difference -1.72 kg, 95% CI -2.80 to -0.64).
b. BWMPs were superior to exercise-only programs at 12-18 months (mean difference -6.29 kg, 95% CI -7.33 to -5.25).

Booth, et al, 2014

1. SR and MA of 15 randomized or cluster randomized trials, N= 4,539 participants of primary care interventions
2. Most in US, women in 50s-60s and obese
3. Small reduction in weight at 12 months (effect size -1.36 kg, 95% CI -2.10 to -0.63) and 24 months (effect size -1.23 kg, 95% CI -2.28 to -0.18) when compared with controls.
4. Conclusion – Benefit present but may not be clinically significant

van Hoek, et al, 2014

1. SR and MA of RCTs in obese young children, ages 3-8
2. 11 studies, N approximately 1,000 participants.
3. behavioral interventions were associated with a modest reduction in BMI z-score of -0.25 (95% CI -.036 to -0.14). In general, reductions of <0.5 in the BMI z-score are not considered to be clinically significant.
4. Only moderate or high intensity multicomponent interventions resulted in weight reductions that approached clinical significance (change in BMI z-core -0.46, 95% CI -0.53 to -0.39).
5. Conclusions – can result in weight loss but may not be clinically significant. Higher intensity and multicomponent more effective.

Ewald, et al, 2013

1. SR of RCTs
2. Comparison parent-only interventions with parent-child or child-only interventions for the treatment of childhood obesity.
3. 10 reports from 6 RCTs, N = 466 children.
4. Ages 5-12, and overweight or at risk for obesity
5. Too heterogeneous to do a MA
6. Conclusion: Evidence from a limited number of randomized trials shows that parent-only interventions are at least as, and possibly more, effective than either parent-child or child-only interventions for weight loss in obese children.

Behavioral interventions for obesity

HERC Staff Assessment:

It appears that there is very modest weight reduction as a result of high intensity interventions for weight loss in obese adults and overweight adults with risk factors. While almost all of the outcomes are intermediate, there is limited data that a reduction in diabetes incidence may be associated with intensive weight management. Many types of behavioral interventions are associated with a weight loss that is unlikely to be of clinical significance. Primary care based interventions appear to be ineffective. The characteristics of effective behavioral interventions are most consistently: high intensity programs, multicomponent (diet and exercise), group-based commercial programs, Mediterranean diet, and the following sub-elements -- calorie counting, contact with a dietician, and comparison to peers. The evidence on individual versus group interventions is mixed. In children, multicomponent, high intensity programs appear to result in weight loss that is of borderline clinical significance.

Obesity Task Force Phase 1 Recommendations (per their 3/3/16 and 3/17/16 meetings)

1. Add Z71.3 Dietary counseling and surveillance to Line 325
2. Consider making the following changes to the guideline:
    a. Remove the limit about not exceeding visits once per week as it may hinder pediatric or other multicomponent/multiple specialty visits.
    b. Discuss whether to modify the language on maintenance visits or remove it
    c. Add distinct language about children
    d. Include language about types of interventions with the most evidence

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 325

Medical treatment of overweight (with known cardiovascular risk factors) and obesity in adults is limited to ~~accepted~~ intensive~~,~~ counseling on nutrition and physical activity, provided by health care professionals. Intensive counseling is defined as face-to-face contact more than monthly. A multidisciplinary team is preferred, but a single clinician could also deliver intensive counseling in primary care or other settings.

~~Visits are not to exceed more than once per week.~~ Intensive counseling visits ~~(once every 1-2 weeks)~~ are included on this line for 6 months. Intensive counseling visits may continue for an additional 6 months (up to 12 months) as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention. Maintenance visits at the conclusion of the intensive treatment are included on this line no more than monthly after this intensive counseling period. The characteristics of effective behavioral interventions include: high intensity programs; multicomponent (including at a minimum

diet and exercise), group-based commercial programs; Mediterranean diet; and the following sub-elements -- calorie counting, contact with a dietician, and comparison to peers.

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, prediabetes~~impaired fasting glucose~~, or the metabolic syndrome.

Medical treatment of obesity in children is limited to comprehensive, intensive behavioral interventions. For treatment of children up to 12 years old, interventions may be targeted only to parents, or to both parents and children.

General Evidence on Behavioral Interventions for Obesity from Systematic Reviews

LeBlanc et al, 2011

This is a systematic review and meta-analysis of primary-care relevant obesity treatments for adults that was conducted by the Agency for Health Research and Quality to inform the deliberations of the U.S. Preventive Services Task Force. The authors identified a total of 58 trials of behavioral interventions; 38 trials (n=13,495) examined behavioral interventions alone, 18 trials (n=11,256) examined behavioral interventions plus orlistat, and 3 trials (n=2,652) examined behavioral interventions plus metformin. Sixty percent of trial participants were women and the average baseline BMI was about 32 kg/m2. Slightly more than half the participants in the included trials had clinical or subclinical cardiovascular risk factors. The quality of included trials was mixed with 24% being rated good and the remainder rated fair (mostly due to issues with allocation concealment, blinding, and outcomes assessment. In general most trials found that behavioral interventions, alone or in combination with orlistat or metformin, resulted in modest weight loss at 12 to 18 months. Specifically, in the meta-analysis behavioral interventions alone were associated with a weight change of -3.01 kg (95% CI -4.02 to -2.01); behavioral interventions plus orlistat with a weight change of -2.98 kg (95% CI -3.92 to -2.05); and behavioral interventions plus metformin with a weight change of -1.52 kg (95% CI -2.82 to -0.21). All groups showed high degrees of statistical heterogeneity. The authors did note that more intensive interventions (12 to 26 sessions) produced greater average weight loss (4 to 7 kg) compared with less intensive interventions (fewer than 12 sessions, average weight loss of 1.5 to 4 kg). The number of sessions appeared to be the only marker of intensity that was associated with greater weight loss; after adjusting for the number of sessions, other intervention characteristics did not alter the effect size. Finally, the authors note that subgroup reporting was sparse and mixed. On average, behavioral interventions produced less weight loss in black patients and women.

Few trials included in the review reported on distal health outcomes like death, cardiovascular disease, hospitalization, or quality of life. Among the few trials that did there were no observed differences in these outcomes between the behavioral intervention and control groups. A small number of trials (n=3) also examined the effect of behavioral intervention on the development of diabetes; these trials did show that behavioral interventions delivered in 7 to 23 sessions over one year reduced incident cases of diabetes by approximately 50% at 2 to 3 years of follow-up.

There was very little available information about harms of behavioral weight loss interventions.

Bottom line: In a general adult population, behavioral interventions are associated with modest reductions in weight at 12-18 months. More intensive behavioral interventions appear to result in greater weight loss. Behavioral interventions also appear to reduce cases of incident diabetes in high risk populations.

Dombrowski, et al, 2014

This is a systematic review and meta-analysis of randomized or cluster randomized trials examining long-term maintenance (>12 months) of weight loss with non-surgical interventions. The review included 45 trials spanning nearly 8,000 patients. All patients were older than age 18, had BMI>30, and had lost >5% of their body weight in the prior 24 months. Study interventions included behavioral counseling focused on diet and exercise, pharmacologic treatments, food replacements, or combinations of these interventions intended to maintain weigh loss. The primary outcome was weight at 12 months after randomization. Most of the studies (n=28) were U.S. based. The behavioral interventions were varied and were delivered by diverse provider types (physicians, therapist, dieticians, physiotherapists, peer supports, etc…) and in diverse formats and settings (internet, phone, clinic, community, and gym). On average, the behavioral interventions had 3.2 contacts with patients each month. In the meta-analysis, behavioral interventions alone were associated with an average weight loss of 1.56 kg (95% CI -2.27 to -.086) There was low to moderate statistical heterogeneity.

Bottom line: In a general adult population, behavioral interventions result in maintenance of weight loss at up to 12 months after an initial weight loss.

Evidence from Pragmatic Trials

Hartmann-Boyce, et al, 2014b

This is a systematic review and meta-analysis that was performed in order to examine the effects of multicomponent behavioral interventions for obese adults when implemented in routine, everyday practice. The outcomes that were studied included 12 month weight change, blood pressure, lipids, and glucose. The interventions that were investigated in the included studies were, a priori, grouped into categories based on intervention type (commercial weight loss programs with and without meal replacements, primary care interventions, and internet based programs). Ultimately, the authors included eight studies spanning over 3,700 participants. Half the studies were done in the U.S., and the remainder were done in Western Europe or Australia. Mean BMI in the studies ranged from approximately 30 to 40 kg/m2. Four studies were deemed to be at low risk of bias while the remaining four studies felt to be at high risk of bias. Weight loss at 12 months varied by intervention type; commercial programs with meal replacements were associated with an average weight loss of 6.83 kg (95% CI -8.39 to -5.26); group based commercial programs without meal replacements were associated with an average weight loss of 2.21 kg (95% CI -2.89 to -1.54); automated internet-based program were associated with an average weight loss of 0.7 kg (95% CI -1.37 to -0.03); and primary care-based programs were associated with an average weight loss of 0.45 kg (95% CI -1.34 to -0.43). At 24 months, weight loss was attenuated in all groups, with only group-based commercial programs, with or without meal replacement, showing statistically significant differences in weight compared to control arms.

Few studies examined the effects of these interventions on blood pressure or fasting glucose. None of the observed differences between intervention and control groups achieved statistical significance.

Bottom line: In routine everyday settings, group-based commercial weight loss programs, with or without meal replacements, appear to be more effective for weight loss than primary care office-based or internet-based behavioral interventions, but this conclusion is based on a small number of studies several of which had high risk of bias.

Diabetes Prevention Programs

Balk, et al, 2015

This is a systematic review and meta-analysis of behavioral interventions targeted at both diet and physical activity to prevent type 2 diabetes mellitus in people at heightened risk. This review was done to inform the recommendations of the Community Preventive Services Task Force. The authors identified 53 studies; 30 studies comparing diet and exercise interventions to usual care, 13 comparing more intensive behavioral interventions with less intensive interventions, and 13 evaluations of single programs. Overall, 33 studies were deemed good quality and the remaining were considered fair quality. The characteristics of interventions are reproduced from the review in Appendix A. All of participants in the included studies were deemed to be at heightened risk of diabetes by various criteria. The average BMI of participants was 31 kg/m2, the average age 39 years, and 65% of participants were women. Participants were of varied ethnicities and levels of educational attainment. The follow-up periods ranged from 1 to 23 years. In the overall meta-analysis, combined diet and physical activity promotion programs were associated with a relative risk of 0.59 (95% CI 0.52 to 0.66) for incident type 2 diabetes. There was little to no statistical heterogeneity and there was no indication of publication bias. In the overall analysis, the effectiveness did not appear to vary by setting, number of sessions, approach, duration, use of individual goals, or tailored diet plans. The authors concluded that programs with an individually tailored exercise plan may be more effective than those that did not.

Among the six studies that directly compared more and less intensive interventions, five favored more intensive interventions (RR 0.28 for incident type 2 diabetes) over less intensive interventions (RR 0.56 for incident type 2 diabetes), though only one of the individual studies showed a statistically significant difference. More intensive programs were variably characterized by greater numbers of sessions, more intensive diet and exercise plans, goal setting, maintenance phases, individual contact, and use of an exercise physiologist.

For the outcomes of incident cases of type 2 diabetes and body weight, there were no significant differences between group and individual interventions. For the outcome of fasting plasma glucose, interventions that included individual diet counseling were associated with a small but statistically significant improvement in fasting plasma glucose (mean difference -4 mg/dL, P=0.02).

Only three of the included studies reported distal clinical outcomes including all-cause or cardiovascular mortality but the authors found that there was “no consistent pattern of results.” Similarly, the authors found limited evidence of no significant effects on cardiovascular events, nephropathy, or neuropathy.

Bottom line: Behavioral interventions targeted at improving diet and physical activity in adults at risk for diabetes are associated with substantial reductions in the risk of incident diabetes. More intensive programs appear to be somewhat more effective than less intensive programs.

Interventions in People with Type 2 Diabetes

Franz, et al, 2015

This is a systematic review and meta-analysis of randomized controlled trials of behavioral weight loss interventions in overweight and obese adults who already have type 2 diabetes. The authors identified 11 RCTs (6,754 participants) that met inclusion criteria including 12 month follow-up and less than 30% attrition rate. Of note, only 3 of the studies compared behavioral interventions with usual care; the remaining trials compared two different behavioral interventions for weight loss. The behavioral interventions were diverse, including meal replacements, reduced energy intake plans, group behavioral weight management programs, intensive physical activity, and diets with various proportions of carbohydrates, fats, and protein. The meta-analytic results are complicated and have high heterogeneity because of the diversity of interventions, but in aggregate behavioral interventions were associated with weight loss of approximately 3% to 9% at 1 year. The greatest percent weight loss was observed in the intensive lifestyle intervention group (ILI, as described in the LookAHEAD trial) and the Mediterranean diet group (8.6% and 7.2% respectively). For the programs with less than 5% weight loss at 12 months, there was no statistically significant change in hemoglobin A1c. The two programs that reported greater than 5% weight loss at 1 year (ILI, Mediterranean diet) were associated with statistically significant improvements in hemoglobin A1c of -0.6% and -1.2% respectively.

Bottom line: In obese adults with type 2 diabetes, intensive lifestyle interventions (as described in the LookAHEAD trial) and Mediterranean diet were associated with >5% weight loss at 1 year and significant reductions in hemoglobin A1c. The authors do caution that the ILI used in the LookAHEAD trial may not be easily adapted to most health care settings.

Behavioral Techniques, Combinations, and Delivery Modes

Hartmann-Boyce, et al, 2014a

This is a systematic review, meta-analysis, and meta-regression meant to explore the techniques and modes of delivery that are correlated with successful behavioral interventions for weight loss. The systematic review identified 37 RCTs spanning over 13,000 participants. In the primary meta-analysis, all behavioral interventions were associated with a mean weight loss of 2.84 kg at 12 months (95% CI -3.61

to -2.07) compared to controls. There was a very high degree of heterogeneity. In the secondary meta-analyses programs involving supervised physical activity, more frequent contact, and in-person contact were not associated with program effectiveness. Similarly, effectiveness did not vary by individual or group interventions. In the meta-regression, programs that included calorie counting, contact with a dietician, and behavioral techniques comparing participants' behavior with others were associated with greater weight loss. No other program characteristics were positively correlated with weight loss.

Bottom line: The authors conclude that most behavioral interventions for weight loss are successful, but that the program characteristics most correlated with successful weigh loss are calorie counting and dietician contact.

Johns, et al, 2014

This is a systematic review and meta-analysis of behavioral interventions for either diet or exercise compared with combined behavioral weight management programs (BWMPs) in obese adults. The authors identified 8 RCTs (spanning 1,022 participants) that directly compared diet or exercise programs with BWMPs. All but one of the studies were judged to have at least moderate risk of bias. The primary outcomes were short- (3-6 months) and long-term (12-18 months) weight loss. In the meta-analysis comparing BWMPs with diet-only programs, there was no statistically significant difference in weight loss at 3-6 months. However, at 12 months BWMPs were associated with greater weight loss than diet-only programs (mean difference -1.72 kg, 95% CI -2.80 to -0.64). BWMPs were superior to exercise-only programs at 3-6 months (mean difference -5.33 kg, 95% CI -7.61 to -3.04), and at 12-18 months (mean difference -6.29 kg, 95% CI -7.33 to -5.25).

Bottom line: Diet-only interventions are comparable to combined behavioral weight management programs in the short term (3-6 months), but BWMPs produce greater weight loss at 12 months and beyond. BWMPs are superior to exercise-only programs for both short- and long-term weight loss.

Primary Care-specific Behavioral Interventions

Booth, et al, 2014

This is a systematic review and meta-analysis of randomized controlled trials of behavioral interventions delivered in primary care settings for obese adults. The authors identified 15 randomized or cluster randomized trials spanning 4,539 participants. Ten of the studies were done in the U.S. with the remainder done in Western Europe. Most participants were in their fifth or sixth decades, were women, and had BMIs between 35 and 50 kg/m2. The behavioral interventions were diverse, but were all delivered in outpatient primary care settings. The methodologic quality of the included studies was difficult to assess because of poor reporting of methods. In the primary meta-analyses, primary care-based behavioral interventions were associated with small but statistically significant reduction in weight at 12 months (effect size -1.36 kg, 95% CI -2.10 to -0.63) and 24 months (effect size -1.23 kg, 95% CI -2.28 to -0.18) when compared with controls. There was moderate heterogeneity.

Bottom line: The authors conclude that primary care-based behavioral interventions are associated with small reductions in weight that may not be clinically significant.

Behavioral Interventions for Children and Adolescents

van Hoek, et al, 2014

This is a systematic review and meta-analysis of behavioral interventions for obese young children (ages 3-8 years). The authors identified 27 studies, of which 11 were included in the meta-analysis. The 11 studies included in the meta-analysis spanned just over 1,000 participants. In the primary meta-analysis, behavioral interventions were associated with a modest reduction in BMI z-score of -0.25 (95% CI -.036 to -0.14). In general, reductions of <0.5 in the BMI z-score are not considered to be clinically significant. There was a very high level of heterogeneity in the overall meta-analysis. In the exploratory analysis, the authors found that only moderate or high intensity multicomponent interventions resulted in weight reductions that approached clinical significance (change in BMI z-core -0.46, 95% CI -0.53 to -0.39).

Bottom line: While behavioral interventions for young children appear to result in weight loss, the difference may not be clinically significant. Moderate or high intensity multicomponent behavioral interventions were associated with greater weight loss than other programs.

Ewald, et al, 2013

This is a systematic review of randomized controlled trials that compared parent-only interventions with parent-child or child-only interventions for the treatment of childhood obesity. The authors identified 10 reports from six randomized trials spanning 466 children. Most of the children were between ages of 5 and 12 years and were either >20% overweight or above the 85th percentile for BMI. Methodologic quality was difficult to assess due to unclear risk of bias in at least one domain of every study. Because of a high degree of heterogeneity, the authors did not perform a meta-analysis. In the narrative summary, the authors conclude that parent-only interventions are associated with similar or greater weight loss when compared with parent-child or child-only interventions.

Bottom line: Evidence from a limited number of randomized trials shows that parent-only interventions are at least as, and possibly more, effective than either parent-child or child-only interventions for weight loss in obese children.

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Appendix A. Table 1, excerpted from Balk, et al, 2015

Table 1. Characteristics of Combined Diet and Physical Activity Promotion Programs

Characteristic, by Category	Value
Median sessions (66 programs) (IQI; range), *n*	
Core	10 (6–16; 0*–72)
Maintenance†	6 (1.5–12; 0*–24)
Total	15 (6.5–24.5; 0*–72)
Median program duration (66 programs) (IQI; range), *mo*	
Core	6 (5–12; 1–60)
Maintenance†	12 (7–18; 4–68)
Total	12 (10–27; 3–72)
Program design (66 programs), *n* (%)‡	
Nominally based on DPP or DPS	27 (41)
Weight-loss goal (66 programs), *n* (%)‡	42 (64)
Diet intervention (66 programs), *n* (%)‡	
Individual sessions	40 (61)
Group sessions	41 (62)
Individual and group sessions	24 (36)
Individually tailored diet plan	16 (24)
Diet goal	19 (29)
Diet counselor	29 (44)
Physical activity intervention (67 programs), *n* (%)‡	
Individual sessions	41 (62)
Group sessions	39 (59)
Individual and group sessions	24 (36)
Individually tailored exercise plan	23 (35)
Exercise goal	32 (48)
Exercise counselor	18 (27)
Counselors (51 programs), *n* (%)‡	
Dietitian	37 (73)
Exercise therapist	26 (51)
Nurse	15 (29)
Layperson	13 (25)
Physician	8 (16)
Diabetes educator	3 (6)
Country (53 studies), *n* (%)	
United States/Canada	22 (42)
Western Europe/Australia	22 (42)
Japan	3 (6)
Middle-income§	6 (11)
Setting (41 studies), *n* (%)	
Community	12 (29)
Health care system	25 (61)
Worksite	0 (0)
Multiple	4 (10)
Location (53 studies), *n* (%)	
Urban	25 (47)
Regional	21 (40)
Suburban	2 (4)
Rural	1 (2)
Mixed	4 (8)

DPP = Diabetes Prevention Program; DPS = Diabetes Prevention Study; IQI = interquartile interval.
* In some programs, the contacts were by telephone, e-mail, Internet, or video only.
† 28 programs.
‡ Probably underestimated because of inadequate or unclear reporting in articles.
§ India (n = 3), Brazil (n = 1), China (n = 1), and Pakistan (n = 1).

Pharmacotherapy for Obesity

Question: How should pharmacotherapy for obesity be addressed in the Prioritized List?

Question source: HERC staff, biennial review topic

Issue: Pharmacotherapy for obesity is not in the funded region of the Prioritized List, as stated explicitly in Guideline Note 5. There have been requests to review the efficacy of pharmacologic therapies for obesity and reconsider placement on the Prioritized List. The Obesity Task Force Phase 1 met 3/3/16 and 3/17/16 and reviewed pharmacotherapy.

Prioritized List Status

Line: 325

Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes 5,64,65)

Treatment: INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS

ICD-10: E66.01-E66.9,Z68.30-Z68.45,Z68.54

CPT: 96150-96154,97802-97804,98966-98969,99051,99060,99070,99078,99201-99215,99281-99285,99341-99355, 99358-99378,99381-99404,99408-99416,99429-99449,99487-99498

HCPCS: G0396,G0397,G0447,G0463,G0466,G0467,G0473

Line: 589

Condition: OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95 PERCENTILE) (See Guideline Notes 8,64,65)

Treatment: NON-INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS;
BARIATRIC SURGERY FOR OBESITY WITH A SIGNIFICANT COMORBIDITY OTHER THAN TYPE II DIABETES & BMI >=35 OR BMI>=40 WITHOUT A SIGNIFICANT COMORBIDITY

ICD-10: E66.01-E66.9,Z68.30-Z68.45,Z68.54,Z71.3

CPT: 43644,43645,43770-43775,43846-43848,98966-98969,99051,99060,99070,99078,99201-99215,99281-99285,
99341-99355,99358-99378,99381-99404,99408-99416,99429-99449,99487-99498,99605-99607

HCPCS: G0396,G0397,G0447,G0463,G0466,G0467,G0473

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 325

Medical treatment of overweight (with known cardiovascular risk factors) and obesity is limited to accepted intensive counseling on nutrition and physical activity, provided by health care professionals. Intensive counseling is defined as face-to-face contact more than monthly. Visits are not to exceed more than once per week. Intensive counseling visits (once every 1-2 weeks) are included on this line for 6 months. Intensive counseling visits may continue for longer than 6 months as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention. Maintenance visits are included on this line no more than monthly after this intensive counseling period.

Pharmacotherapy for Obesity

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome. **Pharmacological treatments are not intended to be included as services on this line.**

Evidence summary

*Cochrane, **2003***

a. Systematic review of RCTs
b. Sixteen orlistat (n = 10,631), 10 sibutramine (n = 2623) and four rimonabant trials (n = 6365) met inclusion criteria.
c. Attrition rates averaged 30% to 40%.
d. Compared to placebo
    a. orlistat reduced weight by 2.9 kg (95% confidence interval (CI) 2.5 to 3.2 kg)
    b. sibutramine by 4.2 kg (95% CI 3.6 to 4.7 kg)
    c. rimonabant by 4.7 kg (95% CI 4.1 to 5.3 kg).
e. Patients on active drug therapy were significantly more likely to achieve 5% and 10% weight loss thresholds.
f. Orlistat reduced diabetes incidence, improved total cholesterol, LDL-cholesterol, blood pressure, and glycaemic control in patients with diabetes but increased rates of gastrointestinal side effects and slightly lowered HDL levels.
g. Sibutramine improved HDL and triglyceride levels but raised blood pressure and pulse rate.
h. Rimonabant improved HDL-cholesterol, triglyceride and blood pressure levels and glycaemic control in patients with diabetes but increased the risk of mood disorders.
i. Conclusions: All three antiobesity agents are modestly effective in reducing weight and have differing effects on cardiovascular risk and adverse effects profiles. Longer and more methodologically rigorous studies of anti-obesity drugs that are powered to examine endpoints such as mortality and cardiovascular morbidity are required.

Staff notes:

Sibutramine was withdrawn from the market
Rimonabant was withdrawn from the market

Yanovski, 2014

a. JAMA Systematic review
b. Methods
    i. Limited to meta-analyses, systematic reviews, and randomized, placebo-controlled trials for currently-approved obesity medications
    ii. Studies ≥1y, that had a primary or secondary outcome of body weight, included ≥50 participants per group, reported ≥50% retention, and reported results on an intention-to-treat basis.
c. Results—Obesity medications approved for long-term use, when prescribed with lifestyle interventions, produce additional weight loss relative to placebo ranging from:

i. Orlistat – 3%
ii. Larcaserin – 3%
iii. Phentermine/topiramate- ER high dose results in 9% at 1y.

Proportion of patients achieving clinically-meaningful (≥5%) weight loss ranges from:

i. 35–73% for orlistat
ii. 37–47% for lorcaserin
iii. 67–70% for top-dose phentermine/ topiramate-ER.
iv. No long term outcomes on morbidity or mortality exist, however, all 3 improve many cardiometabolic risk factors

d. Conclusions/Relevance—Medications approved for long-term obesity treatment, when used as an adjunct to lifestyle intervention, lead to greater mean weight loss and an increased likelihood of achieving clinically-meaningful 1-year weight loss relative to placebo.
e. By discontinuing medication in patients who do not respond with weight loss ≥5%, clinicians can decrease their patients' exposure to the risks and costs of drug treatment when there is little prospect of long-term benefit.
f. No obesity medication has been shown to reduce cardiovascular morbidity or mortality.

Oregon State Drug Review, November, 2015

a. Performed by Pharmacy and Therapeutics Committee pharmacist
b. Reviewed history with multiple weight loss drugs being pulled off market due to dangerous adverse effects
c. Reviewed guidelines that do not support pharmacotherapy over surgery
d. Reviewed FDA approved drugs
    a. Lorcaserin (Belviq)
        i. 3 RCTs, 1 year duration, (n=6139), found modest reduction in body weight compared to placebo (-4.5 to -5.8% vs. -1.5 to -2.8%, p<0.001).
        ii. Harms: adverse psychiatric effects
    b. Phentermine/Topiramate (Qsymia)
        i. 2 placebo controlled trials, 56-weeks, demonstrated a moderate reduction in body weight with both the high (15/92 mg) and low (7.5/46 mg) doses as compared to placebo (-10.9% and -5.1%, respectively vs. -1.6%, p<0.0001 for all comparisons
        ii. Adverse effects include increased heart rate and paresthesias
    c. Naltrexone/buproprion (Contrave)
        i. 4 RCTS, 56-weeks, (n=4468). Weight loss compared to placebo (-5.0 to -9.3% vs. -1.2 to -5.1%).12-15 The proportion of patients who lost more than 5% and 10% of body weight with naltrexone/bupropion was significantly higher than with placebo (52% and 28%, respectively, vs. 24% and 10% with placebo)
        ii. One study found improvement in diabetes. Patients with T2DM and found a higher percentage of patients who took

naltrexone/bupropion achieved an A1C of less than 7% compared with placebo (44.1% vs. 26.3%; p<0.001).

iii. Another study = Light Study was to asseess the impact of naltrexone/bupropion on cardiovascular events, and was halted early, with high CVD events in treatment arm

iv. Harms

1. Can increase heart rate and blood pressure
2. 30% of patients discontinue due to adverse effects
3. Has neuropsychiatric warnings

d. Liraglutide (Saxenda)

i. 3 trials (n=4999) demonstrated statistically significant weight loss compared to placebo or orlistat (-6 to -8% vs. -2.4 to -2.9%, respectively).1 The proportion of patients who lost more than 5% and 10% of body weight with liraglutide was significantly higher than with placebo or orlistat (63-73% and 26-27% respectively with liraglutide, vs. 27-28% and 6-11% with placebo and 44% and 14% with orlistat).

ii. Liraglutide delayed the diagnosis of T2DM in nondiabetics and reduced the onset of pre-diabetes versus placebo at week 56 (30.8% vs. 67.3%; p<0.001).

iii. Adverse events were reported in 80-96% of patients in clinical trials and between 8-10% of patients stopped the medication early due to an adverse event

iv. Black box warning about thyroid tumors

e. Guideline groups recommend bariatric surgery over pharmacologic agents.

f. Conclusions: No weight loss drugs have demonstrated a reduction in obesity-related comorbidities, such as cardiovascular events, nor have they been shown to improve daily functioning, symptom-relief, or quality of life. Many have adverse effects and safety warnings.

<u>Guidelines from others</u>

Apovian, 2015

a. Endocrine Society Clinical Practice Guideline

b. Methods: An Endocrine Society-appointed Task Force of experts, a methodologist, and a medical writer. This guideline was co-sponsored by the European Society of Endocrinology and The Obesity Society. Used GRADE system.

c. Summary of Recommendations

1.0 Care of the patient who is overweight or obese

1.1 We recommend that diet, exercise, and behavioral modification be included in all obesity management approaches for body mass index (BMI)_25 kg/m2 and that other tools such as pharmacotherapy (BMI _ 27 kg/m2 with comorbidity or BMI over 30 kg/m2) and bariatric surgery (BMI _ 35 kg/m2 with comorbidity or BMI over 40 kg/m2) be used as adjuncts to behavioral modificationto reduce food intake and increase physical activity when this is possible. Drugs may amplify adherence to behavior change and may improve physical functioning such that increased physical

activity is easier in those who cannot exercise initially. Patients who have a history of being unable to successfully lose and maintain weight and who meet label indications are candidates for weight loss medications. (1|QQQQ)

1.2 In order to promote long-term weight maintenance, we suggest the use of approved1 weight loss medication (over no pharmacological therapy) to ameliorate comorbidities and amplify adherence to behavior changes, which may improve physical functioning and allow for greater physical activity in individuals with a BMI _ 30 kg/m2 or in individuals with a BMI of _ 27 kg/m2 and at least one associated comorbid medical condition such as hypertension, dyslipidemia, type 2 diabetes (T2DM), and obstructive sleep apnea. (2|QQEE)

1.3 In patients with uncontrolled hypertension or a history of heart disease, we recommend against using the sympathomimetic agents phentermine and diethylpropion. (1|QQQE)

1.4 We suggest assessment of efficacy and safety at least monthly for the first 3 months, then at least every 3 months in all patients prescribed weight loss medications. (2|QQEE)

1.5 If a patient's response to a weight loss medication is deemed effective (weight loss _ 5% of body weight at 3 mo) and safe, we recommend that the medication be continued. If deemed ineffective (weight loss _ 5% at 3 mo) or if there are safety or tolerability issues at any time, we recommend that the medication be discontinued and alternative medications or referral for alternative treatment approaches be considered. (1|QQQQ)

1.6 If medication for chronic obesity management is prescribed as adjunctive therapy to comprehensive lifestyle intervention, we suggest initiating therapy with dose escalation based on efficacy and tolerability to the recommended dose and not exceeding the upper approved dose boundaries. (2|QQEE)

1.7 In patients with T2DM who are overweight or obese, we suggest the use of antidiabetic medications that have additional actions to promote weight loss (such as glucagon-like peptide-1 [GLP-1] analogs or sodium-glucose-linked transporter-2 [SGLT-2] inhibitors), in addition to the first-line agent for T2DM and obesity, metformin. (2|QQQE)

1.8 In patients with cardiovascular disease who seek pharmacological treatment for weight loss, we suggest using using medications that are not sympathomimetics such as lorcaserin and/or orlistat. (2|QEEE)

- *Endocrine Society Pediatric Clinical Guideline*
- Recommendations:
  We suggest that pharmacotherapy (in combination with lifestyle modification) be considered in:
  1) obese children only after failure of a formal program of intensive lifestyle modification; and
  2) overweight children only if severe comorbidities persist despite intensive lifestyle modification, particularly in children with a strong family history of type 2 diabetes or premature cardiovascular disease.
- In general, children with a BMI below the 95th percentile should not be treated with antiobesity drugs.
- Pharmacotherapy should be provided only by clinicians who are experienced in the use of antiobesity agents and aware of the potential for adverse reactions.
- We suggest bariatric surgery for adolescents with BMI above 50 kg/m2, or BMI above 40 kg/m2 with severe comorbidities in whom lifestyle modifications and/or pharmacotherapy have failed.

American College of Cardiology/American Heart Association/Obesity Society 2013 Guideline
http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437739.71477.ee.full.pdf+html

- Convened by NHLBI
- Used evidence-based process
- Endorsed by many other specialty societies
- Recommendations: "May consider" adjunct therapy such as pharmacotherapy, based on expert opinion
- Patients who are otherwise appropriate candidates for obesity drug treatment or bariatric surgery, whose weight and lifestyle history indicates a history of being unable to lose weight or sustain weight loss and who have previously participated in a comprehensive lifestyle intervention, may be offered the option to add pharmacotherapy at the time of initiation of a lifestyle intervention program (BMI ≥30 or ≥27 with comorbidity) or to be referred for evaluation for bariatric surgery (BMI ≥40 or BMI ≥35 with comorbidity) (expert opinion).

Canadian Task Force on Preventive Health Care
Obesity in Adults, 2015

- For adults who are overweight or obese, we recommend that practitioners not routinely offer pharmacologic interventions (orlistat or metformin) aimed at weight loss[v].

(*Weak recommendation; moderate quality evidence*)

- For children and youth aged 2 to 11 years who are overweight or obese, we recommend that primary care practitioners not offer Orlistat aimed at healthy weight management.

(*Strong recommendation; very low quality evidence*)

- For children and youth aged 12 to 17 years who are overweight or obese, we recommend that primary care practitioners not routinely offer Orlistat aimed at healthy weight management.

(*Weak recommendation; moderate quality evidence*)

NICE, 2014
NICE Guidelines, CG 189: Obesity identification, assessment, and management
http://www.nice.org.uk/guidance/cg189/chapter/1-recommendations#pharmacological-interventions

1.8 Pharmacological interventions
Adults
1.8.1
Consider pharmacological treatment only after dietary, exercise and behavioural approaches have been started and evaluated. **[2006]**
1.8.2
Consider drug treatment for people who have not reached their target weight loss or have reached a plateau on dietary, activity and behavioural changes. **[2006]**
1.8.3
Make the decision to start drug treatments after discussing the potential benefits and limitations with the person, including the mode of action, adverse effects and monitoring requirements, and the potential impact on the person's motivation. Make arrangements for appropriate healthcare professionals to offer information, support and counselling on additional diet, physical activity and behavioural strategies when drug treatment is prescribed. Provide information on patient support programmes. **[2006, amended 2014]**
Children
1.8.4
Drug treatment is not generally recommended for children younger than 12 years. **[2006]**
1.8.5
In children younger than 12 years, drug treatment may be used only in exceptional circumstances, if severe comorbidities are present. Prescribing should be started and monitored only in specialist paediatric settings. **[2006, amended 2014]**
1.8.6

In children aged 12 years and older, treatment with orlistat[9] is recommended only if physical comorbidities (such as orthopaedic problems or sleep apnoea) or severe psychological comorbidities are present. Treatment should be started in a specialist paediatric setting, by multidisciplinary teams with experience of prescribing in this age group. **[2006, amended 2014]**

1.8.7

Do not give orlistat to children for obesity unless prescribed by a multidisciplinary team with expertise in:

- drug monitoring
- psychological support
- behavioural interventions
- interventions to increase physical activity
- interventions to improve diet. **[2006, amended 2014]**

1.8.8

Drug treatment may be continued in primary care for example with a shared care protocol if local circumstances and/or licensing allow. **[2006, amended 2014]**

1.9 Continued prescribing and withdrawal

Adults and children

1.9.1

Pharmacological treatment may be used to maintain weight loss rather than to continue to lose weight. **[2006]**

1.9.2

If there is concern about micronutrient intake adequacy, a supplement providing the reference nutrient intake for all vitamins and minerals should be considered, particularly for vulnerable groups such as older people (who may be at risk of malnutrition) and young people (who need vitamins and minerals for growth and development). **[2006]**

1.9.3

Offer support to help maintain weight loss to people whose drug treatment is being withdrawn; if they did not reach their target weight, their self-confidence and belief in their ability to make changes may be low. **[2006]**

Adults

1.9.4

Monitor the effect of drug treatment and reinforce lifestyle advice and adherence through regular review. **[2006, amended 2014]**

1.9.5

Consider withdrawing drug treatment in people who have not reached weight loss targets (see recommendation 1.9.8 for details). **[2006]**

1.9.6

Rates of weight loss may be slower in people with type 2 diabetes, so less strict goals than those for people without diabetes may be appropriate. Agree the goals with the person and review them regularly. **[2006]**

1.9.7

Only prescribe orlistat as part of an overall plan for managing obesity in adults who meet one of the following criteria:

- a BMI of 28 kg/m2 or more with associated risk factors
- a BMI of 30 kg/m2 or more. **[2006]**

1.9.8
Continue orlistat therapy beyond 3 months only if the person has lost at least 5% of their initial body weight since starting drug treatment. (See also recommendation 1.9.6 for advice on targets for people with type 2 diabetes.) **[2006]**
1.9.9
Make the decision to use drug treatment for longer than 12 months (usually for weight maintenance) after discussing potential benefits and limitations with the person. **[2006]**
1.9.10
The co-prescribing of orlistat with other drugs aimed at weight reduction is not recommended. **[2006]**
Children
1.9.11
If orlistat[9] is prescribed for children, a 6–12‑month trial is recommended, with regular review to assess effectiveness, adverse effects and adherence. **[2006, amended 2014]**

Cost analysis
Institute for Clinical and Economic Review (ICER), 2015

1) Methods – used primarily good- and fair-quality (RCTs) and prospective comparative cohort studies. Also derived harms from retrospective comparative cohort studies, and case series of >50 patients (which were also used for long-term benefit.
    i. ***Liraglutide (Saxenda®)***
        1. Small net benefit for BMI ≥27 based on 3 studies of liraglutide + lifestyle modification v lifestyle modification alone. High rates of adverse effects (80-96%) but low rates of discontinuation (8-10%). Long term f/u > 2 years unknown.
    ii. ***Lorcaserin (BELVIQ®)***
    Small net health benefit, based on 3 good quality RCTS, reductions in total body weight were modest, ranging from 4.5-5.8% among lorcaserin recipients, compared to a 1.5-2.8% mean decrease among those taking the placebo ($p<0.001$ for lorcaserin vs. placebo in all studies). A single study reported outcomes related to comorbidity status and found 50.4% of lorcaserin patients versus 26.3% of placebo patients achieved a hemoglobin A1c (HbA1c) <7% ($p>0.001$).5 Discontinuation of lorcaserin from drug-related AEs occurred in 4.3-8.6% of patients across studies, and approximately 80% of study participants experienced any AE. Only 1/3 studies reported comorbidity benefit, the others just reported on weight. Long term f/u > 2 years unknown.
    iii. ***Naltrexone/Bupropion (Contrave®)***
    Moderate certainty of small benefit based on 4 RCTS, recipients lost 5.0-9.3% of total body weight after 56 weeks follow-up; patients who received a placebo lost 1.2-5.1% of total body weight. A single RCT reported outcomes related to improvement of comorbidities and found

that 44.1% of patients taking N/B achieved a target HbA1c <7% compared to 26.3% of placebo patients.6 Discontinuation of N/B from adverse effects occurred in 19.5-29.3% of patients receiving standard-dose N/B across studies, and 83.1-90.4% of patients experienced any AE. No studies > 1 year follow up. low certainty for a small net benefit in patients with BMI 30-34.9 and T2DM based on the results of a single RCT in this population.

iv. ***Phentermine/Topiramate (Qsymia®) – moderate certainty of small net benefit based on 8 good/fair reports from 5 RCTs.*** In these trials, patients receiving the recommended dose combination (7.5/46 mg) lost 7.8-8.5% of total body weight (vs. 1-2% for placebo), while the range for those receiving a higher dose (15/92 mg) was 9.2-10.9%. Patients who received any dose of P/T experienced greater improvement in obesity-related comorbidities such as T2DM, hypertension, and sleep apnea. We found no studies that had a patient population with mean BMI <35. Overall, 91-95% of patients experienced one or more AEs, and 1.3-16.0% discontinued P/T due to AEs. No data extended beyond 2 years.

2) Conclusions re: all pharmacologic therapies - benefits are again relatively modest in comparison to conventional weight-loss management. Across all four medications, total weight loss was 3-7% higher than achieved with placebo or active comparator therapy. In addition, there are limited data on resolution or improvement in comorbidities, lack of information on long-term weight trends, high rates of discontinuation in many studies, and not-inconsequential concerns about potential to harm (two of the four are scheduled substances).
    1. Naltrexone/buproprion - >$100,000 per QALY vs. conventional treatment.
3) CTAF panel conclusion that the evidence was inadequate to distinguish the net health benefit among the reviewed drugs.

HERC Staff Assessment

There is insufficient evidence to support significant improvements in health outcomes for pharmacologic treatment of obesity. A number of obesity drugs have been pulled off the market due to adverse effects. Given that outcomes are only minimal to moderate reductions in weight loss, without evidence of long-term significant morbidity or mortality benefits, there are numerous adverse effects and safety concerns associated with these drugs, and that some are quite costly, there is little reason to support coverage of these medications. Guidelines are mixed with some recommending against the use of pharmacotherapy for obesity, and others offering weak support for their use as an adjunctive therapy.

Obesity Task Force Recommendations

Recommend continued noncoverage of pharmacotherapy. There was a proposal to have it be a covered adjunctive treatment, but because of the lack of long-term patient oriented health outcomes, cost, and safety concerns, the group agreed to recommend continued noncoverage.

1) Make no change to the current noncoverage of pharmacotherapy for obesity.

Devices for Obesity

Question: Should a variety of devices be included on the Prioritized List in the treatment of obesity?

Issue: There are a variety of devices newly approved in the treatment of obesity including gastric balloons and vagal nerve blockade devices. There is also a gastrointestinal lining device being evaluated for use in the U.S. These are not currently included on the Prioritized List but also not explicitly excluded as many do not have identifiable procedure codes associated with them.

Device-related codes

Code	Code Description	Placement
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	Services recommended for non-coverage table
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum	Services recommended for non-coverage table
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open	Services recommended for non-coverage table
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open	Services recommended for non-coverage table
43999	Unlisted Procedure, stomach	Not open for payment
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	DMAP Ancillary Codes File
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	290,428
C1767	Generator, neurostimulator (implantable), non-rechargeable	DMAP Ancillary Codes File

ORBERA - no specific code. Likely would use cpt code *43999 Unlisted Procedure, stomach*

ReShape – no specific code. Likely would use cpt code *43999 Unlisted Procedure, stomach*

Maestro – vagal nerve block. *HCPCS C1767 Generator, neurostimulator (implantable), non-rechargeable*

Duodenal jejunal bypass liner (Endobarrier) – unclear

Evidence summary:

Intragastric balloons

MED, 2016

1. Rapid review on intragastric balloons (ORBERA and ReShape)
    a. Limitations of the evidence
        i. Evidence heavily relies on % excess weight loss (EWL) rather than health outcome or other more objective measures of weight loss
        ii. All trials funded by manufacturers with conflicted authors
        iii. Few experimental studies

iv. Study population 90-95% female. Females have higher fat content, so may be less efficacious in men.

b. ORBERA™ and ReShape™, combined with diet and exercise counseling, are effective at weight loss in the short-term, though weight regain following removal was observed.

ORBERA™

i. A systematic review and meta-analysis conducted by the American Society for Gastrointestinal Endoscopy (ASGE) included experimental and observational studies. 82 studies all conducted outside the US, only 3 RCTs for ORBERA, and 2 RCTs for ReShape.
   1. MA: ORBERA™, the mean % total body weight loss (TBWL) at 3, 6, and 12 months was 12.3%, 13.2%, and 11.3%, respectively. At 36 months, %TBWL was reduced to 6.0%. Based on study design, there were no control groups for these analyses. Therefore, the effect of ORBERA™ is likely being overestimated.

ii. ReShape

   1. 2 US RCTs, one N=30, one N = 326.
   2. In the large study, sham endoscopy and diet and exercise counseling compared to ReShape and counseling were found to have statistically significantly greater %EWL at 24-weeks follow-up (25.1% vs. 11.3%, p = 0.004). However, the effect of ReShape™ on %EWL was reduced by 48-weeks follow-up (from 25.1% to 18.8%).

c. Early removal of device in 7-8% of patients (they should be removed at 6 months in all patients normally)

d. Adverse effects include: nausea (29%), vomiting, abdominal pain (34%), distension, constipation, diarrhea, gastric ulceration, and gastroesophageal reflux disease (18%). Serious side effects include migration (1.4%) and gastric perforation (0.1%). 4 deaths were reported either due to gastric perforation or aspiration event. In one study 28/326 had serious side effects, with 75% requiring Emergency Department visits.

ICER, 2015

1. Technology assessment with experts and public input
   a. Included RCTs, comparative cohort studies (prospective and retrospective)
   b. Case series >50 only for harms and long term benefit
2. Temporary intragastric balloon (IGB) insertion was associated with:
   a. Modest benefits at 1 year of f/u relative to conventional approaches
   b. Higher-quality studies showed incremental BMI changes and percentage weight loss of 1-3 points and 4-8%, respectively – and also tended to worsen after balloon removal (typically after six months).
   c. There was great variability in study design, duration of follow-up (particularly after balloon removal), and treatment approach (i.e., single vs. multiple balloon insertions).
3. “Low certainty of a comparable net benefit for temporary IGB insertion relative to either lifestyle intervention or bariatric surgery in patients with a BMI ≥35.”

Devices for Obesity

Duodenal-Jejunal Bypass Liner *(EndoBarrier®)*

ICER, 2015

1. 2 RCTS, 1 good and 1 fair comparing the duodenal-jejunal bypass liner (DJBL) to conventional weight-loss treatment.
2. No difference in reduction of mean BMI between control and DJBL
3. Patients in both studies reduced or discontinued anti-diabetic medications; however, data on comorbidities were not reported for control patients in one study, and statistical testing for differences was not conducted in either study.
4. Complications of the DJBL included device or anchor migration, epigastric pain, and sleeve obstruction; 2.9-20.5% of patients had the device removed prematurely across studies. Finally, enrollment in a large clinical trial of DJBL is currently stopped pending investigation of a higher-than-expected rate of bacterial liver infection.
5. Conclusion: insufficient evidence to low certainty of no benefit (and possible net harm) and significant adverse effects

Vagus Nerve Block *(Maestro®)*

MED, 2016

1. Rapid review of vagus nerve block (Maestro)
2. 1 RCT (ReCharge) with 2 different articles, one with 12 months and the other with 18 month follow up
3. Results: At 12- and 18-months follow-up, the vagal nerve block group, compared to those who received a sham device, had statistically significantly greater percentage total body weight loss (%TBWL) and percentage excess weight loss (%EWL). However, the clinical meaningfulness of these findings is uncertain. For %TBWL, at 12 months, the difference between groups was 3.3% and at 18 months it was 5.0%. The latter finding was a function of differential weight regain among the sham group between 12 and 18 months.
4. Patient oriented health outcomes (dyslipidemia, hypertension, MACE) not examined
5. Limitations of the evidence: mostly female patients, authors with conflicts (although did have independent review board), single trial
6. Adverse effects: 8.6% experienced a serious adverse event compared to 0.0% in the sham group. Frequent adverse events included pain at the neuroregulator site, heartburn/indigestion, abdominal and other pain, nausea, dysphagia (i.e. difficulty or discomfort with swallowing), and eructation (i.e. belching).

ICER, 2015

1. 2 RCTs. One with earlier version no longer on the market.
2. After 12 months follow-up in each study, vBloc patients lost 17-24.4% of excess body weight versus 15.9-16.0% excess weight loss (EWL) in control patients.
3. No comorbidity outcomes reported
4. “Low certainty of a small or comparable net benefit for the vBloc device compared to a sham device in patients with a BMI ≥35.”

Devices for Obesity

Commercial payers:

Aetna, 2015

1. Considers these procedures experimental and investigational because the peer-reviewed medical literature shows them to be either unsafe or inadequately studied:
    a. Gastric balloon
    b. Vagus nerve blocking (e.g., vBloc therapy provided by the Maestro Rechargeable System)
    c. Gastrointestinal liners (EndoBarrier)

Cigna, 2015

1. Cigna does not cover the following bariatric surgery procedures for the treatment of morbid obesity, when performed alone or in conjunction with another bariatric surgery procedure, because each is considered experimental, investigational or unproven (this list may not be all-inclusive):
    a. Intragastric balloon
    b. Duodenojejunal bypass liner (e.g., Endobarrier™)
    c. Vagus nerve blocking (e.g., Maestro®)

HERC Staff Assessment:

The devices for obesity reviewed here: gastric balloons ORBERA and ReShape, the vagus nerve stimulator (Maestro), and the duodenal jejunal bypass liner (Endobarrier), have insufficient evidence demonstrating long term health outcomes and have high adverse event rates. None of these are recommended for inclusion on the Prioritized List.

Similarly, two prominent commercial insurers do not cover any of these interventions because they are considered experimental. There are not distinct CPT or HCPCS codes for many of these devices, making addition to the Services Recommended for Non-Coverage table logistically difficult.

HERC Staff Recommendations:

1. Add an entry to the Services Recommended for Non-Coverage table for these devices, even though there are no specific codes for many of them.
2. Add language to Guideline Note 5 making it clear that these devices are not included on the funded obesity line.

> **GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT**
>
> *Line 325*
>
> Medical treatment of overweight (with known cardiovascular risk factors) and obesity is limited to accepted intensive counseling on nutrition and physical activity, provided by health care professionals. Intensive counseling is defined as face-to-face contact more than monthly. Visits are not to exceed more than once per week. Intensive counseling visits (once every 1-2 weeks) are included

on this line for 6 months. Intensive counseling visits may continue for longer than 6 months as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention. Maintenance visits are included on this line no more than monthly after this intensive counseling period.

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome.

Pharmacological treatments and devices (e.g. gastric balloons, duodenal jejunal bypass liners, and vagus nerve blocking devices) for obesity are not intended to be included as services on this line or any other line on the Prioritized List.

Multisector Intervention Statement for Obesity

Question: How should the multisector intervention report on obesity be applied to the Prioritized List?

Question Source: Obesity Task Force, HERC Staff

Issue: The obesity task force looked at reviews published in the last five years based on the following scope statement:

Population description	Overweight and obese patients, including adults, children, and adolescents *Population scoping notes: Includes interventions targeted at parents, pregnant women, and others that impact outcomes in children*
Intervention(s)	Multisector interventions such as community interventions, policy, systems, and environmental change *Intervention exclusions: None*
Comparator(s)	No care, usual care, other studied interventions
Outcome(s) (up to five)	Critical: Morbidity, all-cause mortality Important: Weight loss, remission/prevention of diabetes, remission of hypertension *Considered but not selected for GRADE Table: None*
Key questions	1. What interventions are most effective and most cost-effective at achieving weight loss and improving patient outcomes? 2. Does effectiveness vary by socioeconomic factors such as race, ethnicity, income, and educational attainment? 3. What models of care would allow these interventions to be implemented most effectively and cost-effectively?

Summary

The Obesity Task Force Phase 2 reviewed a scope statement to approach multisector interventions for the prevention and treatment of obesity. The OHSU Center for Evidence-based Policy performed a literature search, limited to English-language systematic reviews

published in the last 4 years. They were further limited to the most recent reviews, unless conclusions were divergent. Sixteen systematic reviews were included in the evidence summary. The obesity task force discussed the limitations of the literature, including a lack of data on the critical and some important outcomes, and the need to consider impact on physical activity and improved nutrition instead of only on BMI indices, which are flawed. They also assisted with identifying the policy landscape as well. Ultimately the Obesity Task Force created a summary document of the literature identified. *See the Obesity Task Force Phase 2 summary document.* The proposed Multisector Intervention Statement on the Prevention and Treatment of Obesity lists those interventions for which there is at least limited evidence to support their effectiveness.

The following have insufficient evidence to demonstrate effectiveness to impact obesity:

Intervention	**Outcome**
Changes in food voucher policy (changes in WIC benefits and allowing purchase of food from farmer's market using SNAP benefits, among low-income immigrants) (Mayne et al., 2015)	Evidence shows no association with reduced BMI, but does show an association with increased purchase, presence in home/home availability, and consumption of healthy foods.
Interventions to increase use of stairs (signs, stairwell improvements) (Bellicha et al., 2014)	Limited evidence shows a modest effect on stair use; weight-related outcomes not reported.
Community-based, multicomponent physical activity interventions (e.g., fitness classes and programs, interactive group sessions, walking groups, counseling, social support, health promotion materials, and/or media campaigns) targeting women 18-65 years old	Evidence support for enhanced physical activity outcomes but not for weight-related outcomes
Financial incentives to change health habits in terms of physical activity and healthy eating	Mixed evidence that incentives increase physical activity or healthy eating at up to 12 months while incentives remain in place
Interventions to modify diet, physical activity, sedentary behaviors, or a combination that target children age 2-18 in their homes or include significant family involvement	Inconclusive evidence on BMI; some studies showed significant improvements in diet or physical activity

<u>HERC Staff recommendations:</u>

Add a Multisector Intervention statement on Obesity to the Prioritized List

MULTISECTOR INTERVENTIONS: PREVENTION AND TREATMENT OF OBESITY

Limited evidence supports the following interventions:

School and childcare settings

- School based interventions to reduce BMI (especially with physical activity focus)
- School nutrition policy and day care meal standards
- Family-based group education programs delivered in schools
- Obesity prevention interventions in childcare settings (nutrition education, healthy cooking classes for 2-6 year olds, physical activity and playful games)

Community level interventions

- Environmental interventions (social marketing, cafeteria signs, farmers markets, walking groups, etc)
- Introduction of light rail
- Community-based group health education and counseling interventions, workplace education interventions
- Workplace and college interventions to improve physical activity

Multiple settings:

- Interventions to reduce sedentary screen time (in some studies, also to increase physical activity and nutrition).
- Multicomponent individual mentored health promotion programs to prevent childhood obesity
- Parental support interventions for diet and physical activity (group education, mental health counseling)

Policy changes

- Sugar sweetened beverage taxes
- Elimination of tax subsidy for advertising unhealthy food to children

This Multisector Interventions statement is based on the work of the HERC Obesity Task Force and the full summary of the evidence report is available here: WEBSITE

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

MULTISECTOR INTERVENTIONS FOR THE PREVENTION AND TREATMENT OF OBESITY

For HERC/VbBS meeting materials 10/6/2016

Table of Contents

The interventions listed in the Evidence Summary Table are reviewed in the evidence summary below and are recommended by a major organization with expertise in public health. The Related Recommendations column lists these organizations' recommendations by number (the Policy Landscape section provides more detail on these recommendations). The HERC does not recommend for or against these interventions because the interventions, populations, and settings described here are heterogeneous and may not be suitable for all situations. ID letters are provided for easy reference and do not denote priority.

Note: The HERC's evidence assessment is based on a search conducted in February 2016 of recent systematic reviews (published since 2012). Studies that did not report on weight or body mass index outcomes or were not reviewed in a systematic review published during this time period were not included. More detail on the methodology can be found in Appendix A.

EVIDENCE SUMMARY TABLE

ID	Intervention (with reference)	Type of Intervention & Setting	Evidence Assessment *(Cost-effectiveness findings in italics)*	Related Recommendations*
A	Sugar-sweetened beverage taxes (Cabrera Escobar et al., 2013; Long et al., 2015; Gortmaker et al., 2015)	Public policy U.S., Mexico, France, Brazil	Limited/mixed evidence supports; reduced beverage demand and consumption but effects on weight outcomes are modest *Modeling studies estimate this to be cost-saving*	IOM (Accelerating Progress...) #2 CDC #9 WHO #1 White House #4.9
B	Elimination of tax subsidy for advertising unhealthy food to children (Gortmaker et al., 2015)	Public policy U.S.	*Modeling studies estimate this to be cost saving*	IOM (Accelerating Progress...) #2,5 IOM (Children) #4 WHO #1,5 White House set #1

ID	Intervention (with reference)	Type of Intervention & Setting	Evidence Assessment *(Cost-effectiveness findings in italics)*	Related Recommendations*
C	Changes in food voucher policy (changes in WIC benefits and allowing purchase of food from farmer's market using SNAP benefits, among low-income immigrants) (Mayne et al., 2015)	Public policy U.S. national, U.S. city	Evidence shows no association with reduced BMI, but does show an association with increased purchase, presence in home/home availability, and consumption of healthy foods.	IOM (Accelerating Progress...) #2,3 IOM (Children) #4 ASTHO #2 WHO #1 White House #4.8
D	Environmental interventions (social marketing encouraging stairway signs, cafeteria signs, farmers markets, walking groups, etc.). (Hillier-Brown et al., 2014a)	Community programs, Environmental change Hospital worksite	Limited/mixed evidence supports; showed positive results only among higher-educated participants	IOM (Accelerating Progress...) #1,2,4 White House #3.6
E	Interventions to increase use of stairs (signs, stairwell improvements) (Bellicha et al., 2014)	Environmental change Worksite, public setting (e.g., malls, airports)	Limited evidence shows a modest effect on stair use; weight-related outcomes not reported.	IOM (Accelerating Progress...) #1,2,4

ID	Intervention (with reference)	Type of Intervention & Setting	Evidence Assessment *(Cost-effectiveness findings in italics)*	Related Recommendations*
F	School-based interventions to reduce BMI (programmatic, educational, and environmental programs to influence diet and physical activity). (Lavelle et al., 2012) School-based physical activity interventions (Sun et al., 2013)	Community Programs, Environmental change School	Evidence supports, especially those with a physical activity component. Stratification shows greater effect in girls. Programs targeting overweight/obese participants showed larger effect.	IOM (Accelerating Progress...) #1,5 IOM (Children) #3,4 CDC #12,13,14 WHO #2,5 White House #3.16,5
G	Parental support interventions for diet and physical activity (group education, mental health counseling) (Kader et al., 2015)	Community programs School/preschool, clinic/health care, other community setting	Evidence shows improvement in weight-related outcomes (i.e., dietary habits, physical activity, BMI/BMI Z-score), but not those that provide written information only.	IOM (Accelerating Progress...) #1 IOM (Children) #3,4 WHO #2,4
H	Community-based, multicomponent physical activity interventions (e.g., fitness classes and programs, interactive group sessions, walking groups, counseling, social support, health promotion materials, and/or media campaigns) targeting women 18-65 years old	Community programs Community settings (e.g., fitness facility, school)	Evidence support for enhanced physical activity outcomes but not for weight-related outcomes	IOM (Accelerating Progress...) #1,4

ID	Intervention (with reference)	Type of Intervention & Setting	Evidence Assessment *(Cost-effectiveness findings in italics)*	Related Recommendations*
I	School nutrition policy and day care meal standards (Mayne et al., 2015; Gortmaker et al., 2015)	Public policy School, day care (Chile national)	Evidence supports improvement in weight-related outcomes but results were not sustained at 24 months. *Modeling studies estimate nutrition standards for food and beverages sold in schools outside of meals to be cost-effective. Modeling studies suggest nutrition standards for school meals to be cost effective.*	IOM (Accelerating Progress...) #2,3,5 IOM (Children) #4 CDC #1,2,7,8,9,10 ASTHO #2 WHO #1,5 White House #3
J	Introduction of light rail (Mayne et. al., 2015)	Environmental change Public transit	Limited evidence supports light rail use association with improvement in self-reported BMI	IOM (Accelerating Progress...) #1 ASTHO #2
K	Obesity prevention interventions in childcare settings (nutrition education, healthy cooking classes, physical activity and playful games) (Zhou et al., 2014; Gortmaker et al., 2015)	Community program Childcare centers	Limited/mixed evidence supports *Modeling studies estimate that improved early childhood education policies and practices, including the Nutrition and Physical Activity Self-Assessment for Child Care (NAP SACC) program are cost-effective.*	IOM (Accelerating Progress...) #1 IOM (Children) #3,4 CDC #12,13,14 WHO #2,4

ID	Intervention (with reference)	Type of Intervention & Setting	Evidence Assessment *(Cost-effectiveness findings in italics)*	Related Recommendations*
L	Community-based group health education and counseling interventions, workplace education interventions, family-based group education programs delivered in schools (Hillier-Brown et al., 2014a)	Community program Community settings (e.g., community centers, workplaces, diet/health clubs)	Limited/mixed evidence supports. Community-based education/counseling showed modest, short-term reductions in BMI	CPSTF #2 IOM (Accelerating Progress...) #1,4 IOM (Children) #3,4 ASTHO #2 WHO #2,5,6
M	Workplace and college interventions to improve physical activity (Gudzune et al., 2013, Malik et al., 2014)	Community program, environmental change Workplace, college	Limited/mixed evidence supports increased physical activity, change in weight, BMI, and/or waist circumference	CPSTF #2 IOM (Accelerating Progress...) #1,4 ASTHO #2 WHO #2
N	Financial incentives to change health habits in terms of physical activity and healthy eating (Mantzarei et al., 2015)	Community Program Workplaces, communities, health care settings	Mixed evidence that incentives increase physical activity or healthy eating at up to 12 months while incentives remain in place	IOM (Accelerating Progress...) #4 ASTHO #3

ID	Intervention (with reference)	Type of Intervention & Setting	Evidence Assessment *(Cost-effectiveness findings in italics)*	Related Recommendations*
O	Interventions to reduce sedentary screen time (in some studies, also to increase physical activity and nutrition). (Ramsey Buchanan et al., 2016; Hillier-Brown et al., 2014b)	Community programs, environmental change School, home, community settings, health care settings, academic settings	Evidence supports BMI reduction, particularly among children and in individual settings. (Greater effectiveness with children, lower income participants, higher intensity interventions including electronic monitoring and control).	CPSTF #1 IOM (Accelerating Progress...) #1,5 IOM (Children) #3, #5 CDC #15 WHO #2,4 White House #1.8-1.11
P	Multicomponent group and individual mentored health promotion programs (e.g., physical activity and/or nutrition classes/programs, health education and promotion materials, counseling, therapy, and/or changes to built environment) to prevent childhood obesity (Hillier-Brown et al., 2014b)	Individual, Community programs, environmental change Home, health care settings, academic settings, school, other community sites (e.g., park, convenience store, community center)	Evidence supports for individual programs; inconclusive/mixed evidence for group and societal	IOM (Accelerating Progress...) #1 IOM (Children) #3,4 WHO #2,4

ID	Intervention (with reference)	Type of Intervention & Setting	Evidence Assessment *(Cost-effectiveness findings in italics)*	Related Recommendations*
Q	Interventions to modify diet, physical activity, sedentary behaviors, or a combination that target children age 2-18 in their homes or include significant family involvement (Showell et al., 2013)	Individual, community program, environmental change Home (mostly), school, health care setting, community setting	Inconclusive evidence on BMI; some studies showed significant improvements in diet or physical activity	IOM (Accelerating Progress...) #1,3 IOM (Children) #3,4 WHO #2

*Recommendations referenced are from the Policy Landscape section of this document.

PURPOSE

This document was developed to inform staff recommendations for inclusion of multisector interventions to prevent and manage obesity on Oregon's Prioritized List of Health Services. The Health Evidence Review Commission (HERC) requested that staff members conduct research on available interventions to address obesity, including interventions outside of traditional health care systems.

Increasingly, public and private health care payers, including HERC, recognize that in order to achieve their goals to improve patient experience of care, population health, and the cost-effectiveness of health care, they must consider evidence-based multisector interventions along with individually focused clinical care. In so doing, they can maximize health and economic outcomes.

Multisector interventions such as the ones described here can be cost-effective ways to prevent, treat or manage disease at a population level. This report was prepared in consultation with the Obesity Task Force members (See Appendix B), who served as subject matter experts from a variety of related disciplines.

These interventions will directly inform the Prioritized List and are intended to aid coordinated care organizations as they seek to effectively address obesity, and we hope that they will be useful to private health plans and policymakers interested in using the tools at their disposal to prevent and reduce obesity.

BACKGROUND

Today, more than one in four adults in Oregon are obese, which equates to over 800,000 people. In addition, 15% of Oregon's six- to nine-year-olds were obese in 2012. Children who are obese are more likely to become obese adults, putting them at a greater risk of chronic disease.

Obesity can lead to diabetes, cancer, high blood pressure, high cholesterol, arthritis, heart disease, and stroke, taking a toll on families and the health care system. In Oregon, obesity contributes to 1,500 deaths per year. It is second only to tobacco as a leading cause of preventable death. In 2009 nearly 73% of adult Oregonians with a history of heart attacks were overweight or obese.

According to a 2012 report from the Institute of Medicine, national costs attributed to treating obesity-related diseases are estimated to be $190 billion, which represents 21% of all health care spending. Obesity-related chronic diseases cost Oregonians about $1.6 billion in medical expenses each year, with $339 million of that paid by Medicare and $333 million paid by Medicaid. People who are obese are estimated to have annual medical costs that are $1,429 higher than people who are not obese.

Clinical strategies to prevent and treat obesity include screening, behavioral counseling, medications, referral to weight-loss programs, and surgery. Many of these have limited efficacy and primarily focus on treatment, rather than prevention of obesity. Given the widespread prevalence of obesity and its significant impact on morbidity, mortality, and societal costs, it is important to understand the range of effective interventions that can occur inside and outside of a clinical setting. Preventing obesity is likely to be the most cost-effective strategy, and solutions in the community setting have the potential to affect a large number of people. This report on multisector interventions for obesity examines

interventions for the prevention and treatment of obesity that occur in community settings, which can be policies, programs, or environmental changes.

EVIDENCE REVIEW

General Multisector Interventions

Mayne et al., 2015

This is a narrative systematic review of natural or quasi-experimental studies conducted to examine the effects of policy and built environment changes on obesity outcomes. The authors identified 37 studies, but only three of these studies measured weight or body mass index (BMI) outcomes (the remaining studies only examined changes in dietary composition or physical activity). One study of school nutrition policy and day care meal standards involving almost 68,000 children in Chile found mixed results for the outcomes of BMI z-score and obesity prevalence, and the initial improvements were not sustained at 24 months. The second study examined the effects of changes in food voucher policy among 72,000 low-income immigrant adults in the United States and found no association between the policy change and BMI. The third study measuring weight- or BMI-related outcomes, which was designed as a longitudinal within-person study of the effects of a new light rail system in Charlotte, North Carolina, found that use of the light rail system was associated with a self-reported BMI reduction of 1.18 kg/m2 (95% CI -2.22 to -0.13) and reduced the odds of incident obesity. The authors did note that weaker study designs are more likely to report positive findings.

Two additional studies, which assessed the association between nutrition and changes in food voucher policy, considered non-weight outcomes. One of these studies found an increase in home availability and consumption of healthy foods associated with changing food voucher-eligible foods among Hispanic and African American mothers and children enrolled in Women, Infants, and Children (WIC). The other study found an increase in the purchase of healthy foods associated with local changes to vendor payment systems (i.e., permitting farmers markets to accept food vouchers).

Bottom line: There is limited evidence from a study in one community that the use of a new light rail system was associated with a small reduction in self-reported BMI and incident obesity. The results of nutritional policy interventions were mixed.

Amiri Farahani et al., 2015

This is a narrative systematic review of community-based physical activity interventions targeting women ages 18 to 65 years old. The authors identified nine studies including four methodologically rigorous randomized controlled trials (RCTs). Most of the studies were conducted in the United States and involved multicomponent interventions to promote physical activity. Most of the interventions involved social support, goal setting, barrier anticipation, and self-monitoring; these were provided in theoretical constructs of social cognitive theory and social marketing theory. One trial involved a combined exercise program for mothers and daughters and one included a free gym membership. Although seven of the nine studies reported positive effects on physical activity, only four studies reported statistically significant improvements. No studies reported on weight or BMI outcomes. The authors concluded that there was “insufficient evidence to assess the effectiveness of community-based interventions for enhancing physical activity among women.”

Bottom line: Several programs found improvements in physical activity, but there is insufficient evidence for the effectiveness of community-based physical activity promotion programs for weight loss in adult women.

Hillier-Brown et al., 2014a

This is a narrative systematic review of interventions applied at various levels to reduce socioeconomic disparities in adult obesity. Interventions were classified as occurring at the individual, community, or societal levels. Five studies at the individual level were included: four examined tailored weight-loss plans delivered via primary care, and the fifth was a long-term study of an educational intervention for obesity prevention. The individually tailored weight-loss plans delivered in primary care appeared to be effective at up to 12 months. Several of the studies showed greater effects among African American participants. At the community level, the authors identified 12 studies: eight examined community-based group health education and counseling interventions, two examined workplace education interventions, and two examined family-based group education programs delivered in schools. Overall, the results of the community-based interventions were mixed; some of the studies of community-based education and counseling programs showed modest reductions in BMI, but only in the short term (3 to 6 months).

At the societal level, the authors identified three studies. The first was an initiative involving environmental strategies to encourage healthful eating and physical activity through "social marketing…stairway signs, cafeteria signs, farmers markets, walking groups, challenges, workshops, educational displays, newsletters, project website, project information centre and print materials." This study showed modest positive results, but only among the higher-educated participants. The other two societal-level studies examined the effects of changes in the structure of nutrition assistance programs for poor women; neither study found significant effects on obesity.

Bottom line: There is some evidence of effectiveness for individual-level interventions (particularly those involving tailored weight-loss plans in primary care) in reducing inequalities in adult obesity, but there was less evidence for the effectiveness of community- and societal-level interventions.

Workplace Interventions

Bellicha et al., 2015

This is a narrative systematic review of studies examining the effectiveness of interventions to promote the use of stairs. Fifty studies, conducted in a mix of workplace and public settings, were included. The primary outcome measure was stair climbing (ascent only) or stair use (ascent and descent combined). The interventions consisted of a mix of motivational and directional signs with or without stairwell enhancements. The study designs were nearly all pre-post comparisons and none were judged to be high quality. Modest improvements in stair climbing (absolute median increase of about 4%) were noted in most studies during the intervention period. The combination of motivational and directional signs appeared to be more effective than motivational signs alone. Three of the four studies of stairwell enhancements showed similar results (absolute median increase in stair climbing of 4.4%) to the motivational and directional signs. The authors noted that elements of external validity (i.e., implementation) were "largely underreported" in the literature. No weight, BMI, or health outcomes were reported.

Bottom line: Motivational and directional signs and stairwell improvements probably lead to modest increases in stair use, but the external validity of these studies remains uncertain.

Malik et al., 2014

This is a narrative systematic review of health promotion interventions in the workplace to increase physical activity. The authors identified 58 studies including exercise interventions (6 studies), counseling and support interventions (13 studies), and informational or health promotion message interventions (39 studies). The primary outcomes were measures of physical activity. The exercise intervention studies were mostly RCTs or cluster randomized trials. Two of the six studies showed statistically significant increases in physical activity (increased step counts in both of the positive studies); the remaining studies did not demonstrate an effect. The counseling and support interventions, which included telephonic counseling and peer support programs, used mostly RCT and quasi-experimental designs, but there were substantial issues with blinding, use of intention-to-treat, baseline group differences, and attrition. Of the 13 studies, 8 showed statistically significant increases in measures of physical activity or total energy expenditure. The informational and health promotion message interventions were diverse and mostly studied using RCT and quasi-experimental designs, but as with other included studies there were methodological flaws in most trials. Of the 39 studies, 22 showed statistically significant increases in physical activity; programs that included stage-of-change matched informational materials were more likely to report significant results. Weight, BMI, and health outcomes were not reported. The authors' conclusion was that the evidence for workplace health promotion interventions was mixed and inconclusive.

Bottom line: Evidence that workplace health promotion interventions lead to increased physical activity is mixed.

Gudzune et al., 2013

This is a narrative systematic review of workplace or college-based interventions to prevent weight gain. The authors identified seven workplace and two college-based studies using randomized, cluster-randomized, or quasi-experimental designs. The age, gender, and other participant characteristics varied by study site. The studied interventions were diverse and included environmental changes, health promotion and informational programs, educational programs (including a 4-month college course on preventing weight gain), supported self-management programs, or some combination of the interventions. Five of the workplace studies and both college-based studies reported BMI outcomes at 12 to 24 months.

At 24 months, one of the workplace studies showed that intervention group participants had a BMI 0.3 kg/m2 lower than the control group. Another showed that the intervention group had a BMI 0.2 kg/m2 higher than the control group at 12 months. Both of these results were statistically significant. Three other studies showed no difference between intervention and control groups.

In both of the college-based programs, the intervention group had a lower BMI at 12 months (-0.5 kg/m2 and -1.6 kg/m2), although only the former result was statistically significant. Overall, the authors deemed the evidence for BMI reduction to be low strength because of issues with bias in the nonrandomized trials and inadequate blinding of outcomes assessors. The authors concluded that there was limited evidence for workplace and college-based interventions to prevent weight gain.

Bottom line: There is mixed evidence that workplace interventions are effective to prevent weight gain. There is limited evidence that college-based interventions are effective.

Sugar-sweetened Beverage Taxes

Cabrera Escobar et al., 2013

This is a systematic review and meta-analysis of the effects of sugar-sweetened beverage (SSB) taxes on SSB demand and obesity. Nine studies, six from the US and one each from Mexico, Brazil, and France were included. The primary outcomes were own-price and cross-price elasticity (measured as the percentage change in quantity demanded), and change in obesity rates or BMI. All studies showed negative own-price elasticity ranging from -0.85 to -4.45 with a meta-analytic estimate of -1.3 (95% CI -1.089 to -1.509). These results suggest that the demand for SSBs is elastic and that SSB price increases are associated with reduced demand. Cross-price elasticities meant to measure the effects of SSB price increases on demand for other beverages were studied in five of the nine studies. The overall estimate is that SSB price increases result in slightly increased demand for fruit juice and milk and slightly lower demand for diet beverages.

Meta-analysis could not be performed for the effect of SSB taxes on obesity and BMI. One study estimated that a 10% increase in SSB price would lead to a reduction in the point prevalence of obesity of -0.34% for men and -0.05% for women. A second study estimated that a 20% increase in the SSB price would reduce the point prevalence of overweight by -0.045% and obesity by -0.03%. A third study estimated that a 20% increase in the price of SSBs would reduce BMI by -0.065 kg/m2. A fourth study reported that 1% grocery soda taxes and soft drink vending machine taxes would increase BMI by 0.012 kg/m2 and 0.011 kg/m2 respectively, although neither result was statistically significant. The fifth study found that a 1% increase in SSB price would produce only small effects on BMI of -0.0031 kg/m2 for adults and -0.015 kg/m2 for children and adolescents. Overall, the authors concluded that SSB taxes or price increases may benefit health.

Bottom line: SSB prices are elastic and SSB taxes can reduce demand, but the estimated effects of SSB price increases on obesity prevalence and BMI are modest.

Long et al., 2015

This is a modeling study of the cost-effectiveness of SSB taxes in the U.S. Key assumptions of the model are 1) an own-price elasticity for SSBs of -1.22, 2) a reduction of SSB consumption of 8 oz/day leads to weight loss of about 1 kg in children, and 3) a reduction of 12 oz/day leads to a BMI change of -0.39 kg/m2 for adults. Health gains were estimated for a 10-year period using a Markov cohort model. The model accounts for downstream changes in a variety of obesity-related illnesses to produce estimates of quality-adjusted life years and disability-adjusted life years. The model also estimated differences in health care expenditures using inputs from the Medical Expenditure Panel Survey. Based on the model, a national SSB excise tax of $0.01/oz would lead to a 20% reduction in consumption, which in turn would reduce an average adult's BMI by 0.08 kg/m2 and a youth's BMI by 0.16 kg/m2. The prevalence of obesity among adults and children would decrease by 0.99% and 1.38% respectively. In the 10-year period between 2015 and 2025, the SSB excise tax would lead to 871,000 quality-adjusted life years (QALYs) gained and reduce health care costs by $23.6 billion. Thus, the intervention was deemed cost-saving, a finding that was maintained across varied inputs in the sensitivity analysis.

Bottom line: This modeling study suggests that a national SSB excise tax of $0.01/oz would reduce the prevalence of obesity by about 1% and avert nearly $25 billion in health care costs in a 10-year period.

Financial Incentives

Mantzari et al., 2015

This is a systematic review and meta-analysis of financial incentives for changing health-related behaviors. The review identified 15 studies examining the effects of financial incentives on markers of healthier eating and physical activity and two studies on physical activity alone. Most of the studies were conducted in the U.S. in a variety of settings including workplaces, communities, health care, and academia. The magnitude and duration of the financial incentives varied greatly across studies, and some studies used financial incentives with other interventions such as counseling. The studies were a mix of randomized and cluster randomized designs. Financial incentives targeted at indicators of healthier eating and physical activity showed positive results at up to 12 months (OR for attainment of target behaviors 1.39, 95% CI 1.03 to 1.88), but the improvements were not sustained after removal of the financial incentive (OR 1.11, CI 0.76 to 1.63). The authors observed that higher-value financial incentives were more effective than lower-value incentives for smoking cessation, although they did not observe this effect in the diet and physical activity trials.

Bottom line: Financial incentives to change eating and physical activity habits are effective at up to 12 months, but the effects are attenuated beyond 12 months and appear to not be sustained after the incentive is removed.

Note: A separate systematic review and meta-analysis (Giles et al., 2014) included studies of financial incentives for smoking cessation, vaccinations, and physical activity, although the authors identified only one study on physical activity. Across all the studies, the relative risk for attainment of target behaviors was 1.62 (95% CI 1.38 to 1.91), but the authors observed that the effect size decreased at post-intervention follow-up. Their overall conclusion was that financial incentives are more effective than usual care.

General Multisector Interventions for Children

Ramsey Buchanan et al., 2016

This is a systematic review and meta-analysis of interventions to reduce recreational sedentary screen time. It was prepared for the Centers for Disease Control and Prevention (CDC) Community Guide. The authors identified 49 studies; 12 studies focused on reducing screen time only, and 37 studies examined interventions to reduce sedentary screen time and improve physical activity or nutrition. The interventions in the studies were diverse and included classroom-based education, tracking and monitoring of screen time, coaching or counseling, and family or peer social support. Additional intervention components were devices to monitor and limit screen time, media and educational campaigns, and contingent rewards (i.e., screen time as a reward for physical activity). The authors defined high-intensity interventions as those that included electronic monitoring and limitation of screen time and at least three personal or computer-based interactions. Reported outcomes of interest included BMI, BMI z-score, and obesity prevalence.

For children, two screen time-only and twelve screen time-plus studies showed an aggregate decrease in BMI z-score of -0.13 (interquartile interval [IQI] -0.23 to -0.01). For adults, two studies showed BMI reductions of -0.18 kg/m2 and -0.19 kg/m2. In terms of obesity prevalence, 10 high-intensity screen time-plus interventions were estimated to decrease median obesity prevalence by -2.1% (IQI -3.9 to -1.1, baseline obesity prevalence of 10.3%). Four studies of low-intensity screen time interventions

were estimated to reduce median obesity prevalence by -4.6% (IQI -7.6 to -1.1, baseline obesity prevalence of 12.3%). Among five studies that stratified analysis according to socioeconomic status, four found greater effectiveness for reducing BMI and obesity prevalence among low-income participants.

Bottom line: Interventions to reduce screen time are effective in reducing BMI and obesity prevalence. This effect has been observed mostly in children younger than 13 years old, but a smaller number of studies also support the effectiveness of these interventions in adults. Interventions that include electronic monitoring and control of screen time appear to be more effective. The results also suggest that screen-time interventions may reduce socioeconomic disparities in obesity prevalence in children with high and low socioeconomic status.

Kader et al., 2015

This is a narrative systematic review of studies examining the effectiveness of parental support interventions to promote dietary changes and increase physical activity. The authors identified 35 studies and divided the parental support interventions into four categories: individual counseling, group education, informational-only, and individual telephone counseling. Of the 35 studies, 16 reported on weight outcomes for children, but most of these studies were not powered to detect changes in BMI. One of the four studies of in-person counseling found a decrease in the prevalence of obesity among girls but not boys, and those results were not sustained at later follow-up. Four of the seven studies involving group education showed improvement in weight-related outcomes. Information-only programs appeared to be ineffective. One of the two studies on telephone counseling showed a reduction in BMI z-score. The authors concluded that for weight-related outcomes, group education programs appeared to be more effective than other universal parental interventions. Among five studies conducted exclusively in low socioeconomic status or minority populations, 6 to 12 group education sessions for parents of preschool-age children were associated with “desirable effects on weight status.”

Bottom line: Group education programs appear to be more effective than other types of parental intervention for weight outcomes, especially for low-socioeconomic status and minority children.

Hillier-Brown et al., 2014b

This is a narrative systematic review of interventions applied at various levels to reduce socioeconomic disparities in childhood obesity. Interventions were classified as occurring at the individual, community, or societal levels. The authors identified four studies at the individual level, 17 studies at the community level, and one study at the societal level. Among the individual interventions, screen-time reduction and mentored health-promotion programs showed the most promise for reducing disparities. The authors concluded that the evidence for community-level interventions was inconclusive, with mixed results in studies of school- and community-based health-promotion programs. The single societal-level study of environmental changes in Swiss preschools showed no significant differences in BMI or overweight prevalence, but there was a “trend towards more beneficial effects in higher SES [socioeconomic status] children.” There was no evidence that any of the interventions worsened inequalities in obesity outcomes. The authors concluded that there was limited evidence, but that some individual- and community-level interventions may be effective in reducing disparities in obesity-related outcomes for children.

Bottom line: Some individual interventions (screen-time reduction and mentored health-promotion programs) show promising results for reducing disparities in childhood obesity, and reported outcomes for community interventions were inconclusive or mixed.

Showell et al., 2013

This is a narrative systematic review of home-based interventions on childhood obesity. The authors identified six studies including combined physical activity and diet interventions (three studies), diet-only interventions (one study), interventions spanning home, school, and primary care settings (one study), and interventions with primary care and consumer health informatics components (one study). Overall, none of the studies showed statistically significant reductions in BMI or obesity prevalence, although three studies showed improvements in diet or physical activity. The authors judged the evidence quality to be low or insufficient and called for better studies of home-based interventions.

Bottom line: There is insufficient evidence that home-based interventions are effective for reducing BMI or obesity prevalence in children.

School-based Interventions

Sun et al., 2013

This is a narrative systematic review of trials examining school-based direct delivery of physical activity interventions. The authors identified six large, high-quality RCTs of high-dose physical activity in schools. Three of the six studies found statistically significant reductions in BMI; the three remaining trials did not find statistically significant effects. Overall, the authors observed that high-dose direct delivery of physical activity in schools was associated with improved fitness measures, but that the effects on BMI, body fat, and waist circumference were inconclusive.

Bottom line: High-dose physical activity interventions in schools improve fitness measures, but do not have a clear effect on weight-related outcomes.

Lavelle et al., 2012

This is a systematic review and meta-analysis of school-based interventions to reduce BMI. The authors identified 43 RCTs, cluster-randomized, and quasi-randomized trials of school-based interventions that reported on BMI outcomes. These interventions were diverse (targeting physical activity, sedentary behavior, and nutrition) and varied in terms of which components were included: direct physical activity, nutrition and activity education, self-management and self-esteem building, and environmental changes (i.e., school meal changes or removal of vending machines). As expected, there was a high degree of heterogeneity. Two-thirds of the studies showed reductions in BMI; 16 of those demonstrated statistically significant differences. In the meta-analysis, the estimate of BMI reduction was -0.17 kg/m2 (95% CI -0.26 to -0.08). Notably, in the stratified analyses, the results were only statistically significant for girls. Among the studies in which interventions were only targeted at overweight and obese children, the meta-analysis showed a reduction in BMI of -0.35 kg/m2 (95% CI -0.58 to -0.12).

Bottom line: School-based interventions, particularly those that contain a physical activity component, are associated with a statistically significant reduction in BMI and the effect is greatest in overweight and obese children.

Childcare-based Interventions

Zhou et al., 2014

This is a narrative systematic review of obesity prevention interventions delivered in childcare settings. The authors identified 15 randomized, cluster randomized, and nonrandomized controlled trials that reported on adiposity outcomes. The study participants were two- to six-year-old children in preschool childcare centers in several countries; about half the participants were socioeconomically disadvantaged. The interventions were varied and included structured age-appropriate nutrition education, healthy cooking classes, physical activity, and playful games. Several programs also included a component of parental education. The interventions lasted from six months to two years. Overall, the results were mixed: 7 of the 15 studies reported improvements in measures of adiposity including BMI, body fat percentage, waist circumference, or decreased prevalence of overweight compared to controls. All of the studies with positive results included both nutrition and physical activity components. Among the remaining studies, many reported positive effects on measures of physical activity or nutrition, but did not show improvements in adiposity outcomes.

Bottom line: There is mixed evidence about the effectiveness of interventions delivered in childcare settings to reduce obesity. Studies with positive results for this outcome all included combined physical activity and nutrition interventions.

OTHER DECISION FACTORS

Resource Allocation

A recent article in *Health Affairs* (Gortmaker et al., 2015) summarized research on seven interventions to reduce childhood obesity. The study estimated the effects of each of the seven interventions using an evidence review protocol. A microsimulation model was developed to calculate the costs and effectiveness of the interventions through their impact on BMI changes, obesity prevalence, and obesity-related health care costs in a 10-year period (2015–2025).

Three of the interventions were found to save more in health care costs than they cost to implement:

- Sugar-sweetened beverage excise tax of one cent per ounce
- Nutrition standards for food and beverages sold in schools outside of meals
- Elimination of the tax subsidy for advertising unhealthy food to children

The other studied interventions cost more to implement than they save on health care costs, but are likely still cost-effective:

- Restaurant menu calorie labeling
- Nutrition standards for school meals
- Improved early childhood education policies and practices, including the Nutrition and Physical Activity Self-Assessment for Child Care (NAP SACC) program
- Four-fold increase in the use of bariatric surgery among adolescents. In particular, increasing adolescents' access to bariatric surgery was found to have a negligible impact on obesity prevalence.

POLICY LANDSCAPE

Recommendations from others

The following recommendations are from these major public health organizations:

- The Community Preventive Services Task Force
- The Institute of Medicine
- Centers for Disease Control and Prevention
- Association of State and Territorial Health Officials
- World Health Organization
- White House Task Force on Childhood Obesity

The Community Preventive Services Task Force—Obesity Prevention and Control: Interventions in Community Settings

1. Behavioral interventions that aim to reduce recreational sedentary screen time among children

Definition: These are behavioral interventions that aim to reduce recreational (i.e., neither school-related nor work-related) sedentary screen time by teaching behavioral self-management skills to initiate or maintain behavior change. Interventions may be screen-time only interventions as well as interventions that combine a focus on reducing recreational screen time with increasing physical activity and improving diet.

Evidence Base: The Community Preventive Services Task Force reviewed the evidence in August 2014 and recommended behavioral interventions to reduce recreational sedentary screen time among children aged 13 years and younger. This finding is based on strong evidence of effectiveness in reducing recreational sedentary screen time, increasing physical activity, improving diet, and improving or maintaining weight-related outcomes. Evidence includes studies of interventions that focus only on reducing recreational sedentary screen time (screen-time-only) and studies that focus on reducing recreational sedentary screen time and improving physical activity and/or diet (screen-time-plus). Limited evidence was available to assess the effectiveness of these interventions among adults.

2. Worksite interventions

Definition: These are a suite of interventions operating on both individual and systemic levels through a combination of policy and system change, as well as individual encouragement. Components include:

- Informational and educational strategies that aim to increase knowledge about a healthy diet and physical activity (e.g., educational software or lectures)
- Behavioral and social strategies target the thoughts (e.g. awareness, self-efficacy) and social factors that affect behavior changes (e.g., individual or group counseling and skill building)
- Policy and environmental approaches aim to make healthy choices easier and target the entire workforce by changing physical or organizational structures (e.g., improve access to healthier options in cafeterias, provide on-site facilities for exercise, employers cover health club membership)

- Worksite weight control strategies may occur separately or as part of a comprehensive worksite wellness program that addresses several health issues (e.g., smoking cessation, stress management, cholesterol reduction).

Evidence Base: The Community Preventive Services Task Force reviewed the evidence in 2007 and recommended worksite programs intended to improve diet and/or physical activity behaviors based on strong evidence of their effectiveness for reducing weight among employees.

3. Technology-supported multicomponent coaching or counseling interventions to reduce weight and maintain weight loss

Definition: Technology-supported multicomponent coaching or counseling interventions use technology to facilitate or mediate interactions between a coach or counselor and an individual or group, with a goal of influencing weight-related behaviors or weight-related outcomes. These interventions often also include other components, which may be technological or non-technological (e.g., in-person counseling).

Evidence Base: The Community Preventive Services Task Force reviewed the evidence in 2009 and recommended technology-supported multicomponent coaching or counseling interventions **intended to reduce and maintain weight** loss on the basis of sufficient evidence that they are effective in improving weight-related behaviors or weight-related outcomes.

The Institute of Medicine—Accelerating Progress in Obesity Prevention

Goal 1: Make physical activity an integral and routine part of life

Recommendation: Communities, transportation officials, community planners, health professionals, and governments should make promotion of physical activity a priority by substantially increasing access to places and opportunities for such activity.

Recommended Strategies: 1) Enhance the physical and built environment. 2) Provide and support community programs designed to increase physical activity. 3) Adopt physical activity requirements for licensed child care providers and 4) Provide support for the science and practice of physical activity.

Goal 2: Create food and beverage environments that ensure that healthy food and beverage options are the routine, easy choice

Recommendation: Governments and decision makers in the business community/private sector should make a concerted effort to reduce unhealthy food and beverage options and substantially increase healthier food and beverage options at affordable, competitive prices.

Recommended Strategies: 1) Adopt policies and implement practices to reduce overconsumption of sugar-sweetened beverages. 2) Increase the availability of lower-calorie and healthier food and beverage options for children in restaurants. 3) Utilize strong nutritional standards for all foods and beverages sold or provided through the government, and ensure that these healthy options and available in all places frequented by the public. 4) Introduce, modify, and utilize health-promoting food and beverage retail policies. 5) Broaden the examination and development of U.S. agriculture policy and research to include implications for the American diet.

Goal 3: Transform messages about physical activity and nutrition.

Recommendation: Industry, educators, and governments should act quickly, aggressively, and in a sustained manner on many levels to transform the environment that surrounds Americans with messages about physical activity, food, and nutrition.

Recommended Strategies: 1) Develop and support a sustained, targeted physical activity and nutrition social marketing program. 2) Implement common standards for marketing foods and beverages to children and adolescents. 3) Ensure consistent nutrition labeling for the front of packages, retail store shelves, and menus and menu boards that encourages healthier food choices. 4) Adopt consistent nutrition education policies for federal programs with nutrition education components.

Goal 4: Expand the role of health care providers, insurers and employers in obesity prevention.

Recommendation: Health care and health service providers, employers, and insurers should increase the support structure for achieving better population health and obesity prevention.

Recommended Strategies: 1) Provide standardized care and advocate for health community environments. 2) Ensure coverage of, access to, and incentives for routine obesity prevention, screening, diagnosis and treatment. 3) Encourage active living and healthy eating at work. 4) Encourage healthy weight gain during pregnancy and breastfeeding, and promote breastfeeding-friendly environments. IOM (Children) #3

Goal 5: Make schools a national focal point for obesity prevention.

Recommendation: Make schools a national focal point for obesity prevention.

Recommended Strategies: 1) Require quality physical education and opportunities for physical activity in schools. 2) Ensure strong nutritional standards for all foods and beverages sold or provided through schools. 3) Ensure food literacy, including skill development, in schools.

Institute of Medicine—Recommendations on Early Childhood Obesity Prevention Policies

[This report does not include a recommendation 1]

2. Growth Monitoring

Goal: Assess, monitor, and track growth from birth to age five.

Recommendation 2-1: Healthcare providers should measure weight and length or height in a standardized way, plotted on World Health Organization growth charts (ages 0–23 months) or Centers for Disease Control and Prevention growth charts (ages 24–59 months), as part of every well-child visit.

Recommendation 2-2: Healthcare professionals should consider 1) children's attained weight-for-length or BMI ≥ 85th percentile, 2) children's rate of weight gain, and 3) parental weight status as risk factors in assessing which young children are at highest risk of later obesity and its adverse consequences.

3. Physical Activity

Goal: Increase physical activity in young children.

Recommendation 3-1: Child care regulatory agencies should require child care providers and early childhood educators to provide infants, toddlers, and preschool children with opportunities to be physically active throughout the day.

Recommendation 3-2: The community and its built environment should promote physical activity for children from birth to age five.

Goal: Decrease sedentary behavior in young children.

Recommendation 3-3: Child care regulatory agencies should require child care providers and early childhood educators to allow infants, toddlers, and preschoolers to move freely by limiting the use of equipment that restricts infants' movement and by implementing appropriate strategies to ensure that the amount of time toddlers and preschoolers spend sitting or standing still is limited.

Goal: Help adults increase physical activity and decrease sedentary behavior in young children.

Recommendation 3-4: Health and education professionals providing guidance to parents of young children and those working with young children should be trained in ways to increase children's physical activity and decrease their sedentary behavior, and in how to counsel parents about their children's physical activity.

4. Healthy Eating

Goal: Promote the consumption of a variety of nutritious foods, and encourage and support breastfeeding during infancy.

Recommendation 4-1: Adults who work with infants and their families should promote and support exclusive breastfeeding for six months and continuation of breastfeeding in conjunction with complementary foods for 1 year or more

Recommendation 4-2: To ensure that child care facilities provide a variety of healthy foods and age-appropriate portion sizes in an environment that encourages children and staff to consume a healthy diet, child care regulatory agencies should require that all meals, snacks, and beverages served by early childhood programs be consistent with the Child and Adult Care Food Program meal patterns and safe drinking water be available and accessible to the children.

Recommendation 4-3: The Department of Health and Human Services and the U.S. Department of Agriculture should establish dietary guidelines for children from birth to age two years in future releases of the Dietary Guidelines for Americans.

Goal: Create a healthful eating environment that is responsive to children's hunger and fullness cues.

Recommendation 4-4: State child care regulatory agencies should require that child care providers and early childhood educators practice responsive feeding.

Goal: Ensure access to affordable healthy foods for all children.

Recommendation 4-5: Government agencies should promote access to affordable healthy foods for infants and young children from birth to age five in all neighborhoods, including those in low-income areas, by maximizing participation in federal nutrition assistance programs and increasing access to healthy foods at the community level.

Goal: Help adults increase children's healthy eating.

Recommendation 4-6: Health and education professionals providing guidance to parents of young children and those working with young children should be trained and educated and have the right tools to increase children's healthy eating and counsel parents about their children's diet.

5. Marketing and Screen Time

Goal: Limit young children's screen time and exposure to food and beverage marketing.

Recommendation 5-1: Adults working with children should limit screen time, including television, cell phone, or digital media, to less than two hours per day for children aged two–five.

Recommendation 5-2: Healthcare providers should counsel parents and children's caregivers not to permit televisions, computers, or other digital media devices in children's bedrooms or other sleeping areas.

Recommendation 5-3: The Federal Trade Commission, the U.S. Department of Agriculture, Centers for Disease Control and Prevention, and the Food and Drug Administration should continue their work to establish and monitor the implementation of uniform voluntary national nutrition and marketing standards for food and beverage products marketed to children.

Goal: Use social marketing to provide consistent information and strategies for the prevention of childhood obesity in infancy and early childhood.

Recommendation 5-4: The Secretary of the Department of Health and Human Services, in cooperation with state and local government agencies and interested private entities, should establish a sustained social marketing program to provide pregnant women and caregivers of children from birth to age five with consistent, practical information on the risk factors for obesity in young children and strategies for preventing overweight and obesity.

6. Sleep

Goal: Promote age-appropriate sleep durations among children.

Recommendation 6-1: Child care regulatory agencies should require child care providers to adopt practices that promote age-appropriate sleep durations.

Recommendation 6-2: Health and education professionals should be trained in how to counsel parents about their children's age-appropriate sleep durations.

Centers for Disease Control and Prevention—Recommended Community Strategies to Prevent Obesity

Strategies to Promote the Availability of Affordable Healthy Food and Beverages

Strategy 1. Communities should increase availability of healthier food and beverage choices in public service venues.

Strategy 2. Communities should improve availability of affordable healthier food and beverage choices in public service venues.

Strategy 3. Communities should improve geographic availability of supermarkets in underserved areas.

Strategy 4. Communities should provide incentives to food retailers to locate in and/or offer healthier food and beverage choices in underserved areas.

Strategy 5. Communities should improve availability of mechanisms for purchasing foods from farms.

Strategy 6. Communities should provide incentives for the production, distribution, and procurement of foods from local farms.

Strategies to Support Healthy Food and Beverage Choices

Strategy 7. Communities should restrict availability of less healthy foods and beverages in public service venues.

Strategy 8. Communities should institute smaller portion size options in public service venues.

Strategy 9. Communities should limit advertisements of less healthy foods and beverages.

Strategy 10. Communities should discourage consumption of sugar-sweetened beverages.

Strategies to encourage Breastfeeding

Strategy 11. Communities should increase support for breastfeeding.

Strategies to Encourage Physical Activity or Limit Sedentary Activity among Children and Youth

Strategy 12. Communities should require physical education in schools.

Strategy 13. Communities should increase the amount of physical activity in PE programs in schools.

Strategy 14. Communities should increase opportunities for extracurricular physical activity.

Strategy 15. Communities should reduce screen time in public service venues.

Strategies to Create Safe Communities That Support Physical Activity

Strategy 16. Communities should improve access to outdoor recreational facilities.

Strategy 17. Communities should enhance infrastructure supporting bicycling.

Strategy 18. Communities should enhance infrastructure supporting walking.

Strategy 19. Communities should support locating schools within easy walking distance of residential areas.

Strategy 20. Communities should improve access to public transportation.

Strategy 21. Communities should zone for mixed use development.

Strategy 22. Communities should enhance personal safety in areas where persons are or could be physically active.

Strategy 23. Communities should enhance traffic safety in areas where persons are or could be physically active.

Strategy to Encourage Communities to Organize for Change

Strategy 24. Communities should participate in community coalitions or partnerships to address obesity.

Association of State and Territorial Health Officials—Recommendations for Preventing and Reducing Obesity

1. Support Infrastructure for State and Territorial Health Agencies to Address Obesity.

Partnerships

- Promote partnerships across state, territorial, federal, and local governments, private sector partners and businesses, community groups, and healthcare systems that provide safe, culturally competent, and appropriate programs. These partnerships should transform communities by affecting policy and implementing initiatives, cross-cutting programs, and consistent targeted messages.
- Promote partnerships within state and territorial health agencies to support coordination among all programs, such as nutrition and physical activity, heart disease and stroke prevention, injury and violence prevention, diabetes prevention and control, maternal and child health, the Behavioral Risk Factor Surveillance System, and other related chronic disease prevention programs.
- Promote partnerships across state and territorial health agencies that support obesity prevention policy and environmental change in cooperation with agencies overseeing education, transportation, housing, agriculture, healthcare, and other sectors.

Coordination

- Foster engagement among multiple sectors, including state health agency leadership and to provide comprehensive systematic change to address issues such as food deserts, which encourage unhealthy eating and are most often found in low-income, rural, and minority neighborhoods.
- Address healthy eating and active living policies and programs with an effective, coordinated, sustainable infrastructure within state health agency programs.
- Coordinate chronic disease programs to provide infrastructure for all programs in order to have adequate and coordinated leadership that supports communication, evaluation, surveillance, and management of related programs.

Leadership

- Adopt comprehensive healthy workplace policies within health agencies and throughout state government with the support of state leadership, including implementing health risk assessments; healthy food procurement policies that include agency food purchasing, events and meetings, vending machines, and cafeterias; and other incentives for employees to improve their health.

2. Support Policy and Environmental Changes across the Lifespan.

National Guidelines

- Implement policy, programmatic, and other system changes in accordance with the Dietary Guidelines for Americans and the Physical Activity Guidelines for Americans to ensure that healthy food and physical activity is accessible to all populations and consider regulatory approaches to implement and enforce obesity prevention measures. (For example, breastfeeding policies in government nutrition programs, such as the Women, Infants, and Children program and Adult Care Food program; encouraging and supporting hospitals to pass Baby-Friendly Hospital practices; and supporting adequate time and space for breastfeeding or expressing milk in all workplaces.)
- Promote the food marketing principles developed by the U.S. Interagency Working Group that guides the food industry in determining which foods would be appropriate and desirable to market to children ages 2 to 17 to encourage a healthful diet and which foods the industry should voluntarily refrain from marketing to children.
- Encourage and enforce nutrition labeling in restaurants and similar establishments and vending policies that provide consumers with appropriate information at the point of purchase and encourage support for state health agencies to provide the regulatory structure to enforce these policies.

Education

- Support early childhood education policies that describe access to healthy foods and beverages through the Child and Adult Food Care Program and state child care licensing standards that include nutrition and wellness guidelines, age-appropriate physical activity time and intensity, limited screen time, and meals and snacks that meet nutrition guidelines.
- Support education policies that encourage healthy students through coordinated K-12 school health programs, adequate time and intensity of physical education and activity, access to healthy foods and beverages through the National School Lunch and Breakfast Program and throughout the school day that meet updated standards developed by USDA and the Dietary Guidelines 2010, and implementation of school wellness policies, farm to school programs, and joint use agreements.

Improved Industry Standards

- Promote worksite wellness policies and accreditation programs that encourage a healthy work environment, such as incentive programs for individuals to maintain healthy weight; inclusion of preventive services in routine clinical practice, including reimbursement for proven clinical preventive services; healthy foods and physical activity at meetings and events, and healthy foods in vending machines; and policies for breastfeeding or expressing milk in the workplace. Work closely with business and private sector partners to support efforts for spread and sustainability.
- Support agriculture policies that shift federal subsidies; support less processed foods; increase access to affordable fresh fruit and vegetables through commodity programs; create agriculture policies that support healthy foods in food assistance programs; expand farmers markets and encourage the use of electronic benefit transfer at farmers markets; increase access to fresh fruit and vegetable through distribution to schools; and address the problem of food deserts.
- Support transportation policies that boost partnerships with planners, transportation, and developers; support mixed-use, healthy communities that meet the needs of users of all ages and abilities; support key walking and biking programs and access to public transportation; support Safe Routes to Schools programs; encourage Complete Streets policies; and increase the use of Health Impact Assessments to analyze policies and programs.

3. Support Outreach and Education to Inform and Prepare Providers.

Incentives

- Identify opportunities to assist and advocate for financial incentives for healthcare professionals and institutions, such as physicians, nurses, and other clinicians, hospitals, accountable care organizations, and insurers that track body mass index (BMI) and other health indicators. Offer evidence-based nutrition and physical activity counseling (including breastfeeding), develop targeted and culturally appropriate interventions, and provide leadership in community-based obesity prevention efforts.
- Provide training, educational materials, and technical assistance to communities, worksites, early care and education, and schools interested in offering healthy eating and physical activity programs and policies, especially targeting health disparities and other social determinants of health.

4. Support the Evaluation of Obesity Efforts

Data Collection

- Practice routine data collection and use of public health surveillance data, including the Behavioral Risk Factor Surveillance System, the Youth Risk Behavior Surveillance System, electronic health information, and hospital discharge data to identify jurisdictions' most pressing needs and efficiently target scarce resources.
- Conduct collection of community design data as communities redesign environments to promote physical activity and access to nutritious foods.
- Gather state-level quantitative and qualitative data on obesity disparities and the social and environmental factors that contribute to them to identify and prioritize populations with the greatest need.

Analysis and Tracking

- Track progress of obesity rates in populations, schools, worksites, communities, and states and territories through public health metrics, including vital statistics, hospital discharge data, and health surveillance systems.
- Utilize clear benchmark goals and measurement of overall rates of obesity according to the best attainable average level of "goodness" and the smallest feasible differences in obesity rates among individuals and groups, or "fairness."

Evaluation

- Engage state leadership in the development of robust health information exchange with the clinical sector to improve public health and clinical services.
- Evaluate the feasibility of harmonizing state data collection with HHS data collection on race, ethnicity, sex, primary language, and disability status as required by Section 3101 of the Public Health Services Act.

World Health Organization—Recommendations of the Commission on Ending Childhood Obesity

1: Implement comprehensive programmes that promote the intake of healthy foods and reduce the intake of unhealthy foods and sugar-sweetened beverages by children and adolescents.

1.1 Ensure that appropriate and context-specific nutrition information and guidelines for both adults and children are developed and disseminated in a simple, understandable and accessible manner to all groups in society.

1.2 Implement an effective tax on sugar-sweetened beverages.

1.3 Implement the Set of Recommendations on the Marketing of Foods and Non-alcoholic Beverages to Children to reduce the exposure of children and adolescents to, and the power of, the marketing of unhealthy foods.

1.4 Develop nutrient-profiles to identify unhealthy foods and beverages.

1.5 Establish cooperation between Member States to reduce the impact of cross-border marketing of unhealthy foods and beverages.

1.6 Implement a standardized global nutrient labelling system.

1.7 Implement interpretive front-of-pack labelling, supported by public education of both adults and children for nutrition literacy.

1.8 Require settings such as schools, child-care settings, children's sports facilities and events to create healthy food environments.

1.9 Increase access to healthy foods in disadvantaged communities.

2: Implement comprehensive programmes that promote physical activity and reduce sedentary behaviours in children and adolescents.

2.1 Provide guidance to children and adolescents, their parents, caregivers, teachers and health professionals on healthy body size, physical activity, sleep behaviours and appropriate use of screen-based entertainment.

2.2 Ensure that adequate facilities are available on school premises and in public spaces for physical activity during recreational time for all children (including those with disabilities), with the provision of gender-friendly spaces where appropriate.

3: Integrate and strengthen guidance for noncommunicable disease prevention with current guidance for preconception and antenatal care, to reduce the risk of childhood obesity.

3.1 Diagnose and manage hyperglycaemia and gestational hypertension.

3.2 Monitor and manage appropriate gestational weight gain.

3.3 Include an additional focus on appropriate nutrition in guidance and advice for both prospective mothers and fathers before conception and during pregnancy.

3.4 Develop clear guidance and support for the promotion of good nutrition, healthy diets and physical activity, and for avoiding the use of and exposure to tobacco, alcohol, drugs and other toxins.

4: Provide guidance on, and support for, healthy diet, sleep and physical activity in early childhood to ensure children grow appropriately and develop healthy habits.

4.1 Enforce regulatory measures such as The International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly resolutions.

4.2 Ensure all maternity facilities fully practice the Ten Steps to Successful Breastfeeding.

4.3 Promote the benefits of breastfeeding for both mother and child through broad-based education to parents and the community at large.

4.4 Support mothers to breastfeed, through regulatory measures such as maternity leave, facilities and time for breastfeeding in the work place.

4.5 Develop regulations on the marketing of complementary foods and beverages, in line with WHO recommendations, to limit the consumption of foods and beverages high in fat, sugar and salt by infants and young children.

4.6 Provide clear guidance and support to caregivers to avoid specific categories of foods (e.g. sugar-sweetened milks and fruit juices or energy-dense, nutrient-poor foods) for the prevention of excess weight gain.

4.7 Provide clear guidance and support to caregivers to encourage the consumption of a wide variety of healthy foods.

4.8 Provide guidance to caregivers on appropriate nutrition, diet and portion size for this age group.

4.9 Ensure only healthy foods, beverages and snacks are served in formal child-care settings or institutions.

4.10 Ensure food education and understanding are incorporated into the curriculum in formal child-care settings or institutions.

4.11 Ensure physical activity is incorporated into the daily routine and curriculum in formal child-care settings or institutions.

4.12 Provide guidance on appropriate sleep time, sedentary or screen-time, and physical activity or active play for the 2–5 years of age group.

4.13 Engage whole-of-community support for caregivers and child-care settings to promote healthy lifestyles for young children.

5: Implement comprehensive programmes that promote healthy school environments, health and nutrition literacy and physical activity among school-age children and adolescents.

5.1 Establish standards for meals provided in schools, or foods and beverages sold in schools, that meet healthy nutrition guidelines.

5.2 Eliminate the provision or sale of unhealthy foods, such as sugar-sweetened beverages and energy-dense, nutrient-poor foods, in the school environment.

5.3 Ensure access to potable water in schools and sports facilities.

5.4 Require inclusion of nutrition and health education within the core curriculum of schools.

5.5 Improve the nutrition literacy and skills of parents and caregivers.

5.6 Make food preparation classes available to children, their parents and caregivers.

5.7 Include Quality Physical Education in the school curriculum and provide adequate and appropriate staffing and facilities to support this.

6: Provide family-based, multicomponent, lifestyle weight management services for children and young people who are obese.

6.1 Develop and support appropriate weight management services for children and adolescents who are overweight or obese that are family-based, multicomponent (including nutrition, physical activity and psychosocial support) and delivered by multi-professional teams with appropriate training and resources, as part of Universal Health Coverage.

White House Task Force on Childhood Obesity—Solving the Problem of Childhood Obesity

I. Early Childhood				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 1.1: Pregnant women and women planning a pregnancy should be informed of the importance of conceiving at a healthy weight and having a healthy weight gain during pregnancy, based on the relevant recommendations of the Institute of Medicine.	x	x	x	12
Recommendation 1.2: Education and outreach efforts about prenatal care should be enhanced through creative approaches that take into account the latest in technology and communications. Partners in this effort could include companies that develop technology-based communications tools, as well as companies that market products and services to pregnant women or prospective parents.			x	12
Recommendation 1.3: Hospitals and health care providers should use maternity care practices that empower new mothers to breastfeed, such as the Baby-Friendly hospital standards.	x	x	x	16
Recommendation 1.4: Health care providers and insurance companies should provide information to pregnant women and new mothers on breastfeeding, including the availability of educational classes, and connect pregnant women and new mothers to breastfeeding support programs to help them make an informed infant feeding decision.	x	x	x	16
Recommendation 1.5: Local health departments and community- based organizations, working with health care providers, insurance companies, and others should develop peer support programs that empower pregnant women and mothers to get the help and support they need from other mothers who have breastfed.	x	x	x	16
Recommendation 1.6: Early childhood settings should support breastfeeding.	x	x	x	16
Recommendation 1.7: Federal and State agencies conducting health research should prioritize research into the effects of possibly obesogenic chemicals.	x			17

I. Early Childhood				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 1.8: The AAP guidelines on screen time should be made more available to parents, and young children should be encouraged to spend less time using digital media and more time being physically active.		x	x	18
Recommendation 1.9: The AAP guidelines on screen time should be made more available in early childhood settings.		x	x	18
Recommendation 1.10: The Federal government, incorporating input from health care providers and other stakeholders, should provide clear, actionable guidance to states, providers, and families on how to increase physical activity, improve nutrition, and reduce screen time in early child care settings.	x			21
Recommendation 1.11: States should be encouraged to strengthen licensing standards and Quality Rating and Improvement Systems to support good program practices regarding nutrition, physical activity, and screen time in early education and child care settings.		x	x	21
Recommendation 1.12: The Federal government should look for opportunities in all early childhood programs it funds (such as the Child and Adult Care Food Program at USDA, the Child Care and Development Block Grant, Head Start, military child care, and Federal employee child care) to base policies and practices on current scientific evidence related to child nutrition and physical activity, and seek to improve access to these programs.	x			21

II. Empowering Parents and Caregivers				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 2.1: The Federal government, working with local communities, should disseminate information about the 2010 Dietary Guidelines for Americans through simple, easily actionable messages for consumers and a next generation Food Pyramid.	x			26
Recommendation 2.2: The FDA and USDA's Food Safety and Inspection Service should collaborate with the food and beverage industry to develop and implement a standard system of nutrition labeling for the front of packages.	x		x	27
Recommendation 2.3: Restaurants and vending machine operators subject to the new requirement in the Affordable Care Act should be encouraged to begin displaying calorie counts as soon as possible.			x	27
Recommendation 2.4: Restaurants should consider their portion sizes, improve children's menus, and make healthy options the default choice whenever possible.			x	27
Recommendation 2.5: The food and beverage industry should extend its self-regulatory program to cover all forms of marketing to children, and food retailers should avoid in-store marketing that promotes unhealthy products to children.			x	32
Recommendation 2.6: All media and entertainment companies should limit the licensing of their popular characters to food and beverage products that are healthy and consistent with science-based nutrition standards			x	32
Recommendation 2.7: The food and beverage industry and the media and entertainment industry should jointly adopt meaningful, uniform nutrition standards for marketing food and beverages to children, as well as a uniform standard for what constitutes marketing to children.			x	32

II. Empowering Parents and Caregivers				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 2.8: Industry should provide technology to help consumers distinguish between advertisements for healthy and unhealthy foods and to limit their children's exposure to unhealthy food advertisements.	x		x	32
Recommendation 2.9: If voluntary efforts to limit the marketing of less healthy foods and beverages to children do not yield substantial results, the FCC could consider revisiting and modernizing rules on commercial time during children's programming.	x			32
Recommendation 2.10: Pediatricians should be encouraged to routinely calculate children's BMI and provide information to parents about how to help their children achieve a healthy weight.			x	35
Recommendation 2.11: Federally-funded and private insurance plans should cover services necessary to prevent, assess, and provide care to overweight and obese children.	x		x	35
Recommendation 2.12: Dentists and other oral health care providers should be encouraged to promote healthy habits and counsel families on childhood obesity prevention as part of routine preventive dental care.			x	35
Recommendation 2.13: Medical and other health professional schools, health professional associations, and health care systems should ensure that health care providers have the necessary training and education to effectively prevent, diagnose, and treat obese and overweight children.			x	35

III. Healthier Food in Schools				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 3.1: Update Federal nutritional standards for school meals and improve the nutritional quality of USDA commodities provided to schools.	x			39
Recommendation 32: Increase resources for school meals.	x	x	x	40
Recommendation 3.3: USDA should continue its outreach and technical assistance to help provide training for school food service professionals.	x	x	x	40
Recommendation 3.4: Schools should consider upgrading their cafeteria equipment to support the provision of healthier foods, for example, by swapping out deep fryers for salad bars.	x	x	x	41
Recommendation 3.5: USDA should work with all stakeholders to develop innovative ways to encourage students to make healthier choices.	x	x		41
Recommendation 3.6: USDA should work to connect school meals programs to local growers, and use farm-to-school programs, where possible, to incorporate more fresh, appealing food in school meals.	x	x	x	41
Recommendation 3.7: Schools should be encouraged to make improvements in their school meal programs through the HealthierUS Schools Challenge in advance of updated Federal standards.	x	x	x	42
Recommendation 3.8: Increase the alignment of foods sold at school, including in the a la carte lines and vending machines, with the Dietary Guidelines.	x			43

III. Healthier Food in Schools				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 3.9: Food companies should be encouraged to develop new products and reformulate existing products so they meet nutritional standards based on the Dietary Guidelines and appeal to children.			x	43
Recommendation 3.10: USDA and the U S Department of Education should collaborate with states to increase the availability and consistency of nutrition education in schools.	x	x		44
Recommendation 3.11: Where possible, use school gardens to educate students about healthy eating.		x	x	45
Recommendation 3.12: Technical assistance should be provided to schools about how to a cafeteria and lunch room environment can support and encourage a healthful meal.		x		45
Recommendation 3.13: Schools should be encouraged to ensure that choosing a healthy school meal does not have a social cost for a child.		x		45
Recommendation 3.14: Schools should be encouraged to consider the impact of food marketing on education.		x	x	45
Recommendation 3.15: School districts should be encouraged to create, post, and implement a strong local school wellness policy.	x	x	x	45
Recommendation 3.16: Promote good nutrition through afterschool programs.	x	x	x	47
Recommendation 3.17: Promote healthy behaviors in juvenile correctional and related facilities.	x	x	x	47

IV. Access to Healthy, Affordable Food				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 4.1: Launch a multi-year, multi-agency Healthy Food Financing Initiative to leverage private funds to increase the availability of affordable, healthy foods in underserved urban and rural communities across the country.	x	x	x	53
Recommendation 4.2: Local governments should be encouraged to create incentives to attract supermarkets and grocery stores to under- served neighborhoods and improve transportation routes to healthy food retailers.		x		54
Recommendation 4.3: Food distributors should be encouraged to explore ways to use their existing distribution chains and systems to bring fresh and healthy foods into underserved communities.	x		x	54
Recommendation 4.4: Encourage communities to promote efforts to provide fruits and vegetables in a variety of settings and encourage the establishment and use of direct–to-consumer marketing outlets such as farmers' markets and community supported agriculture subscriptions.		x		54
Recommendation 4.5: Encourage the establishment of regional, city, or county food policy councils to enhance comprehensive food system policy that improve health.		x		54
Recommendation 4.6: Encourage publicly and privately-managed facilities that serve children, such as hospitals, afterschool programs, recreation centers, and parks (including national parks) to implement policies and practices, consistent with the Dietary Guidelines, to promote healthy foods and beverages and reduce or eliminate the availability of calorie-dense, nutrient-poor foods.	x	x	x	54
Recommendation 4.7: Provide economic incentives to increase production of healthy foods such as fruits, vegetables, and whole grains, as well as create greater access to local and healthy food for consumers.	x			59

IV. Access to Healthy, Affordable Food				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 4.8: Demonstrate and evaluate the effect of targeted subsidies on purchases of healthy food through nutrition assistance programs.	x			59
Recommendation 4.9: Analyze the effect of state and local sales taxes on less healthy, energy-dense foods.	x	x		59
Recommendation 4.10: The food, beverage, and restaurant industries should be encouraged to use their creativity and resources to develop or reformulate more healthful foods for children and young people.			x	60
Recommendation 4.11: Increase participation rates in USDA nutrition assistance programs through creative outreach and improved customer service, state adoption of improved policy options and technology systems, and effective practices to ensure ready access to nutrition assistance program benefits, especially for children.	x	x	x	62

V. Increasing Physical Activity				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 5.1: Developers of local school wellness policies should be encouraged to include strong physical activity components, on par with nutrition components.		x		73
Recommendation 5.2: The President's Challenge should be updated to ensure consistency with the Physical Activity Guidelines for Americans and to ensure ease of use and implementation by schools. Private sector partners with an interest in physical activity should help enroll children in the Presidential Active Lifestyle Award program.	x		x	73
Recommendation 5.3: State and local educational agencies should be encouraged to increase the quality and frequency of sequential, age- and developmentally-appropriate physical education for all students, taught by certified PE teachers.		x	x	73
Recommendation 5.4: State and local educational agencies should be encouraged to promote recess for elementary students and physical activity breaks for older students, and provide support to schools to implement recess in a healthy way that promotes physical activity and social skill development.		x		73
Recommendation 5.5: State and local educational agencies should be encouraged to provide opportunities in and outside of school for students at increased risk for physical inactivity, including children with disabilities, children with asthma and other chronic diseases, and girls.		x	x	74
Recommendation 5.6: Federal, state, and local educational agencies, in partnership with communities and businesses, should work to support programs to extend the school day, including afterschool programs, which offer and enhance physical activity opportunities in their programs.	x	x	x	77

V. Increasing Physical Activity				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 5.7: State and local educational agencies should be encouraged to support interscholastic sports and help decrease prohibitive costs of sports by curbing practices such as "pay-to-play," working with other public and private sector partners.	x	x	x	78
Recommendation 5.8: Reauthorize a Surface Transportation Act that enhances livability and physical activity.	x	x		81
Recommendation 5.9: The Environmental Protection Agency should assist school districts that may be interested in siting guidelines for new schools that consider the promotion of physical activity, including whether students will be able to walk or bike to school.	x	x		81
Recommendation 5.10: Communities should be encouraged to consider the impacts of built environment policies and regulations on human health.	x	x		81
Recommendation 5.11: The Federal Safe Routes to School Program (SRTS) should be continued and enhanced to accommodate the growing interest in implementing Safe Routes to Schools plans in communities.	x			82
Recommendation 5.12: "Active transport" should be encouraged between homes, schools, and community destinations for afterschool activities, including to and from parks, libraries, transit, bus stops, and recreation centers.		x	x	82
Recommendation 5.13: Increase the number of safe and accessible parks and playgrounds, particularly in underserved and low-income communities.	x	x	x	83
Recommendation 5.14: The Federal government should continue to support investments in a wide range of outdoor recreation venues, such as National Parks, Forests, Refuges and other public lands, and expand opportunities for children to enjoy these venues.	x			84

V. Increasing Physical Activity				
Recommendation	**Federal action**	**State or local action**	**Private sector action**	**Page**
Recommendation 5.15: Local governments should be encouraged to enter into joint use agreements to increase children's access to community sites for indoor and outdoor recreation.		x		84
Recommendation 5.16: The business sector should be encouraged to consider which resources and physical assets like fields and gyms can be used to increase students' access to outdoor and indoor recreational venues.			x	84
Recommendation 5.17: Entertainment and technology companies should continue to develop new approaches for using technology to engage children in physical activity.			x	84

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APPENDIX A. METHODOLOGY

Scope Statement

Populations

Overweight and obese patients, including adults, children, and adolescents

Population scoping notes: Includes interventions targeted at parents, pregnant women, and others that impact outcomes in children

Interventions

Multisector interventions such as community interventions, policy, systems, and environmental change

Comparators

No care, usual care, other studied interventions

Outcomes

Critical: Morbidity, all-cause mortality

Important: Weight loss, remission/prevention of diabetes, remission of hypertension

Key Questions

1. What interventions are most effective and most cost-effective at achieving weight loss and improving patient outcomes?

2. Does effectiveness vary by socioeconomic factors such as race, ethnicity, income, and educational attainment?

3. What models of care would allow these interventions to be implemented most effectively and cost-effectively?

Search Strategy

A search of MEDLINE® was conducted to identify systematic reviews, meta-analyses, and guidelines related to reducing obesity that were published since 2011. Search terms included "Weight Reduction Programs"[Mesh], "Diet, Reducing"[Mesh], and physical activity. In addition, a Google search was conducted for guidelines or recommendations related to obesity control. Systematic reviews were excluded if they did not report on at least one of the following outcomes: morbidity, mortality, weight loss, remission/prevention of diabetes, remission of hypertension. The included interventions were those that were not limited to clinical settings, such as community interventions, policy, systems, and environmental change. Due to the large number of systematic reviews for some interventions, the most recent and/or comprehensive review was used unless the overall conclusions of the reviews were divergent.

APPENDIX B. MEMBERSHIP

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Section 3.0

New Discussion Items

Coverage Guidance Process efficiencies

Question: Coverage Guidance Process efficiencies

Question source: HERC Staff

Issue: The 2016 coverage guidance monitoring is straining staff resources, with 21 coverage guidances approved in 2014 needing to be scoped and to have an updated evidence search performed. Currently, coverage guidances are considered either "approved" or "retired," and all "approved" coverage guidances are rescanned every two years.

Recommendations: Add a new status for a coverage guidance, "Passive Monitoring," for which additional evidence searches are unlikely to change coverage policy. Such coverage guidances may be cases where evidence is already strong, or the prior recommendation to cover a service would require evidence of ineffectiveness or harm. For these topics, staff would not update the scope statement or perform a new evidence search every two years. Rather these topics would be rescoped and have a new evidence search only if stakeholders request a review or if staff becomes aware of a significant new piece of evidence which might substantially change the Coverage Guidance.

If so, the scope statement would be posted for a 7-day public comment period and brought to EbGS or HTAS. Then, an updated evidence search would be performed and staff would bring a recommendation to EbGS or HTAS about whether to update the coverage guidance as is done during the normal monitoring process. Then if a rescan is in order, the topic would be prioritized with other topics during the annual coverage guidance topic prioritization process. If a coverage guidance is in need of an update but is not prioritized for development, it may be retired.

The new status of a Coverage Guidance would therefore be either:

1) Active monitoring – 2 year standing rereview. Earlier review is possible if there is a dramatic change in the literature.
2) Passive monitoring – do not rescan the literature on a regular basis unless a specific concern is raised
3) Retired

Section 4.0

Coverage Guidances

RHEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: NONINVASIVE TESTING FOR LIVER FIBROSIS IN PATIENTS WITH CHRONIC HEPATITIS C

DRAFT for VbBS/HERC meeting materials 10/6/2016

HERC Coverage Guidance

If a fibrosis score of ≥F2 is the threshold for antiviral treatment of Hepatitis C, the following are recommended for coverage *(weak recommendation)*:

Imaging tests:

- Transient elastography (FibroScan®)
- Acoustic radiation force impulse imaging (ARFI) (Virtual Touch™ tissue quantification, ElastPQ)
- Shear wave elastography (SWE) (Aixplorer®)

Blood tests (only if imaging tests are unavailable):

- Enhanced Liver Fibrosis (ELF™)
- Fibrometer™
- FIBROSpect® II

If a fibrosis score of ≥F3 is the threshold for antiviral treatment of Hepatitis C, one or more of the following are recommended for coverage *(strong recommendation*):

Imaging tests:

- Transient elastography (FibroScan®)
- Acoustic radiation force impulse imaging (ARFI)
- Shear wave elastography (SWE)

Magnetic resonance elastography is recommended for coverage for ≥F2 or ≥F3 only when at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminant results, a second one is similarly indeterminant, contraindicated or unavailable, and MRE is readily available *(weak recommendation).*

Noninvasive tests should be performed no more often than once per year *(weak recommendation).*

The following tests are not recommended for coverage for the detection of liver fibrosis to guide treatment decisions with antivirals in chronic hepatitis C *(strong recommendation):*

Imaging tests

- Real time tissue elastography

Blood tests (proprietary):

- Hepascore® (FibroScore®)
- FibroSure® (FibroTest®)

Blood tests (non-proprietary):

- Age-platelet index
- AST-platelet ratio index (APRI)
- AST-ALT ratio
- Cirrhosis discriminant score (Bonacini index)
- FIB-4
- Fibro-α score
- FibroIndex
- Fibronectin discriminant score
- FibroQ
- Fibrosis–cirrhosis index
- Fibrosis index
- Fibrosis probability index (Sud index)
- Fibrosis–protein index
- Fibrosis Routine Test
- Forns index
- Globulin–albumin ratio
- Göteborg University Cirrhosis Index (GUCI)
- HALT-C model (Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis)
- King's score
- Lok index
- MP3 score
- Pohl index
- Sabadell NIHCED index (Non-Invasive Hepatitis-C–Related Cirrhosis Early Detection)
- Significant fibrosis index
- Zeng index

Note: Definitions for strength of recommendation are provided in Appendix A *GRADE Informed Framework Element Description*.

RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as they seek to improve patient experience of care, population health and the cost-effectiveness of health care. In the era of the Affordable Care Act and health system transformation, reaching these goals may require a focus on population-based health interventions from a variety of sectors as well as individually-focused clinical care. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that happen outside of the typical clinical setting.

HERC selects topics for its reports to guide public and private payers based on the following principles:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

Our reports are based on a review of the relevant research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat or manage disease at a population level. For some conditions, the HERC has reviewed evidence and identified effective interventions, but has not made coverage recommendations, as many of these policies are implemented in settings beyond traditional healthcare delivery systems.

GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are several elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by the Commission based on assessment of two independent reviewers from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the Commission.

Coverage question: Should noninvasive testing for liver fibrosis for chronic hepatitis C be recommended for coverage?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Hepatitis-related morbidity/ progression *(Critical outcome)*	Diagnostic strategies have not been directly compared to assess the effect on hepatitis-related morbidity or progression. FibroTest® and liver biopsy may offer similar prognostic information for overall mortality in patients with liver disease AUROCs for prognostic value for overall survival: • 0.80 for FibroTest® (95% CI 0.76 to 0.95) • 0.77 for biopsy (95% CI 0.62 to 0.93) • 0.68 for FIB-4 (95% CI 0.58 to 0.78) • 0.58 for APRI (95% CI 0.53 to 0.63) ●○○○ *(Very low confidence)* Liver stiffness measurements (LSM) offer prognostic information for: • Overall mortality	Non-invasive imaging tests are generally less costly than liver biopsy, but more costly than serum tests. Given that both serum and noninvasive tests are less invasive that biopsy, it is likely that more patients will be referred for, and receive treatment with noninvasive testing. Some patients who have noninvasive tests	Most patients would strongly prefer to have a noninvasive test over a liver biopsy in order to avoid the procedural risks associated with the biopsy. Policy makers will need to balance the value of this greater access to less sensitive/specific tests with the	Guidelines are mixed in their recommendations about the use of serum biomarker testing as an adjunct or alternative to imaging. Many of the serum biomarkers are commonly obtained and inexpensive. Many institutions

Coverage question: Should noninvasive testing for liver fibrosis for chronic hepatitis C be recommended for coverage?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	○ Elevated baseline LSM (HR 5.76, 95% CI 3.74 to 8.87) ○ Positive change in LSM (HR 1.19, 95% CI 1.11 to 1.28) • Development of hepatocellular carcinoma ○ RR of 16 to 45 for LSM >10 kPa ●○○○ *(Very low confidence)*	may also still require additional testing if findings are inconclusive. In cases where treatment decisions are based on the results of these tests, false positives may lead to high treatment costs; false negatives may lead to undertreatment or delayed treatment. MRE is much more expensive than the other imaging tests.	potential undertreatment or overtreatment that could occur as a result of the inferior accuracy of these tests compared to liver biopsy.	may only have one type of imaging modality available. It could be equally appropriate to do a second imaging test versus going straight to liver biopsy depending on the institution and availability of nearby alternatives.
Need for liver biopsy *(Critical outcome)*	No studies directly addressed whether the use of noninvasive tests reduce the need for liver biopsy. However, in clinical practice, these tests are used to replace liver biopsy. Therefore, their diagnostic operating characteristics, in comparison to liver biopsy, are reported here as AUROC for ≥F2, and tests with adequate diagnostic performance may be indirectly assumed to reduce the use of liver biopsy: Magnetic Resonance Elastography AUROC 0.88 (95%CI 0.84 to 0.91) ●●●○ *(Moderate confidence)* Transient Elastography AUROC 0.89 (95% CI 0.86 to 0.91) ●●●○ *(Moderate confidence)* Acoustic Radiation Force Impulse Imaging AUROC 0.88 (95% CI 0.81 to 0.96) ●●○○ *(Low confidence)* Shear Wave Elastography			

Coverage question: Should noninvasive testing for liver fibrosis for chronic hepatitis C be recommended for coverage?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	AUROC 0.88 (95% CI 0.85 to 0.91) ●●○○ *(Low confidence)* Real-time Tissue Elastography AUROC 0.69 (95% CI NR) ●○○○ *(Very low confidence)* Platelet count Median AUROC 0.71 (range 0.38 to 0.94) ●○○○ *(Very low confidence)* Platelet count Median AUROC 0.71 (range 0.38 to 0.94) ●○○○ *(Very low confidence)* Hyaluronic acid Median AUROC 0.75 (range 0.65 to 0.88) ●○○○ *(Very low confidence)* Age-platelet index Median AUROC 0.74 (range 0.64 to 0.79) ●●○○ *(Low confidence)* APRI Median AUROC 0.77 (range 0.58 to 0.95) ●○○○ *(Very low confidence)* AST-ALT ratio			

Coverage question: Should noninvasive testing for liver fibrosis for chronic hepatitis C be recommended for coverage?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	Median AUROC 0.59 (range 0.50 to 0.82) ●○○○ *(Very low confidence)* Bonacini index Median AUROC 0.66 (range 0.58 to 0.71) ●●○○ *(Low confidence)* ELF™ Median AUROC 0.81 (range 0.72 to 0.87) ●○○○ *(Very low confidence)* FIB-4 Median AUROC 0.74 (range 0.61 to 0.81) ●○○○ *(Very low confidence)* FibroIndex Median AUROC 0.76 (0.58 to 0.86) ●○○○ *(Very low confidence)* FibroMeter™ Median AUROC 0.82 (range 0.78 to 0.85) ●○○○ *(Very low confidence)* FIBROSpect® II Median AUROC 0.86 (range 0.77 to 0.95) ●○○○ *(Very low confidence)* FibroTest®			

Coverage question: Should noninvasive testing for liver fibrosis for chronic hepatitis C be recommended for coverage?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
	Median AUROC 0.79 (range 0.70 to 0.89) ●○○○ *(Very low confidence)* Forns index Median AUROC 0.76 (0.60 to 0.86) ●○○○ *(Very low confidence)* Hepascore® Median AUROC 0.79 (range 0.69 to 0.82) ●○○○ *(Very low confidence)* Pohl index Median AUROC 0.52 (range 0.52 to 0.53) ●●○○ *(Low confidence)*			
Quality of life *(Critical outcome)*	No data identified			
Testing-related adverse events *(Important outcome)*	No data identified			
Change in treatment plan *(Important outcome)*	No data identified			

Coverage question: Should noninvasive testing for liver fibrosis for chronic hepatitis C be recommended for coverage?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Balance of benefits and harms: Given the good (F2) and excellent (F3) performance of the recommended imaging tests and the potential harms of liver biopsy, the balance is strongly in favor of offering these tests as an option for patients for whom Hepatitis C direct-acting antiviral therapy is being considered. Because these tests sometimes return inconclusive results, additional testing including liver biopsy may still be required for some patients. Though they are inferior to the recommended imaging tests, blood tests also have a good performance at the F2 threshold and have a favorable balance when imaging tests are unavailable and biopsy is not required.				
Rationale: The diagnostic operating characteristic of the recommended imaging tests are good to excellent (defined as an AUROC ≥0.8). Patient-oriented health outcomes are not available. However, given the characteristics of the tests, the strong values and preferences for noninvasive tests when results are comparable, and the improved individual-level resource allocation, these tests are recommended for coverage. The strong recommendation for imaging tests when the cutoff is F3 is due to the excellent performance at this level of cutoff (defined as an AUROC ≥0.9) and the other factors in favor of their use. The weak recommendation at the F2 cutoff is based on "good" but not "excellent" performance, and the high societal cost of treating patients at levels of fibrosis who are not at short-term risk. The diagnostic operating characteristics of the blood tests are variable. Though tests recommended at the F2 threshold can accurately assess the fibrosis stage F2 or higher, they are inferior to the imaging tests at this level, and expert input suggests less clinically reliable, and so are recommended only when imaging tests are unavailable. No existing blood test can accurately distinguish between F2 and F3. Therefore, blood tests cannot be recommended (alone or in combination with noninvasive imaging tests) when the treatment planning revolves around an accurate diagnosis of F3. Many of the non-recommended blood tests have fair to poor operating characteristics regardless of the treatment threshold. MRE is much more expensive than the other imaging tests and thus is only recommended when available after two other imaging tests fail to return useful results.				
Recommendation: If a fibrosis score of ≥F2 is the threshold for antiviral treatment of Hepatitis C, the following are recommended for coverage *(weak recommendation)*: Imaging tests:				

Coverage question: Should noninvasive testing for liver fibrosis for chronic hepatitis C be recommended for coverage?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
• Transient elastography (FibroScan®) • Acoustic radiation force impulse imaging (ARFI) (Virtual Touch™ tissue quantification, ElastPQ) • Shear wave elastography (SWE) (Aixplorer®) Blood tests (only if imaging tests are unavailable): • Enhanced Liver Fibrosis (ELF™) • Fibrometer™ • FIBROSpect® II If a fibrosis score of ≥F3 is the threshold for antiviral treatment of Hepatitis C, one or more of the following are recommended for coverage *(strong recommendation*): Imaging tests: • Transient elastography (FibroScan®) • Acoustic radiation force impulse imaging (ARFI) • Shear wave elastography (SWE) Magnetic resonance elastography is recommended for coverage for ≥F2 or ≥F3 only when at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminant results, a second one is similarly indeterminant, contraindicated or unavailable, and MRE is readily available *(weak recommendation).* Noninvasive tests should be performed no more often than once per year *(weak recommendation).* Other imaging and blood tests are not recommended for coverage *(strong recommendation).*				

*The Quality of Evidence rating was assigned using information from the editing sources and judgments made by CEbP staff based on direction from the subcommittee.

Note: GRADE framework elements are described in Appendix A. A GRADE Evidence Profile is provided in Appendix B.

EVIDENCE OVERVIEW

Clinical background

Hepatitis C virus (HCV) is a major cause of liver disease in the United States, and chronic hepatitis C infection is the leading indication for liver transplantation (Centers for Disease Control and Prevention [CDC], 2016). The CDC estimates that 3.5 million people in the United States are currently infected with HCV, though the precise number is not known. One study cited by the CDC estimated that around 15,000 deaths were attributable to HCV in 2007. Well established modes of transmission for HCV infection include injection drug use and receipt of blood products prior to 1992. According to the CDC, the prevalence of HCV infection among injection drug users ranges from about 30% for younger users (aged 18 to 30) to 70-90% for older injection drug users.

The natural history of HCV infection is variable, and 15-25% of people will clear the infection and not develop chronic hepatitis C. Between 5% and 20% of those with HCV infection will develop cirrhosis, generally over the course of 20 to 30 years, and between 1% and 5% will die from HCV-related liver disease (CDC, 2016). There are no highly accurate tools to predict which individuals with chronic hepatitis C will go on to develop cirrhosis.

The United States Preventive Services Task Force recommends birth-cohort screening for hepatitis C for anyone born between 1945 and 1965. HCV testing is also recommended for those in high risk groups included people with a history of injection drug use, those who received blood products before 1992, those with HIV infection, and those born to HCV-positive mothers (CDC, 2016).

Before 2013, treatment for chronic hepatitis C relied on interferon and ribavirin, sometimes with the addition of a protease inhibitor in the case of genotype 1 infections. These treatments were long (24 to 48 weeks), entailed a high burden of adverse effects, and response rates were highly variable. The advent of direct-acting antiviral treatments (i.e. sofosbuvir, simeprevir, and others) appears to have improved the success rates (as measured by the surrogate marker of sustained virologic response at 12 weeks) and acceptability of treatment, though at considerable cost.

Traditionally, staging of chronic hepatitis C infection was done by examining histologic specimens from liver biopsies of the liver for evidence of fibrosis. The METAVIR fibrosis stage is the most commonly used measure for assessing the histologic degree of hepatic fibrosis:

- F0 = No fibrosis
- F1 = Portal fibrosis without septa
- F2 = Portal fibrosis with few septa
- F3 = Portal fibrosis with numerous septa without cirrhosis
- F4 = Cirrhosis

Progression from fibrosis to cirrhosis is associated with complications of end-stage liver disease including portal hypertension, portosystemic encephalopathy, and hepatocellular carcinoma. Noninvasive tests of liver fibrosis and cirrhosis have developed as an alternative to biopsy for staging chronic hepatitis C infection.

Indications

In patients with chronic hepatitis C infection, the likelihood of progression is closely correlated with the presence and severity of liver fibrosis (Chou et al., 2013). Thus, tests to diagnose the presence and ascertain the degree of fibrosis are indicated in the staging of patients with chronic hepatitis C, particularly when that information is relevant to decisions about HCV treatment. For instance, accurate determination of fibrosis stage is essential when treatment eligibility decisions are made on the basis of fibrosis severity. Beyond decisions about HCV treatment, tests to determine the presence of cirrhosis may be indicated in order to ensure appropriate supportive care and screening for complications of cirrhosis for these patients.

Until recently, the only options for staging fibrosis in hepatitis C patients was histological examination of the liver by percutaneous, transjugular, transfemoral, or laparoscopic surgical biopsy. However, biopsy entails procedural risks (including bleeding, infection, and pain), and the results are prone to sampling and interpretation errors. Despite these drawbacks, liver biopsy remains the "gold standard" for the diagnosis of fibrosis and cirrhosis (Chou et al., 2013).

The accuracy of noninvasive tests of liver fibrosis are measured against the reference standard of the results from a liver biopsy, using these definitions:

- **Sensitivity** refers to the proportion of patients who actually have the condition in question who have a positive test result.
- **Specificity** refers to the proportion of patients who really do not have the condition in question who have a negative test result.
- **Positive likelihood ratio** is the ratio of the probability of a positive test result in a patient with the condition to the probability of a positive test result in a patient without the condition. Likelihood ratios are most useful when the pre-test probability of the condition is known and the post-test probability at which treatment would be recommended is well established.
- **Negative likelihood ratio** is the ratio of the probability of a negative test in a patient with the condition to the probability of a negative test in a patient without the condition.
- The receiver operating curve **(ROC)** is a graphical illustration of the trade-off between sensitivity and specificity for an index diagnostic test (specifically for a test that has continuous rather than binary, or yes/no results) compared to a reference standard. The "index" test refers to the test that we are looking at to see how good it is. The reference standard has sometimes been referred to as the "gold standard," but given that some reference standards are not themselves perfectly accurate the terminology has shifted to "reference standard."
- The area under the receiver operating curve **(AUROC)** is an overall measure of how well the index test compares to the reference standard across a range of possible cutoffs. An index test that has cutoff value that allows perfect sensitivity and specificity (i.e. perfect classification of those with and without the condition) would have an AUROC of 1.0, while an AUROC of 0.5 represents a useless test (no better than a coin flip, on average). A test with an

AUROC of 0.80-0.89 is generally regarded as a good test, while tests with an AUROC >0.90 are regarded as excellent tests. These distinctions are conventional, but arbitrary.

Technology description

Noninvasive techniques for staging liver fibrosis include imaging and blood tests. Five types of imaging tests are available: transient elastography (TE), acoustic radiation force impulse imaging (ARFI), shear wave elastography (SWE), magnetic resonance elastography (MRE), and real-time tissue elastography (RTE).

Transient Elastography (FibroScan®) measures the velocity of a low-frequency (50 Hz) elastic shear wave propagating through the liver. The velocity of the wave indicates the tissue stiffness, with the stiffer the tissue, the faster the shear wave propagates. The patient lies supine during the procedure, which takes less than five minutes.

Acoustic radiation force impulse imaging (Virtual Touch™ tissue quantification, ElastPQ) measures the speed of short-duration acoustic pulses that propagate shear waves and generate localized displacements in liver tissue. Commercial ultrasound machines can be easily modified to implement ARFI.

Shear wave elastography (Aixplorer® Supersonic Imagine) creates ultrasonic beams that are focused on liver tissues, and a very high frame rate ultrasound imaging sequences monitors the transient propagation of the shear waves in real time. This procedure can be implemented on commercial ultrasound machines.

Magnetic resonance elastography images the propagation characteristics of a shear wave in the liver using a modified phase-contrast method. Almost the entire liver can be analyzed with MRE, and it can be used effectively in patients with obesity or ascites. This procedure is more costly and more time consuming than the other imaging techniques.

Real-time tissue elastography constructs elasticity images of the liver by measuring the tissue strain induced by compression from a high-frequency ultrasound scanner. Tissue compression produces strain in the tissue, where the strain is smaller in harder tissue than in softer tissue.

Five proprietary blood testing protocols are available in the U.S., which use a combination of biochemical markers and patented algorithms to determine fibrosis stage. There are 25 additional blood tests that are not proprietary. The components of these blood tests are shown in Table 1 below. The most common components of the blood tests are platelet count, aspartate aminotransferase (AST), and alanine aminotransferase (ALT). About half of the tests include patient's age in the algorithm.

Table 1: Blood Tests for Measuring Liver Fibrosis in Patients with Hepatitis C

Blood tests	Components of test/algorithm
Proprietary tests	
ELF™ Test (Enhanced Liver Fibrosis)	Hyaluronic acid, tissue inhibitor of metalloproteinase 1, and procollagen III amino terminal peptide
FibroMeter™	Alanine aminotransferase (ALT), α_2-macroglobulin, gamma-glutamyl transpeptidase (GGT), aspartate aminotransferase (AST), platelet count, prothrombin index, urea, and patient's age and gender
FIBROSpect® II	Hyaluronic acid, tissue inhibitor of metalloproteinase, and α_2-macroglobulin
FibroSure® (FibroTest®)	α2-macroglobulin, haptoglobin, apolipoprotein A1, total bilirubin and gamma-glutamyl transpeptidase (GGT), and patient's age and gender ActiTest® is similar, with the addition of alanine aminotransferase (ALT)
Hepascore® (FibroScore®)	α_2-macroglobulin, hyaluronic acid, gamma-glutamyl transferase (GGT), bilirubin, and patient's age and gender
Non-proprietary tests	
Age–platelet index	Platelet count and patient's age
AST–platelet ratio index (APRI)	Platelet count and aspartate aminotransferase (AST)
AST–ALT ratio	Aspartate aminotransferase (AST) and alanine aminotransferase (ALT)
Cirrhosis discriminant score (Bonacini index)	Platelet count, aspartate aminotransferase (AST), alanine aminotransferase (ALT), prothrombin index, presence of ascites, and presence of spider angiomata
FIB-4	Platelet count, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and patient's age
Fibro-α score	Platelet count, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and α-Fetoprotein
FibroIndex	Platelet count, aspartate aminotransferase (AST), and gamma globulin
Fibronectin discriminant score	Platelet count, aspartate aminotransferase (AST), albumin, and fibronectin
FibroQ	Platelet count, aspartate aminotransferase (AST), alanine aminotransferase (ALT), prothrombin index, and patient's age
Fibrosis–cirrhosis index	Platelet count, Alkaline phosphatase, bilirubin, and albumin
Fibrosis index	Platelet count and albumin

Blood tests	Components of test/algorithm
Fibrosis probability index (Sud index)	Aspartate aminotransferase (AST), total cholesterol, insulin resistance, alcohol intake, and patient's age
Fibrosis–protein index	α_2-macroglobulin and hemopexin
Fibrosis Routine Test	Platelet count, aspartate aminotransferase (AST), α-Fetoprotein, albumin, and patient's age
Forns index	Platelet count, gamma-glutamyl transpeptidase (GGT), cholesterol, and patient's age
Globulin–albumin ratio	Globulin and albumin
Göteborg University Cirrhosis Index (GUCI)	Platelet count, aspartate aminotransferase (AST), and prothrombin index
HALT-C model (Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis)	Platelet count, tissue metalloproteinase inhibitor 1 (TIMP-1), and hyaluronic acid
King's score	Platelet count, aspartate aminotransferase (AST), international normalized ratio (INR), and patient's age
Lok index	Platelet count, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and international normalized ratio (INR)
MP3 score	Matrix metalloproteinase-1 (MMP-1) and procollagen III propeptide
Pohl index	Platelet count, aspartate aminotransferase (AST), and alanine aminotransferase (ALT)
Sabadell NIHCED index (Noninvasive Hepatitis-C–Related Cirrhosis Early Detection)	Platelet count, aspartate aminotransferase (AST), alanine aminotransferase (ALT), prothrombin time, right hepatic lobe atrophy, splenomegaly, caudate lobe hypertrophy, and patient's age
Significant fibrosis index	Haptoglobin, α_2-macroglobulin, tissue metalloproteinase inhibitor 1 (TIMP-1), matrix metalloproteinase-2 (MMP-2), and gamma-glutamyl transpeptidase (GGT)
Zeng index	α_2-macroglobulin, gamma-glutamyl transpeptidase (GGT), hyaluronic acid, and patient's age

Adapted from Chou & Wasson (2013)

Key Questions and Outcomes

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods please see Appendix C.

1. What is the comparative effectiveness of noninvasive tests for the diagnosis and management of hepatic fibrosis in patients with chronic hepatitis C?
2. Does the comparative effectiveness of noninvasive tests of liver fibrosis in patients with chronic hepatitis C vary based on:
    a. Duration of infection
    b. Fibrosis score
    c. Body habitus
    d. Operator/interpreter training or experience
    e. Co-existence of other etiologies of liver disease (e.g., non-alcoholic steatohepatitis)
3. What are the comparative diagnostic operating characteristics of tests of liver fibrosis?
4. What is the evidence for the timing of the initial testing for fibrosis and intervals for subsequent reassessment of fibrosis?

Critical outcomes selected for inclusion in the GRADE table were hepatitis-related morbidity/progression, need for liver biopsy, and quality of life. Important outcomes selected for inclusion in the GRADE table were testing-related adverse events and change in treatment plan (especially a decision to begin antiviral therapy).

Evidence review

We identified no randomized controlled evidence on the use of noninvasive tests of liver fibrosis compared to liver biopsy with respect to clinical outcomes in hepatitis C infection.

We identified a poor quality systematic review and meta-analysis of six studies reporting on the relative prognostic value of liver biopsy, FibroTest®, FIB-4, and APRI for predicting overall survival. All of the tests offered statistically significant prognostic value for overall survival with AUROCs of 0.58 for APRI (95% CI 0.53 to 0.63), 0.68 for FIB-4 (95% CI 0.58 to 0.78), 0.77 for biopsy (95% CI 0.62 to 0.93), and 0.80 for FibroTest® (95% CI 0.76 to 0.95). The authors did not describe the methodologic rigor of the included studies. There was significant heterogeneity in the included studies (for example, in one study of APRI and FIB-4 in HCV patients, 68% of the patients had HIV co-infection). Lastly, the review was authored by the inventor of the FibroTest® and two employees of the company that market the test.

A more recent study (Vergniol et al., 2014) examined the prognostic value of evolving measurements of liver stiffness. In this study, about 1,025 people with chronic hepatitis C and two recorded measurements of liver stiffness (separated by >1,000 but <1,500 days) recorded between 2004 and 2008 were included. The average age of included patients was 52 years, half were men, the average BMI was 25 kg/m^2, and about 12% reported excessive alcohol consumption. During the mean follow-up period of three years (after the second measurement of liver stiffness), 16% of patients achieved sustained virologic response from HCV treatment. Survival data was available for 95% of patients; of those, 35 patients had died and 7 had undergone liver transplantation. Twenty-one of the deaths were from liver-related causes. In the univariate analysis, several factors were associated with statistically significantly increased hazard ratios for death: age (HR 1.03, 95% CI 1.01 to 1.06), male sex (HR 2.25, 95% CI 1.17 to 4.43), baseline liver stiffness measurement (HR 4.27, 95% CI 2.94 to 6.22), follow-up liver stiffness measurement (HR 5.47, 95% CI 3.82 to 7.84), and change in liver stiffness measurement (HR 1.25, 95% CI

1.16 to 1.36). Unusually, alcohol abuse appeared to have a protective effect in this study (HR 0.42, 95% CI 0.18 to 0.97). In the multivariate analysis, baseline liver stiffness measurement (HR 5.76, 95% CI 3.74 to 8.87), change in liver stiffness measurement (HR 1.19, 95% CI 1.11 to 1.28), and achievement of SVR (HR 0.19, 95% CI 0.05 to 0.80) were statistically significant independent predictors of death. Overall, the authors concluded that patients with low-baseline liver stiffness measurements, those who achieve SVR, and those with non-cirrhotic baseline liver stiffness measurements and stable or decreasing measurements at follow-up all have an excellent prognosis. Conversely, patients with cirrhotic baseline liver stiffness measurement or those with advancing significant fibrosis have a poorer prognosis.

Cross-sectional data has correlated liver stiffness measurements by TE with the presence of portal hypertension (Kim et al., 2013), but TE has not been demonstrated in prospective studies to predict clinical outcomes related to portal hypertension in hepatitis C patients. A prospective cohort study of nearly 900 Japanese patients with HCV investigated the correlation between liver stiffness measurements by TE and the development of hepatocellular carcinoma (HCC) over a mean follow-up of 3 years (Masuzaki et al., 2009). Compared to a reference value of less than 10 kilopascals (kPa), various cut-offs of liver stiffness were associated with relative risk of HCC ranging from 16 to 45.

The remainder of the identified systematic reviews summarized diagnostic accuracy studies of various tests compared to a reference standard of liver biopsy. Most of these studies report diagnostic performance by way of sensitivity, specificity, and AUROC. A test that perfectly matches the diagnoses assigned by the reference test would have an AUROC of 1. Conventionally, tests with an AUROC of 0.9 to 1 are considered excellent, 0.8-0.89 are good, 0.7-0.79 are fair, and below 0.7 are poor, and though widely used, these distinctions are arbitrary.

Magnetic Resonance Elastography

Singh et al., 2015

This is a good quality systematic review and meta-analysis of patient-level data to determine the diagnostic performance of magnetic resonance elastography (MRE) compared to liver biopsy as the reference standard. The use of patient-level data in the meta-analysis allowed them to perform stratified analyses to determine if the diagnostic performance of MRE varied based on sex, obesity, or the etiology of the liver disease, and also allowed the authors to reduce the risk of spectrum bias and standardize diagnostic cut-offs for various fibrosis stages. The authors included 12 studies that met inclusion criteria and for which they were able to obtain the individual participant data (n=697). Overall, the included studies were judged to be at low to moderate risk of bias. Three of the studies did not adequately report on blinding procedures, raising the possibility of review bias.

Among the included patients, the average age was 55 years old, the majority were males (60%), and the average BMI was 27. Nearly half of the participants had HCV-related liver disease (47%), with smaller numbers of patients with HBV, NAFLD, ALD, AIH, or other miscellaneous etiologies. The distribution of fibrosis level on biopsy was 19.5% F0, 19.4% F1, 15.5% F2, 15.9% F3, and 29.7% F4.

The diagnostic operating characteristics of MRE from the meta-analysis, including both positive and negative likelihood ratios, are reported in Table 2 below.

Table 2: Diagnostic Operating Characteristics of MRE

Fibrosis Stage	AUROC (95% CI)	Sensitivity	Specificity	Positive LR	Negative LR
Any: ≥F1	0.84 (0.76 - 0.92)	0.73	0.79	3.48	0.34
Significant: ≥F2	0.88 (0.84 - 0.91)	0.79	0.81	4.16	0.26
Advanced: ≥F3	0.93 (0.90 - 0.95)	0.85	0.85	5.67	0.18
Cirrhosis: F4	0.92 (0.90 - 0.94)	0.91	0.81	4.79	0.11

In the subgroup and sensitivity analysis, the diagnostic performance of MRE did not significantly vary based on sex, presence of obesity, or etiology of liver disease. In this review, MRE had a failure rate of about 4%, and this was most commonly due to interference from hepatic iron overload.

Overall, the authors concluded that MRE was highly accurate for diagnosing fibrosis and cirrhosis regardless of BMI or the etiology of chronic liver disease.

Transient Elastography

Steadman et al., 2013

This is a good-quality, comprehensive technology assessment of transient elastography (TE) for the diagnosis of significant fibrosis in adults with chronic liver disease. Overall, 57 studies reporting diagnostic performance of TE compared with liver biopsy were included. The results were stratified by the etiology of liver disease, and 13 of the included studies were in patients with HCV. The included studies were methodologically rigorous with the authors rating nearly 80% of them as high quality.

The diagnostic operating characteristics of TE (in HCV patients only) from the meta-analysis are reported in Table 3 below.

Table 3: Diagnostic Operating Characteristics of Transient Elastography

Fibrosis Stage	AUROC (95% CI)	Sensitivity	Specificity	Positive LR	Negative LR
Significant: ≥F2	0.89 (0.86 - 0.91)	0.76	0.86	5.43	0.28
Advanced: ≥F3	0.92 (0.89 - 0.94)	0.88	0.91	9.7	0.13
Cirrhosis: F4	0.94 (0.92 - 0.96)	0.85	0.91	9.4	0.16

The authors also performed a basic economic analysis to calculate the incremental cost per correct diagnosis gained by liver biopsy over TE. In the subgroup of patients with HCV, the incremental cost per correct diagnosis using biopsy ranged from $1,861 for patients with F2 disease to $3,260 for patients with F3 disease. The authors were careful to note that their economic modeling does not account for the practice of monitoring progression of liver fibrosis and observe that the common practice in Alberta, Canada is yearly TE and biopsy every 3-5 years.

Overall, the authors concluded that TE was an accurate method for diagnosing fibrosis or cirrhosis and was less costly than liver biopsy.

Acoustic Radiation Force Impulse Imaging

Nierhoff et al., 2013

This is a good-quality systematic review and meta-analysis of the diagnostic operating characteristics of ARFI in patients with chronic liver disease using liver biopsy as the reference standard. The authors included 36 studies (both published manuscripts and abstracts) of nearly 4,000 patients. Among the included studies, 7 examined only patients with HCV as the etiology of their liver disease while another 18 studies reported on populations with mixed etiologies of chronic liver disease, including HCV. The methodologic quality of the included studies was mixed, and about half of the studies had potential flaws related to spectrum bias (bias introduced because the range and distribution of disease severity in the study is not representative of the overall population of people with the condition) and review bias (bias introduce when the interpreter of the index test is already aware of the result of the reference test, or vice-versa). The main reported measure of diagnostic performance was AUROC. The results of the meta-analysis of the HCV only and mixed etiology studies are reported in Table 4 below.

Table 4: AUROC of Acoustic Radiation Force Impulse (ARFI) Imaging Tests

Fibrosis Stage	AUROC – HCV only studies (95% CI)	AUROC – Mixed studies (95% CI)
Significant: ≥F2	0.88 (0.81 - 0.96)	0.83 (0.80 - 0.86)
Advanced: ≥F3	0.93 (0.89 - 0.97)	0.87 (0.85 - 0.90)
Cirrhosis: F4	0.92 (0.85 - 0.99)	0.91 (0.89 - 0.93)

One possible explanation for the poorer diagnostic performance in the mixed studies is the finding in subgroup analysis that higher BMI is associated with reduced diagnostic accuracy and a higher failure rate for testing.

Overall, the authors concluded that the diagnostic performance of ARFI is good to excellent for detecting fibrosis and cirrhosis. The authors also note that their findings are consistent with those of an earlier, smaller meta-analysis of ARFI using individual participant data.

Acoustic Radiation Force Impulse (ARFI) vs. Transient Elastography (TE)

Bota et al., 2013

This is a good-quality systematic review and meta-analysis of studies comparing ARFI and TE to a reference standard of liver biopsy for the evaluation of fibrosis. The authors included 13 trials; 10 of the trials reported diagnostic accuracy of ARFI and TE for the diagnosis of significant fibrosis (≥F2), and all the trials reported diagnostic accuracy for cirrhosis (F4). The etiology of liver disease in each study was variable, and all but one study included patients with chronic hepatitis C. The authors observed that failure rates (i.e. inability to obtain any valid measurements) were higher for TE (6.6%) than ARFI (2.1%), and five of the trials only included patients with valid ARFI and TE. The authors' risk of bias assessment for most studies was low. The results of the meta-analysis are reported in Table 5 below.

Table 5: Diagnostic Operating Characteristics of ARFI and TE

Test and Fibrosis Stage	AUROC (95% CI)	Sensitivity	Specificity	Positive LR	Negative LR
ARFI: ≥F2	0.85 (0.82 - 0.88)	0.74	0.83	4.29	0.31
TE: ≥F2	0.87 (0.83 - 0.89)	0.78	0.84	4.79	0.26
ARFI: F4	0.93 (0.91 - 0.95)	0.87	0.87	6.48	0.15
TE: F4	0.93 (0.91 - 0.95)	0.89	0.87	6.79	0.13

Overall, the authors concluded that there were no significant differences in the diagnostic accuracy of ARFI and TE. They note that while the higher failure rate for TE is concerning, new and more sensitive probes may mitigate this limitation.

Blood Tests

Dozens of blood tests and related interpretive indices or scores have been proposed for the diagnosis of fibrosis or cirrhosis in patients with HCV. The components of these tests are discussed in detail in the technology description section of this report.

Chou & Wasson, 2013

This is a good-quality systematic review of blood tests for the diagnosis of fibrosis and cirrhosis in patients with HCV. The authors did not perform a meta-analysis but present results for measures of diagnostic accuracy as medians and ranges. The number of studies for each test and the authors' GRADE assessment of the strength of evidence are provided in Table 6 below.

The results of the review of these tests are also summarized in Table 6. Because of the large number of tests as well as the various cut-offs used for each test, only the AUROC (median and range) are presented in this table.

Table 6: Studies of Blood Tests for Liver Fibrosis

Test	Number of studies	Strength of evidence	Fibrosis (≥F2) AUROC median (range)	Cirrhosis AUROC median (range)
Platelet count	18	Moderate	0.71 (0.38 - 0.94)	0.89 (0.64 - 0.99)
Hyaluronic acid	8	Moderate	0.75 (0.65 - 0.88)	0.90 (0.80 - 0.97)
Age-platelet index	11	Moderate	0.74 (0.64 - 0.79)	0.86 (0.64 - 0.91)
AST-platelet ratio index	7	High	0.77 (0.58 - 0.95)	0.84 (0.54 - 0.97)
AST-ALT ratio	32	High	0.59 (0.50- 0.82)	0.72 (0.52 - 0.91)
Bonacini index	12	Moderate	0.66 (0.58 - 0.71)	0.74 (0.61 - 0.91)
ELF™	8	Moderate	0.81 (0.72 - 0.87)	0.88 (0.78 - 0.91)
FIB-4	19	Moderate	0.74 (0.61 - 0.81)	0.87 (0.83 - 0.92)
FibroIndex	9	Moderate	0.76 (0.58 - 0.86)	0.86 (0.78 - 0.92)
Fibrometer™	8	Moderate	0.82 (0.78 - 0.85)	0.91 (0.89 - 0.94)
FIBROSpect® II	7	Low	0.86 (0.77 - 0.90)	NR
FibroTest®	32	High	0.79 (0.70 - 0.89)	0.86 (0.71 - 0.92)
Forns index	22	High	0.76 (0.60 - 0.86)	0.87 (0.85 - 0.91)
GUCI	5	Low	NR	0.82 (0.78 - 0.86)
Hepascore®	12	High	0.79 (0.69 - 0.82)	0.89 (0.88 - 0.94)
Lok index	10	Moderate	NR	0.80 (0.61 - 0.91)
Pohl index	12	Low	0.52 (0.52 - 0.53)	0.65 (0.64 - 0.66)

The Chou & Wasson review also summarized the results of trials making direct comparisons between APRI or FibroTest® and various other blood tests. Very few of these direct comparisons showed substantial differences in the median AUROC for fibrosis, but median differences in excess of 0.05 are reported in Table 7 below. Only one of the direct comparisons (APRI vs. AST-ALT ratio) for the diagnosis of cirrhosis exceed a median difference in AUROC of greater than 0.05; in those studies APRI was more accurate than the AST-ALT ratio.

Table 7. Studies of Direct Comparisons between Two Blood Tests

Number of studies	Test A AUROC median	Test B AUROC median	Median difference (range)
13	APRI 0.76	AST-ALT ratio 0.58	0.17 (-0.06 to 0.23)
4	APRI 0.74	Bonacini index 0.66	0.08 (0.07 to 0.09)
8	APRI 0.79	Fibrometer™ 0.84	-0.06 (-0.07 to -0.02)
8	APRI 0.76	Platelet count 0.67	0.08 (-0.06 to 0.53)
3	APRI 0.69	Pohl index 0.52	0.17 (0.13 to 0.23)
3	FibroTest® 0.78	FibroIndex 0.72	0.08 (0.02 to 0.10)

The authors also include 9 studies that report on the use of combinations of blood tests or indices. Four studies reported on diagnostic performance of the Sequential Algorithm for Fibrosis Evaluation that combines results from APRI and FibroTest®. In two studies of patients with fibrosis (≥F2), the algorithm had an AUROC of 0.90 and 0.94. In 3 studies of cirrhosis, the algorithm had a median AUROC of 0.87. The remaining combinations of tests or indices were only studied in single trials.

The authors point out several limitations of the review, the most important of which is the binary interpretation of presence or absence of clinically significant fibrosis. As they note, "Measures that incorporate the accuracy of tests at each fibrosis stage would therefore be more informative than estimates based on dichotomized classifications." Additionally, because nearly all the included studies grouped patients with both lesser stages of fibrosis and cirrhosis, it was not possible to ascertain the diagnostic performance of blood tests for less severe fibrosis independent from the diagnostic accuracy of the full spectrum of significant fibrosis, and distinguishing between F2 and F3 is not possible. Overall, the authors conclude that a variety of blood tests are moderately useful for the identification of clinically significant fibrosis in patients with HCV.

Shear Wave Elastography

Li et al., 2016

This is a good-quality systematic review and meta-analysis of diagnostic accuracy studies of real-time shear wave elastography (SWE) for staging liver fibrosis. The authors identified eight studies with a total of 934 patients comparing SWE to a reference standard of liver biopsy. Most patients in the included studies had chronic viral hepatitis, but the precise breakdown was not provided. The included studies were generally at low risk of bias, though three were judged to be susceptible to disease progression bias because of the time difference between the two tests. The diagnostic operating characteristics from the meta-analysis are reported in Table 8 below.

Table 8. Diagnostic Operating Characteristics for Shear Wave Elastography

Fibrosis Stage	AUROC (95% CI)	Sensitivity	Specificity	Positive LR	Negative LR
Significant: ≥F2	0.88 (0.85 - 0.91)	0.85	0.81	4.47	0.18
Advanced: ≥F3	0.94 (0.92 - 0.96)	0.90	0.81	4.73	0.12
Cirrhosis: F4	0.92 (0.89 - 0.94)	0.87	0.88	7.25	0.15

The authors note that the primary limitations of their review include the small number of studies and the inability to perform subgroup analysis by etiology of chronic liver disease.

The authors observe that compared with reported diagnostic accuracy of other modalities, SWE is comparable to TE and ARFI for diagnosis of cirrhosis, and comparable to ARFI but better than TE for the diagnosis of significant fibrosis (≥F2). Overall, the authors conclude that the diagnostic accuracy of SWE for fibrosis staging is good.

Real-Time Tissue Elastography

Kobayashi et al., 2014

This is a good-quality systematic review and meta-analysis of diagnostic accuracy studies of real-time tissue elastography (RT-TE) compared to a reference standard of liver biopsy. The authors identified 15 trials including over 1,600 patients. Ten of 15 studies included patients with HCV. The authors expressed concerns over the risk of bias in several included studies related to patient selection bias and the absence of pre-specified cut-off values for the index tests. They also identified possible publication bias in their funnel plots. The meta-analytic results for sensitivity and specificity are reported in Table 9 below.

Table 9. Diagnostic Operating Characteristics for Real-Time Tissue Elastography

Fibrosis Stage	AUROC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	Positive LR (95% CI)	Negative LR (95% CI)
Significant: ≥F2	0.69 (NR)	0.79 (0.75 - 0.83)	0.76 (0.68 - 0.82)	3.29 (NR)	0.27 (NR)
Advanced: ≥F3	0.86 (NR)	0.82 (0.75 - 0.88)	0.81 0.72 - 0.88)	4.31 (NR)	0.22 (NR)
Cirrhosis: F4	0.72 (NR)	0.74 (0.63 - 0.82)	0.84 0.79 - 0.88)	4.6 (NR)	0.30 (NR)

Overall, the authors conclude that, “RTE is not highly accurate for any cut-off stage of fibrosis.”

Direct Comparisons of FibroTest®, FIB-4, APRI, and TE

Houot et al., 2016

This is a poor-quality systematic review and meta-analysis of trials making direct comparisons between FibroTest®, APRI, FIB-4, and TE compared to a reference standard of liver biopsy. The authors identified 71 trials, of which 37 included only patients with HCV. The main purpose of the review was to determine whether there were differences between the AUROC of these tests for the diagnosis of advanced fibrosis (defined here as ≥F2) or cirrhosis. The review did not provide information on the methodologic quality of the included studies. The authors applied three meta-analytic methods to ascertain whether the differences in test performance were statistically significant: an indirect pooled AUROC difference, a standard pooled AUROC difference, and a Bayesian pooled AUROC difference. Among the HCV-only studies, the differences in AUROC for most comparisons were generally small (<0.05). In the indirect pooled analysis, only one comparison showed a statistically significant difference in favor of TE over APRI for diagnosis of cirrhosis. In the standard pooled analysis FibroTest® was favored over TE and APRI for diagnosis of fibrosis; TE and FIB-4 were favored over APRI for the diagnosis of cirrhosis. In the Bayesian pooled analysis, FibroTest® was favored over APRI for the diagnosis of fibrosis and TE and FIB-4 were favored over APRI for the diagnosis of cirrhosis. This review is subject to potential conflict of interest as the senior author is the inventor of FibroTest® and the study was funded in part by BioPredictive, the company that markets FibroTest®.

Factors Influencing Accuracy of TE

Perazzo et al., 2015

This is a narrative review article that summarizes research on various factors that influence the accuracy and interpretation of transient elastography. The authors identify four factors that are associated with overestimation of fibrosis by TE: heightened necroinflammatory activity as denoted by alanine transaminases greater than 10 times the upper limit of normal, extrahepatic cholestasis and hepatic congestion, non-fasting status, and the presence of severe steatosis. The authors also note that the reliability of TE measurements is modified by operator experience and propose a definition of an experienced operator as greater than 100 examinations. Similarly, large ranges of inter-observer variability are reported in the literature and discrepancies between assessments of adjacent fibrosis stages are more common. The authors suggest that longitudinal follow-up and examination by the same experienced operator may prove most accurate.

We did not identify any evidence that addresses the question of initial timing of staging or the appropriate intervals for re-staging using non-invasive tests. The systematic review of TE did observe that the common practice in Alberta, Canada is to perform non-invasive tests to assess fibrosis stage every 3 to 5 years.

EVIDENCE SUMMARY

Although an imperfect test itself, liver biopsy remains the reference standard by which noninvasive tests of liver fibrosis and cirrhosis are judged. There is no direct comparative evidence that examines the effects of different diagnostic strategies on the predetermined clinical outcomes:

- Hepatitis-related morbidity/progression
- Need for liver biopsy
- Quality of life
- Testing-related adverse events
- Change in treatment plan

Furthermore, there is only sparse evidence on the value and reliability of prognostic information obtained from noninvasive tests. However, there are a large number of studies comparing the diagnostic accuracy of noninvasive tests of liver fibrosis to the reference standard of liver biopsy. Many of these studies (see Appendix D) demonstrated good or excellent performance of non-invasive tests for the detection of various levels of fibrosis; in general, imaging studies appear to have greater ability to distinguish between intermediate stages of fibrosis (i.e. between F2 and F3), while blood tests appear to be suitable for establishing the presence of significant fibrosis (≥F2) or cirrhosis (F4).

OTHER DECISION FACTORS

Resource Allocation

The price of noninvasive tests is generally significantly less than liver biopsy and avoids the costs associated with harms from liver biopsy. However, noninvasive testing is likely to be done at a higher frequency than liver biopsy and the increased number of total procedures may somewhat reduce the cost-savings associated with avoiding liver biopsy. The more significant cost driver is the impact noninvasive testing may have on determining the eligible population for treatment with hepatitis C. Health plans have prioritized treatment of hepatitis C patients with the newer expensive medications both because of the high cost of these medications and the prevalence of chronic hepatitis C infection in the general population. The cutoff point for some plans in Oregon include only treating persons with a score of F3 or above. This requires testing that can accurately distinguish between the cutoff points for treatment. If a test has a high false positive rate, that would lead more people into a hepatitis C treatment pathway (increasing overall costs of the population in the near term). If a test has a high false negative rate, then people with more advanced fibrosis who may particularly benefit from treatment would not qualify for treatment (decreasing health system costs, but at the expense of fewer eligible people receiving appropriate treatment).

Values and preferences

Patients would highly value avoiding an invasive procedure as long as the information provided by a noninvasive test was comparable. There would be minimal variability in this preference. From a population perspective, it would be very important that these tests can accurately distinguish between those persons who would benefit the most from the very expensive treatment versus others who may be able to delay or avoid treatment altogether.

POLICY LANDSCAPE

Quality measures

No quality measures were identified when searching the National Quality Measures Clearinghouse.

Payer coverage policies

The Oregon Medicaid fee-for-service Approval Criteria for Hepatitis C Direct-Acting Antivirals requires liver fibrosis staging by either:

- A biopsy, transient elastography (FibroScan®), or serum test (FibroSure®) to indicate advanced fibrosis (METAVIR F3) or cirrhosis (METAVIR F4)
- Radiologic, laboratory (APRI score >1.5 or FIB-4 score >3.25), or clinical evidence (ascites, portal hypertension) of cirrhosis

The Washington Health Care Authority outlines the treatment policy for patients with HCV, with the accepted diagnostic tests for liver damage including imaging procedures (FibroScan®, ARFI, SWE) and blood tests (FibroSure®, APRI). The Table 10 below shows the allowed tests and cutoffs used to stage liver fibrosis to determine hepatitis C treatments.

Table 10: Washington Health Care Authority Accepted Diagnostic Tests and Procedures to Stage Liver Damage in Patients with Chronic HCV Infection

METAVIR Score	Biopsy	FibroScan®	Elastography (ARFI/PSWE)	FibroSure®	APRI	Other Imaging
F4	F4	≥ 12.5 kPa	≥ 2.34 m/s	≥ 0.75	≥ 2.0	Cirrhosis
F3	F3	9.6 - 12.4 kPa	2.01 - 2.33 m/s	0.58 - 0.74	1.5 - 1.9	
F2	F2	7.1 - 9.5 kPa	1.38 - 2.0 m/s	0.49 - 0.57	1.0 - 1.4	
F1/0	F1/0	≤ 7.0 kPa	≤ 1.37 m/s	≤ 0.48	≤ 0.9	

On May 27, 2016, a United States District Court issued a preliminary injunction requiring the Washington Medicaid program to cover direct-acting antiviral medications for Medicaid clients with hepatitis C, regardless of the extent of liver fibrosis.

Coverage policies for noninvasive tests of liver fibrosis were searched for four commercial payers: Aetna, Cigna, Moda, and Regence. Transient elastography (FibroScan®) is covered by three of these payers: Aetna, Cigna, and Moda. MRE for staging liver fibrosis is covered by only Moda. None of the other imaging tests are covered by these payers. Three of the four payers do not cover the blood tests for staging liver fibrosis. Moda Health covers the blood tests FibroSure®, FIBROSpect®, APRI, ActiTest®, and Hepascore®.

Aetna's precertification criteria for direct-acting antivirals require the staging of liver disease by liver biopsy, METAVIR scores, FibroScan® score, APRI score, radiological imaging consistent with cirrhosis (i.e., evidence of portal hypertension), or physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician. The Regence Medical Policy Manual states that, "Liver biopsy is

typically recommended prior to the initiation of antiviral therapy." Coverage policies for direct-acting antivirals for Cigna and Moda do not indicate specific methods for staging of liver fibrosis.

For Medicare, no National Coverage Determinations or Local Coverage Determinations related to noninvasive tests for liver fibrosis were identified.

Professional society guidelines

American Association for the Study of Liver Disease (AASLD) and Infectious Disease Society of America (IDSA) Guideline, 2016

The AASLD and IDSA guideline endorses the use of biopsy, imaging, and/or noninvasive markers to evaluate advanced fibrosis in HCV patients for treatment planning and to ascertain whether additional screening and management of cirrhosis is needed (Class I, Level A). It also endorses the continued monitoring of liver disease in those who defer treatment, but does not specify the use of noninvasive tests or provide an optimal interval for re-assessment.

Regarding noninvasive tests, the AASLD and IDSA guideline makes the following statements:

- "No single method is recognized to have high accuracy alone and each test must be interpreted carefully. A recent publication of the Agency for Healthcare Research and Quality found evidence in support of a number of blood tests; however, at best, they are only moderately useful for identifying clinically significant fibrosis or cirrhosis."
- "Vibration-controlled transient liver elastography is a noninvasive way to measure liver stiffness and correlates well with measurement of substantial fibrosis or cirrhosis in patients with chronic HCV infection. The measurement range does overlap between stages."
- "The most efficient approach to fibrosis assessment is to combine direct biomarkers and vibration-controlled transient liver elastography. A biopsy should be considered for any patient who has discordant results between the 2 modalities that would affect clinical decision making. For example, one shows cirrhosis and the other does not. The need for liver biopsy with this approach is markedly reduced."
- "Alternatively, if direct biomarkers or vibration-controlled transient liver elastography are not available, the AST-to-platelet ratio index (APRI) or FIB-4 index score can help, although neither test is sensitive enough to rule out substantial fibrosis. Biopsy should be considered in those in whom more accurate fibrosis staging would impact treatment decisions. Individuals with clinically evident cirrhosis do not require additional staging (biopsy or noninvasive assessment)."

European Association for the Study of the Liver (EASL) and Asociación Latinoamericano para el Estdio del Hígado (ALEH), 2015

This is a comprehensive clinical practice guideline on the use of noninvasive tests for evaluating liver disease across a variety of etiologies. In general, EASL/ALEH endorse the use of noninvasive tests of liver fibrosis. Specific recommendations and statements include:

- "Non-invasive tests should always be interpreted by specialists in liver disease, according to the clinical context, considering the results of other tests (biochemical, radiological and endoscopic) and taking into account the recommended quality criteria for each test and its possible pitfalls (A1)."
- "TE is a fast, simple, safe and easy to learn procedure that is widely available. Its main limitation is the impossibility of obtaining results in case of ascites or morbid obesity and its limited applicability in case of obesity and limited operator experience (A1)."
- "TE should be performed by an experienced operator (>100 examinations) following a standardized protocol with the patient, fasting for at least 2 hours, in the supine position, right arm in full abduction, on the midaxillary line with the probe-tip placed in the 9th to 11th intercostal space with a minimum of 10 shots (A1)."
- "Although alternative techniques, such as pSWE/ARFI or 2D-SWE seem to overcome limitations of TE, their quality criteria for correct interpretation are not yet well defined (A1)."
- "MR elastography is currently too costly and time consuming for routine clinical practice use and seems more suited for research purposes (A1)."
- "When compared in HCV patients, the different patented tests have similar levels of performance in diagnosing significant fibrosis and cirrhosis (A1). Although non-patented tests might have lower diagnostic accuracy than patented tests, they are not associated with additional costs, are easy to calculate, and are widely available (A2)."
- "Among the different available strategies, algorithms combining TE and serum biomarkers appear to be the most attractive and validated one (A2). In patients with viral hepatitis C, when TE and serum biomarkers results are in accordance, the diagnostic accuracy is increased for detecting significant fibrosis but not for cirrhosis. In cases of unexplained discordance, a liver biopsy should be performed if the results would change the patient management (A1)."

The EASL/ALEH guideline includes the following proposed algorithm for noninvasive testing in HCV patients.

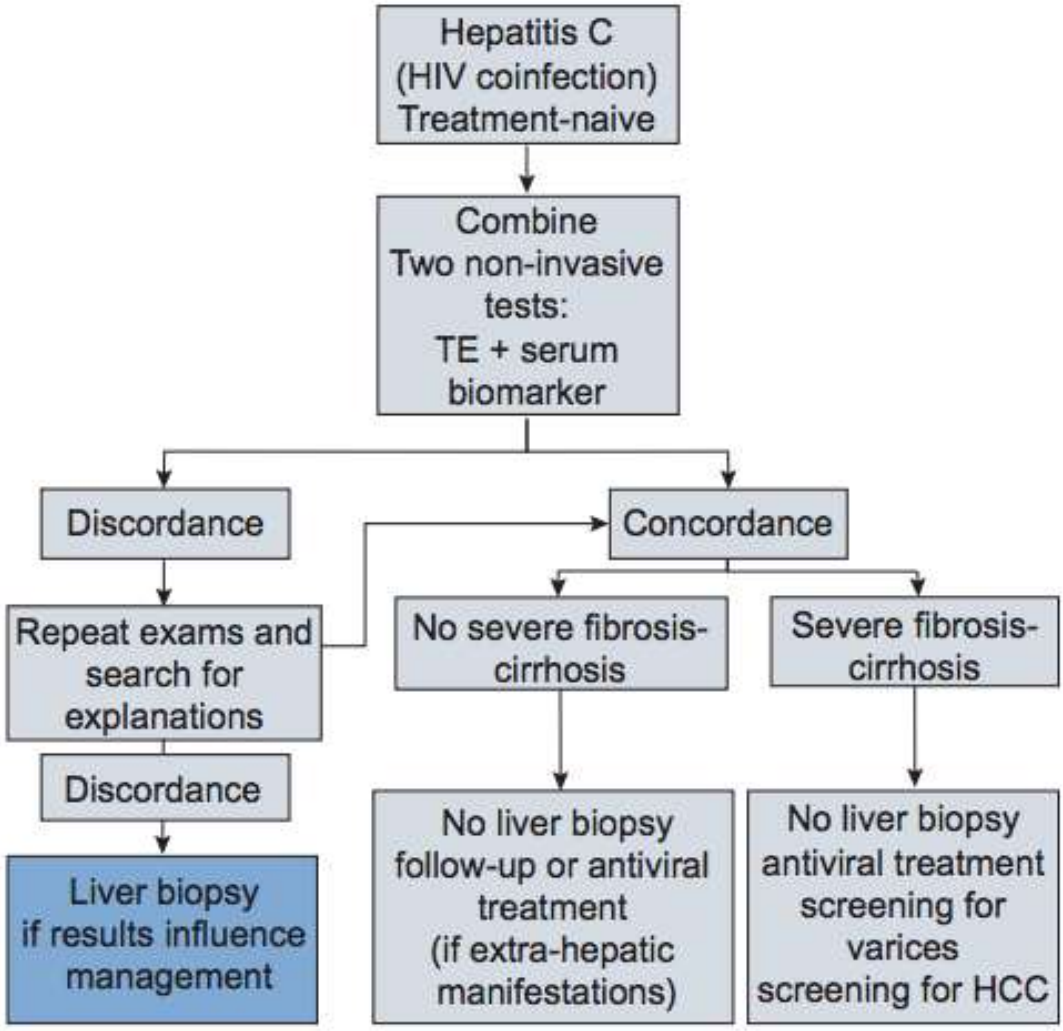

Fig. 1. Proposed algorithm for the use of non-invasive tests in treatment-naive patients with Hepatitis C with or without HIV coinfection.

National Institute for Health and Care Excellence (NICE), 2015

NICE issued medical technology guidance on the use of Virtual Touch™ Quantification (VTq, a proprietary system for performing ARFI) for diagnosing and monitoring liver fibrosis in chronic hepatitis B and C. The panel endorsed the use of VTq as an option for assessing liver fibrosis in chronic hepatitis B or C. They concluded that VTq is as accurate as transient elastography and cost modelling suggested that VTq would likely to be cost saving compared to transient elastography and liver biopsy.

Scottish Intercollegiate Guidelines Network (SIGN), 2013

SIGN published a comprehensive guideline on the management of hepatitis C in 2013 including recommendations regarding the use of noninvasive tests for diagnosing fibrosis and cirrhosis. The SIGN guideline states that while biochemical markers may be able to distinguish cirrhosis from less degrees of fibrosis, "intermediate stages are not distinguishable." Thus, SIGN recommends that biochemical markers should not be considered an alternative to biopsy for staging intermediate levels of fibrosis, but may be used in place of biopsy to diagnose cirrhosis (B recommendations, 2++ evidence). The guideline does offer that measurement of liver stiffness by noninvasive testing may be considered a "recommended best practice based on the clinical experience of the guideline development group."

Society of Radiologists in Ultrasound Consensus Conference Statement, 2015

This consensus conference statement (Barr et al., 2015) asserts that elastography (using either ultrasound or magnetic resonance techniques) can be used to diagnose liver fibrosis in patients "without overt decompensated cirrhosis." The panel stated that elastography should be used to group patients into three categories: those with minimal fibrosis (F0 or F1), those with a high likelihood of cirrhosis (F4), and those with values in between suggesting moderate to severe fibrosis (F2 and F3). The panel also proposed consensus diagnostic thresholds which are reproduced in Table 11.

Table 11: Consensus of Suggested Thresholds in Patients with Hepatitis C

Device	No Clinically Significant Fibrosis: METAVIR Stage < F2, Unlikely to Need Follow-up	Advanced Fibrosis and/or Cirrhosis: METAVIR Stage of F4 and Some Stages of F3 – Clinically Significant Fibrosis
TE FibroScan® (Echosens)	<7 kPa (1.5 m/sec)	>15 kPa (2.2 m/sec)
Siemens pSWE	1.2 m/sec (Siemens suggests <1.34 m/sec, <5.6 kPa)	>2.2 m/sec (>15 kPa)
Philips pSWE	<5.7 kPa (1.37 m/sec)	>2.2 m/sec (>15 kPa)
2D SWE (SuperSonic Imagine)	<7 kPa (1.5 m/sec)	>2.2 m/sec (>15 kPa)
MR elastography (GE, Siemens, Philips)	<3.0 kPa* (27–30)	>5.0 kPa*

*MR elastography is reported as shear modulus, while U.S. elastography techniques are reported in Young modulus. The Young modulus is three times the shear modulus.

World Health Organization, 2014

The WHO released a comprehensive guideline in 2014 focused on management of hepatitis C in resource limited settings. In general, the guideline states that noninvasive tests should be favored over liver biopsy and "in resource-limited settings, it is suggested that aminotransferase/platelet ratio index (APRI) or FIB4 be used for the assessment of hepatic fibrosis rather than other noninvasive tests that require more resources such as elastography or Fibrotest." (Conditional recommendation, low quality evidence)

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APPENDIX A. GRADE INFORMED FRAMEWORK – ELEMENT DESCRIPTIONS

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issue about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality or strength of evidence rating across studies for the treatment/outcome[1]

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

[1] Includes risk of bias, precision, directness, consistency and publication bias

***Low*:** The subcommittee's confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

***Very low*:** The subcommittee has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

APPENDIX B. GRADE EVIDENCE PROFILE

Quality Assessment for MRE (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
12	Diagnostic accuracy studies (cross-sectional or cohort designs)	Low	Not serious	Serious	Not serious		Moderate confidence ●●●○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for TE (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
2	Prospective prognostic studies	Moderate to high	Not serious	Serious	Serious		Very low confidence ●○○○
Need for liver biopsy (Critical outcome)							
57	Diagnostic accuracy studies (cross-sectional or cohort	Low	Not serious	Serious	Not serious		Moderate confidence ●●●○

Quality Assessment for TE (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
	designs)						
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for ARFI (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
36	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Not serious		Low confidence ●●○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for SWE (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
8	Diagnostic accuracy studies (cross-sectional or cohort designs)	Low to Moderate	Not serious	Serious	Not serious		Low confidence ●●○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for RT-TE (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
15	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Unclear	Possible publication bias	Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient

Quality Assessment for RT-TE (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for Platelet count (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
18	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for Hyaluronic acid (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
8	Diagnostic	Moderate	Not serious	Serious	Serious		Very low

Quality Assessment for Hyaluronic acid (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
	accuracy studies (cross-sectional or cohort designs)						confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for Age-platelet index (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
11	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Not Serious		Low confidence ●●○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for APRI (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
6	Retrospective prognostic studies	High	Not serious	Serious	Not serious		Very low confidence ●○○○
Need for liver biopsy (Critical outcome)							
7	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for AST-ALT ratio (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
32	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○

Quality Assessment for AST-ALT ratio (Confidence in Estimate of Effect)							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for Bonacini index (Confidence in Estimate of Effect)							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
12	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Not serious		Low confidence ●●○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for ELF™ (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
8	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for FIB-4 (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
6	Retrospective prognostic studies	High	Not serious	Serious	Not serious		Very low confidence ●○○○
Need for liver biopsy (Critical outcome)							
19	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○

Quality Assessment for FIB-4 (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for FibroIndex (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
9	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for FibroMeter™ (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
8	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for FIBROSpect® II (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
7	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient

Quality Assessment for FIBROSpect® II (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for FibroTest® (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
6	Retrospective prognostic studies	High	No serious	Serious	Serious		Very low confidence ●○○○
Need for liver biopsy (Critical outcome)							
32	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for Forns index (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
7	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for Hepascore® (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
12	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Serious		Very low confidence ●○○○
Quality of life (Critical outcome)							
0							Insufficient

Quality Assessment for Hepascore® (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

Quality Assessment for Pohl index (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Hepatitis related morbidity/progression (Critical outcome)							
0							Insufficient
Need for liver biopsy (Critical outcome)							
12	Diagnostic accuracy studies (cross-sectional or cohort designs)	Moderate	Not serious	Serious	Not serious		Low confidence ●●○○
Quality of life (Critical outcome)							
0							Insufficient
Testing related adverse events (Important outcome)							
0							Insufficient
Change in treatment plan (Important outcome)							
0							Insufficient

APPENDIX C. METHODS

Scope Statement

Populations

Adults and children with chronic hepatitis C infection

Population scoping notes: *None*

Interventions

Noninvasive tests of liver fibrosis (e.g., acoustic radiation force impulse imaging, transient elastography, magnetic resonance elastography, biochemical tests with predictive algorithms)

Intervention exclusions: *None*

Comparators

Liver biopsy, other interventions listed above

Outcomes

Critical: Hepatitis-related morbidity/progression, need for liver biopsy, quality of life

Important**:** Testing-related adverse events, change in treatment plan (especially decision to begin antiviral therapy)

Considered but not selected for the GRADE table: *None*

Key Questions

1. What is the comparative effectiveness of noninvasive tests for the diagnosis and management of hepatic fibrosis in patients with chronic hepatitis C?

2. Does the comparative effectiveness of noninvasive tests of liver fibrosis in patients with chronic hepatitis C vary based on:
   a. Duration of infection
   b. Fibrosis score
   c. Body habitus
   d. Operator/interpreter training or experience
   e. Co-existence of other etiologies of liver disease (e.g., non-alcoholic steatohepatitis)

3. What are the comparative diagnostic operating characteristics of tests of liver fibrosis?

4. What is the evidence for the timing of the initial testing for fibrosis and intervals for subsequent reassessment of fibrosis?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using terms for each of the studied interventions. Searches of core sources were limited to citations published after 2010.

The core sources searched included:

- Agency for Healthcare Research and Quality (AHRQ)
- Blue Cross/Blue Shield Health Technology Assessment (HTA) program
- BMJ Clinical Evidence
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Cochrane Library (Wiley Interscience)
- Hayes, Inc.
- Institute for Clinical and Economic Review (ICER)
- Medicaid Evidence-based Decisions Project (MED)
- National Institute for Health and Care Excellence (NICE)
- Tufts Cost-effectiveness Analysis Registry
- Veterans Administration Evidence-based Synthesis Program (ESP)
- Washington State Health Technology Assessment Program

A MEDLINE search was then conducted to identify randomized control trials, systematic reviews, meta-analyses, and technology assessments published after the end search date of the most recent SR for each studied intervention.

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice guidelines was also conducted, using the following sources:

- Australian Government National Health and Medical Research Council (NHMRC)
- Centers for Disease Control and Prevention (CDC) – Community Preventive Services
- Choosing Wisely
- Institute for Clinical Systems Improvement (ICSI)
- National Guidelines Clearinghouse
- New Zealand Guidelines Group
- NICE
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Preventive Services Task Force (USPSTF)
- Veterans Administration/Department of Defense (VA/DOD)

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English or did not address the scope statement.

APPENDIX D: TEST CHARACTERISTICS

Noninvasive Tests with Good or Excellent Accuracy by Pooled or Median AUROC

Test	Pooled/Median AUROC ≥F2 (95% CI/Range)	Pooled/Median AUROC ≥F3 (95% CI/Range)
MRE	0.88 (0.84 - 0.91)	0.93 (0.90 - 0.95)
TE	0.89 (0.86 - 0.91)	0.92 (0.89 - 0.94)
ARFI	0.88 (0.81 - 0.96)	0.93 (0.89 - 0.97)
SWE	0.88 (0.85 - 0.91)	0.94 (0.92 - 0.96)
RT-TE		0.86 (NR)
ELF™	0.81 (median) (Range 0.72 - 0.87)	
Fibrometer™	0.82 (median) (Range 0.78 - 0.85)	
FIBROSpect® II	0.86 (median) (Range 0.77 - 0.90)	

Noninvasive Tests with Fair or Poor Accuracy by Median AUROC

Test	Median AUROC ≥F2 (Range)
Platelet count	0.71 (0.38 - 0.94)
Hyaluronic acid	0.75 (0.65 - 0.88)
Age-platelet index	0.74 (0.64 - 0.79)
APRI	0.77 (0.58 - 0.95)
AST-ALT ratio	0.59 (0.50 - 0.82)
Bonacini index	0.66 (0.58 - 0.71)
FIB-4	0.74 (0.61 - 0.81)
FibroIndex	0.76 (0.58 - 0.86)
FibroTest®	0.79 (0.70 - 0.89)
Forns index	0.76 (0.60 - 0.86)
Hepascore®	0.79 (0.69 - 0.82)
Pohl index	0.52 (0.52 - 0.53)

Illustrative Effects of Reported Cut-Offs on Sensitivity and Specificity

MRE (Singh et al., 2015)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	3.66 kPa	0.79	0.81
≥F3	4.11 kPa	0.85	0.85

TE (Steadman et al., 2013)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	7.4 (SD ±1.5) kPa	0.80	0.81
≥F3	9.9 (SD ±2.4) kPa	0.84	0.87

ARFI (selected individual studies included in Nierhoff et al., 2013)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	1.22 m/s	1.0	0.71
	1.37 m/s	0.69	0.92
	1.63 m/s	0.59	1.0
≥F3	1.71 m/s	1.0	0.73
	1.73 m/s	0.93	0.85

SWE (selected individual studies included in Li et al., 2016)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	7.2 kPa	0.86	0.86
	8.6 kPa	0.78	0.93
≥F3	9.1 kPa	0.92	0.85
	10.46 kPa	0.89	0.80

APRI (Chou & Wasson, 2013)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	≥0.5 to >0.55	0.81	0.55
	≥1.5	0.37	0.95
F4	≥1.0	0.77	0.75
	≥2.0	0.48	0.94

ELF™ (Chou & Wasson, 2013)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	>8.75	0.86	0.62
	>9.78	0.84	0.80

FIB-4 (Chou & Wasson, 2013)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	≥1.45	0.64	0.68
	≥3.25	0.5	0.79
F4	≥1.45	0.90	0.58
	≥3.25	0.55	0.92

Fibrometer™ (Chou & Wasson, 2013)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	>0.419 to >0.59	0.69	0.81

FIBROSpect® II (Chou & Wasson, 2013)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	>0.36	0.95	0.66
	≥0.42	0.67	0.74

FibroTest® (Chou & Wasson, 2013)

Fibrosis Stage	Cut-off	Sensitivity	Specificity
≥F2	>0.10 to >0.22	0.92	0.38
	>0.70 to >0.80	0.22	0.96
F4	>0.56	0.85	0.77
	>0.73 to >0.862	0.56	0.81

APPENDIX E. APPLICABLE CODES

CODES	DESCRIPTION
ICD-10 Diagnosis Codes	
B18.2	Chronic viral hepatitis C
CPT Codes	
0346T	Ultrasound elastography (with diagnosis code)
91200	Liver elastography, mechanically induced shear wave (e.g. vibration), without imaging, with interpretation and report
91299	Other diagnostic gastroenterology procedures
0001M	Infectious disease, HCV, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores of fibrosis and necroinflammatory activity in liver
81599	Unlisted multianalyte assay with algorithm
82172	Apolipoprotein
82246	Bilirubin
82977	Glutamiltransferase, gamma (GGT)
83010	Hepatoglobin; quantitative
83519	Immunoassay, analyte quantitative by radiopharmaceutical technique
83520	Immunoassay NOS
83883	Nephelometry, each analyte not elsewhere specified
84450	Transferase; aspartate amino (AST) (SGOT)
84460	Transferase; alanine amino (ALT) (SGPT)

Note: Inclusion on this list does not guarantee coverage

Coverage Guidance - Noninvasive diagnosis of liver fibrosis

Question: How should the Coverage Guidance on Noninvasive diagnosis of liver fibrosis be applied to the Prioritized List?

Question source: HTAS

Current Prioritized List Status:

Line:	**203**
Condition:	CHRONIC HEPATITIS; VIRAL HEPATITIS (See Guideline Notes 64,65,76)
Treatment:	MEDICAL THERAPY
ICD-10:	B15.0-B15.9,B16.0-B16.9,B17.0,B17.10-B17.9,B18.0-B18.9,B19.0,B19.10-B19.9,B25.1,K73.0-K73.9,K74.1-K74.2, K75.4,K75.81,K76.0,K76.4
CPT:	91200,96150-96154,98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404, 99408-99416,99429-99449,99468-99480,99487-99498,99605-99607
HCPCS:	G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

CODES	DESCRIPTION
ICD-10 Diagnosis Codes	
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HERC Staff Assessment:
Most of the codes are nonspecific for the particular type of testing. A guideline note is necessary to help identify tests that are included and excluded from Line 203.

HERC Staff Recommendations:

1) Add a guideline note
GUIDELINE NOTE XXX DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE TREATMENT OF HEPATITIS C
Line 203

If a fibrosis score of ≥F2 is the threshold for antiviral treatment of Hepatitis C, the following are included on this line:

Imaging tests:

- Transient elastography (FibroScan®)
- Acoustic radiation force impulse imaging (ARFI) (Virtual Touch™ tissue quantification, ElastPQ)
- Shear wave elastography (SWE) (Aixplorer®)

Blood tests (only if imaging tests are unavailable):

- Enhanced Liver Fibrosis (ELF™)
- Fibrometer™
- FIBROSpect® II

If a fibrosis score of ≥F3 is the threshold for antiviral treatment of Hepatitis C, one or more of the following are included on this line:

Imaging tests:

- Transient elastography (FibroScan®)
- Acoustic radiation force impulse imaging (ARFI)
- Shear wave elastography (SWE)

Magnetic resonance elastography is included on this line for ≥F2 or ≥F3 only when at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminant results, a second one is similarly indeterminant, contraindicated or unavailable, and MRE is readily available.

Noninvasive tests are covered no more often than once per year.

2) Add entries to the Services Recommended for Non-Coverage list

- Real time tissue elastography
- Hepascore® (FibroScore®)
- FibroSure® (FibroTest®)

The development of this guideline note was informed by a HERC Coverage Guidance. See http://www.oregon.gov/oha/herc/Pages/blog-liver-fibrosis.diagnosis.aspx

HERC Coverage Guidance –
Noninvasive Testing for Liver Fibrosis in Patients with Chronic Hepatitis C
Disposition of Public Comments

Table of Contents

Commenters

Identification	Stakeholder
	No comments submitted