



Health Evidence Review Commission

January 12, 2017

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
1/12/2017
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	Som Saha	
2	1:35 PM	Approval of Minutes (11/10/2016)	Som Saha	X
3	1:40 PM	Director's Report	Darren Coffman	
4	1:45 PM	Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women • Coverage Guidance • Prioritized List changes	Adam Obley Wally Shaffer	X
5	2:45 PM	Value-based Benefits Subcommittee Report	Ariel Smits Cat Livingston	X
6	3:45 PM	Coverage Guidance Monitoring (Rescan) Results	Cat Livingston Adam Obley	X
7	4:20 PM	Next Steps • Schedule next meeting – 3/9/2017 Wilsonville Training Center, Rooms 111-112	Som Saha	
8	4:30 PM	Adjournment	Som Saha	

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
November 10, 2016

Members Present: Som Saha, MD, MPH, Chair; Wiley Chan, MD; Beth Westbrook, PsyD; Mark Gibson; Leda Garside, RN, MBA; Susan Williams, MD (by phone, left at 2:30); Kim Tippens, ND, MSAOM, MPH; Kevin Olson, MD; Derrick Sorweide, DO; Chris Labhart; Holly Jo Hodges, MD; Gary Allen, DMD; Irene Croswell, RPh.

Members Absent: None.

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

Also Attending: Jim Rickards, MD; Jesse Little, Kim Wentz, MD, MPH (Oregon Health Authority); Valerie King, MD, MPH, Craig Mosbaek, Rachel Hatchet (OHSU Center for Evidence-based Policy); Margaret Olmon (ABBVIE); Sara Love* (CCO Oregon); Blair Elgren (Osiris); Grant Hamilton (SI-Bone); Duncan Neilson, MD (Legacy); BJ Cavnor* (One in Four); Maria Rodriguez, MD (OHSU, by phone).

*provided testimony

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](#) page 4

MOTION: To approve the minutes of the 10/6/2016 meeting as presented. CARRIES 13-0.

Director's Report [Meeting materials](#) page 117

Darren Coffman oriented members to the new beverage service which will help conserve the Commission's resources.

He asked for the Commission's permission to begin a new multisector interventions topic: Early Childhood Caries Prevention. The Oral Health Advisory Panel, who meet 11/28, are ready and able to take on this topic. Livingston said there likely will be recommendations on services that are outside a dental office, such as in at a primary care office or schools. Members were directed to the scoping statement, found on page 114 of the meeting materials; there were no comments or discussion.

MOTION: To approve a new multisector interventions topic: Early Childhood Caries Prevention.
CARRIES: 13-0.

Coffman asked the Commission's permission to make two other coverage guidance changes:

- Expedite review of a coverage guidance for *Minimally Invasive Back Interventions*. It would be useful to be able to link to another back-related topic, *Low Back Pain-Corticosteroid Injections*, and allow staff to engage the same experts for both topics at the same or back-to-back meetings.
- Retire *MRI for Breast Cancer Screening*, which will become part of the coverage guidance on screening in above-average risk women.

MOTION: Retire the coverage guidance on MRI for Breast Cancer Screening, and fold the topic into the review on Breast Cancer Screening in above-average risk women AND expedite the review time-frame of Minimally Invasive Back Interventions. CARRIES 13-0.

Coffman urged everyone to submit their recommended topics during the official [Topic Nomination Process](#) (closes 12/1/2016). So far, he said, we have had very little. Saha said we should ask the CCO reps to think about what topics are most important to them. Coffman agreed and said that Smits and/or Livingston meet monthly with the CCO medical directors and plan to stress the process at the very next meeting.

Value-based Benefits Subcommittee (VbBS) Report [Meeting materials](#) page 17

Ariel Smits reported the VbBS met earlier in the day, 11/10/2016. She summarized the subcommittee's recommendations.

The Genetic Advisory Panel requested the commission help address two issues:

- Training for genetic counselors
- Licensing of genetic counselors

Olson said the balance of utility and harms of new testing modalities vary wildly. Having more trained and potentially licensed practitioners would help sort out the vast and confusing tests. Training more genetic counselors would help resolve non-urgent requests; urgent requests must bypass the requirement to see a counselor.

MOTION: To approve creating and sending a letter to the Oregon Health Policy Board (or other appropriate body) to advocate for the training and licensing of genetic counselors in Oregon. CARRIES: 13-0.

The Behavioral Health Advisory Panel (BHAP) met and made several recommendations to VbBS which were all accepted.

Recommended Code Movement:

- Delete residential treatment from several covered lines.
- Delete supportive employment and crisis intervention codes from the Prioritized List and place on the Ancillary File.
- Add the new 2017 CPT and HCPCS codes to various lines and Health Systems Division (HSD) files.

- Add and delete various codes reflecting straightforward changes.
- Add the procedure code for sacroiliac joint fusion and the diagnosis code for sacroiliitis to an uncovered line with a new guideline note.
- Add coverage for diagnostic sacroiliac joint injections with a new guideline.
- Remove skin substitute codes from the deep open wound line.
- Add a dietary surveillance code to the obesity line.

Recommended Guideline Changes:

- Update the non-prenatal genetic testing guideline to include the most current NCCN guidelines.
- Add a new guideline regarding repair of paravalvular leaks.
- Edit the Preventive Services guideline note to clarify that USPSTF “D” recommendations were included on the uncovered lower preventive services line.
- Edit the back surgery guideline to clarify coverage, including coverage of spinal fusion with cervical decompression or for spondylolisthesis.
- Edit the guideline on noninvasive testing for liver fibrosis to exclude 3 tests.
- Delete the guideline note on liver elastography, as it was superseded by the new guideline on noninvasive testing for liver fibrosis.
- Add a new guideline note on skin substitutes for chronic skin ulcers.
- Update the ventral hernia guideline to clarify the current non-coverage of repair.

Livingston and Mosbaek gave a brief summary of the work of the Obesity Task Force, [meeting materials page 116](#), resulting in these recommendations:

- Modify the guideline on obesity and overweight to clarify coverage of behavioral interventions and add specific detail about children.
- Add language to the guideline on obesity to clarify non-coverage of devices for obesity.
- Add devices for obesity treatment to the Services Recommended for Non-Coverage table.
- Add a new multisector intervention statement on the prevention and treatment of obesity.

MOTION: To approve the Obesity Task Force report. Carries: 12-0. *(Absent: Williams)*

MOTION: To accept the VbBS recommendations on Prioritized List changes not related to coverage guidances, as stated. See the VbBS minutes of 11/10/2016 for a full description. Carries: 12-0. *(Absent: Williams)*

Coverage Guidance Topic: Timing of Long-Acting Reversible Contraceptive (LARC) Placement
[Meeting materials](#) page 201

Staff introduced appointed ad hoc experts who assisted the subcommittee with this work. Dr. Duncan Neilson, Legacy and Dr. Maria Rodriguez, OHSU (by phone).

Dr. Moira Ray, clinical epidemiologist for the Center for Evidence-based Policy presented the evidence.

Intrauterine devices (IUDs) are effective for 10 years; subdermal implants are effective for 3 years. They are 20 times more effective at preventing pregnancy than pills, patches, or rings and are safe for the

majority of women. Regional and statewide initiatives have demonstrated lower rates of unintended pregnancy, teen pregnancy, high risk births and abortion. Data shows women may be motivated to receive contraception immediately postpartum and postabortion but rates of attendance at 6-weeks post-partum—when LARCs are typically placed—falls sharply.

There are barriers to placing LARCs postpartum, including the high initial cost compared to some shorter acting contraceptives, high cost of the product limiting practitioners ability to have on-hand stock, varying insurance reimbursement rates, billing issues and provider training.

Critical (unintended pregnancies, abortions) and important outcomes (presence of LARC at one year, harms) were identified for this study. Evidence from trusted sources were found to address key and contextual questions.

Key Questions

1. What is the comparative effectiveness of offering immediate postpartum or postabortion placement of a LARC?
2. What are the harms of immediate postpartum or postabortion placement of a LARC?

Contextual Questions

1. What payer and provider practices and policies promote effective use of LARC?

Evidence summary

Immediate postabortion IUD insertion is associated with greater IUD use and equivalent or fewer pregnancies in 6 months with similar rates of infection (moderate confidence); statistically increased expulsion rates (moderate confidence), although rates were still low (and lower than the typically estimated expulsion rate in the outpatient setting); and with equivalent perforation risk (very low confidence).

Immediate postpartum IUD insertion is associated with greater IUD use at 6 months (moderate confidence) and greater expulsion rates (moderate confidence), yet women who experience expulsion opt for replacement (very low confidence). No differences were identified in unintended pregnancy rates (because no pregnancies occurred).

Guidelines

The American Congress of Obstetricians and Gynecologists (ACOG) recommends offering LARC at the time of delivery, abortion, or dilation and curettage for miscarriage. ACOG offer the same recommendations for adolescents. The American Academy of Pediatrics (AAP) recommends pediatricians counsel adolescents on contraception in order of efficacy, starting with the most effective methods (i.e., LARC); AAP encourages offering LARC to postpartum teens in the immediate postpartum period, including while still in the hospital.

Policies

Federal law requires coverage of an option in each category of birth control for most commercial health insurance plans and Medicaid alternative benefit plans. An [informational bulletin from the Center for Medicaid and CHIP Services \(April 2016\)](#) highlights state efforts to improve access to LARC:

- Provide timely, comprehensive contraception coverage
- Raise payment rates for LARC
- Reimburse for immediate postpartum LARC
- Remove logistical barriers to managing supply of LARC
- Remove administrative barriers for LARC provision

Oregon Medicaid has no specific policy about the use of LARC in the immediate postpartum period and does not currently provide additional reimbursement for the cost of the device. The Oregon Health Plan and CCARE, Oregon's Medicaid family planning waiver, will cover the provision of an immediate postabortion LARC device.

Medicaid agencies in 17 states and the District of Columbia have policies providing reimbursement for LARC in the inpatient postpartum setting. For example, Washington Medicaid reimburses professional services for immediate postpartum LARC insertion if billed separately from global obstetric procedure codes.

Approximately 25 public comments were received, all in support of the Evidence-based Guidelines Subcommittee (EbGS) recommendation to cover immediate LARC placement in both the postpartum and postabortion setting. Nearly half of the commenters asked for coverage for the *Citizen/Alien-Waived Emergent Medical (CAWEM)* population which is beyond the scope of the coverage guidance. Those comments were noted in the "Other Considerations" section and staff forwarded the suggestion to the OHA's Health Systems Division.

In developing this coverage guidance, EbGS noted significant administrative barriers to implementation. A letter to CCO medical directors has been developed to accompany the Coverage Guidance that addresses some of these barriers, and includes a summary of solutions that other states around the US have developed to resolve those barriers.

Proposal

Livingston read through the GRADE-Informed Framework ([page 206](#)), noting that this issue affects all insurance payers.

Appointed experts Dr. Neilson and Dr. Rodriguez pointed out this guidance is one step in helping to fix the billing issues associated with providers being reimbursed for this product/service outside a global billing reimbursement for the delivery.

MOTION: To approve the proposed coverage guidance for Timing of Long-Acting Reversible Contraceptive (LARC) Placement as presented. Carries 12-0. (Absent: Williams)

MOTION: To approve the proposed Long-Acting Reversible Contraceptive (LARC) Placement guideline note for the Prioritized List as amended to include a web link to the accompanying letter to explain the administrative issues surrounding LARC placement. Carries 12-0. (Absent: Williams)

MOTION: To approve the letter from the HERC and EbGS chairs as drafted (As appears in Appendix A). Carries 12-0. (Absent: Williams)

Approved Coverage Guidance:

HERC Coverage Guidance

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

Changes for the Prioritized List of Health Services:

GUIDELINE NOTE 162 LONG-ACTING REVERSIBLE CONTRACEPTIVE (LARC) PLACEMENT

Line 6

Long-acting reversible contraceptives (implant or intrauterine device) are included on Line 6 in all settings, including (but not limited to) immediately postpartum and postabortion.

The development of this guideline note was informed by a HERC coverage guidance. See <http://www.oregon.gov/oha/herc/Pages/blog-long-acting-reversible-contraceptives.aspx>. HERC leadership added a letter (<http://www.oregon.gov/oha/herc/Documents/LARC-Implementation.pdf>) to Medical Directors regarding implementation issues, which references CMS requirements around contraceptive coverage and guidance on ways to implement effective LARC policy.

Review of Prioritization of Acute and Chronic Hepatitis C [Meeting materials](#) page 328

Dr. James Rickards, Oregon Health Authority's Chief Medical Officer, addressed the Commission with a request. Rickards said that, based on the Pharmacy & Therapeutics Committee's limited scope, OHA is asking HERC to re-evaluate the prioritization for the treatment of hepatitis C based on stage of disease.

Coffman, providing history, said the Commission (and its predecessor, the Health Service Commission) reviewed treatment of hepatitis C a number of times from 1999 to present. Most recently, in 2014, HERC focused on different treatments, not stage of disease. Some CCOs submitted testimony that they would prefer to manage the coverage criteria for these drugs themselves; others expressed support for HERC to determine coverage criteria for these medications. HERC elected not to pursue the topic and made no changes to the Prioritized List. Since then, fee-for-service and CCOs have managed coverage criteria for treatment with oversight from the OHA to ensure compliance with CMS guidance.

In November, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a letter to all state governments addressing treatment of hepatitis C, clearly stating the agency shared equal concerns about the budgetary impact to Medicaid programs and patient's access to needed care. In the letter, CMS urged states to take advantage of competition with pricing arrangements and/or supplemental rebates. Other points include:

- States retain discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes though limitations should not result in the denial of access to effective, clinically appropriate and medically necessary treatments for patients with chronic hepatitis C virus (HCV) infections.

- States should examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new direct-acting antiviral (DAA) HCV drugs.
- CCOs need to provide coverage no less than the amount, duration and scope of coverage by fee-for-service (FFS).

P&T has been reviewing this topic with some frequency, and at their September 29, 2016 meeting asked if HERC could be asked to review the current prioritization of hepatitis C. Current FFS prior authorization criteria covers hepatitis C treatments for patients with liver fibrosis stages F3-F4, and for those with stage fibrosis 2 as well as HIV co-infection. These criteria were created in consultation with hepatologists to define priority patients in 2014. The new review should consider prioritization of different fibrosis stages, including: prioritization methodology components, safety considerations (harms/reactivation of HBV/increased resistance), with cost as a clear reason for the review; if the cost threshold were lower, it wouldn't be such a strong consideration in ranking.

Livingston said of those who contract hepatitis C, 5-25% progress to cirrhosis. She suggested HERC stratify treatment based on disease severity/fibrosis staging and examine the potential benefits versus harms at each stage in determining how they should be prioritized. This approach would look at clinical evidence of benefit to patients in the early stages vs. later stages of the disease as well as cost effectiveness. Coffman said HERC may want to use the coverage guidance process as a framework for this review, but assign the topic directly to VbBS to take testimony/begin deliberations at 1/12/17 meeting and finish no later than the March meeting to incorporate it into the current biennial review of the Prioritized List.

Discussion centered on finding a way to review this topic using a shortened/hybrid coverage guidance process assigned to VbBS. Coffman said the review must be completed and adopted at the March 9, 2017 meeting for inclusion in the Biennial Report to go to the legislature in May. Since it has a potential fiscal impact the interim modification process is not appropriate. Missing this deadline could delay implementation of the findings for an additional two years. There is a possibility to amend the CCO contracts sooner, though the state does not generally like to do that.

Some members expressed their concern this topic requires more than a compressed review. Members settled on a two-step process: 1) complete a two-month review focused on the prioritization of stage 2 disease to meet the biennial review deadline, then a 2) full review of the remaining stages of the disease to follow.

Public Testimony:

BJ Cavnor, Executive Director for 1 in 4 Chronic Health, stated his organization receives money from the pharmaceutical industry, but they have not received any funds in past years from a company that has had a hepatitis C drug on the market. He said he is available as a resource to HERC as an advocate for patients to address questions. He went on to say that hepatitis C is a public health issue, affecting 10,000 persons in Oregon alone; with numbers growing due to patients seeking heroin when they are denied opioid medication, then using and sharing needles. The disease disproportionately affects people of color and Native Americans. Treating hepatitis C early may save costly treatment of other co-morbid conditions. It is expensive but the costs are going down: he has heard they are as low as \$15-30k per patient through the 340(b) program; they are now able to treat three people for the price it formerly cost to treat one person.

Sara Love, Policy Director of CCO Oregon, a nonprofit organization, also testified, stating no conflicts of interest other than stakeholders in her organization who pay dues. Dr. Love urged the Commission to address the need for an adequate provider network and robust case management using a biopsychosocial approach to achieve a high sustained viral response (SVR). She asked the Commission to take into account safety, clinical effectiveness and cost-effectiveness.

Public Comment

There was no other public comment at this time.

Adjournment

Meeting adjourned at 4:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, January 12, 2017 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon.

Appendix A



OFFICE FOR OREGON HEALTH POLICY & RESEARCH
Health Evidence Review Commission

Kate Brown, Governor



November 10, 2016

500 Summer Street NE, E-65
Salem, OR 97301
Voice (503) 373-1985
FAX (503) 378-5511

Dear Medical Directors:

In developing our Coverage Guidance on Timing of Long-Acting Reversible Contraceptive (LARC) Placement, we have become aware that administrative issues, rather than coverage policy per se, are discouraging the use of highly effective LARC devices (intrauterine devices and subdermal implants). While placement of LARC devices is already covered for most plans, administrative issues are preventing patients from receiving these devices at the point when they are most likely to achieve the objective of preventing unintended pregnancy. The LARC devices are safe and effective, and are more cost-effective than any other contraceptive method. For example, one cost-effectiveness analysis found that over 2 years, placement of a postpartum IUD was associated with a savings of \$282,540 per 1,000 women. They cannot be effective or cost-saving, however, unless they are placed.

In order for placement to occur, an appropriate device must be offered and placed at a time convenient to the woman desiring contraception, preferably when she is already receiving care for another condition. Best practices for timing of insertion include placement immediately following birth or abortion, as well as same-day placement in the outpatient setting. Currently, due to administrative barriers, women are often required to return for one or more visits in order to receive a LARC device. Many women do not return for follow up visits, including postpartum visits. Others may become pregnant before such a visit can occur. In order to offer immediate placement, providers must be confident that they and the facilities in which they work will be appropriately compensated for the devices and related care. We have heard reports of major hospital systems halting placement of these devices in the postpartum setting due to reimbursement issues and are aware of others that simply do not offer postpartum LARC placement unless funded through a grant for a very limited population.

As you implement the changes related to this coverage guidance, we urge you to address the following administrative barriers, if they are present in your plans and provider networks.

- Lack of reimbursement for the cost of these devices when provided after an in-hospital birth due to global DRG-based payment for delivery services
- Lack of reimbursement to professionals and facilities for the service of placing these devices in the inpatient setting
- Inadequate inventory of these devices to allow for their placement on a timely basis in all settings of care
- Lack of health system support for the uptake of policies and procedures supporting the immediate placement of LARC.
- Reimbursement rates to providers which are lower than the provider's cost of the devices
- Lack of providers able to perform postpartum placement of IUDs

Appendix A

- For devices provided through a pharmacy benefit, lack of a mechanism for providers to recoup the cost of the device if a device assigned to a particular woman is not placed
- Lack of provider reimbursement when LARC removal, replacement or re-insertion is required
- Any prior authorization requirements, which can delay or block placement of these devices
- Payer refusal to pay for two distinct services on the same day (e.g., a birth or the termination of pregnancy followed by LARC placement)

We have attached two documents to the coverage guidance from the Center for Medicaid and CHIP Services. The first (Appendix F) is an [Informational Bulletin from April, 2016](#) which outlines these issues as well as options other states have implemented to resolve them. Appendix G is a [State Health Official's Letter](#) outlining implementations option for same day LARC placement as well as other coverage requirements for state Medicaid programs, including limitations on prior authorization and applicability to managed care plans.

We hope that this information will help you as you work with your plan and contracted providers to ensure effective access to these important devices.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Saha'.

Somnath Saha, MD, Chair, Health Evidence Review Commission

A handwritten signature in black ink, appearing to read 'Wiley Chan'.

Wiley Chan, MD, Chair, Evidence-based Guidelines Subcommittee

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
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- Remove logistical barriers to managing supply of LARC
- Remove administrative barriers for LARC provision

Oregon Medicaid has no specific policy about the use of LARC in the immediate postpartum period and does not currently provide additional reimbursement for the cost of the device. The Oregon Health Plan and CCARE, Oregon's Medicaid family planning waiver, will cover the provision of an immediate postabortion LARC device.

Medicaid agencies in 17 states and the District of Columbia have policies providing reimbursement for LARC in the inpatient postpartum setting. For example, Washington Medicaid reimburses professional services for immediate postpartum LARC insertion if billed separately from global obstetric procedure codes.

Approximately 25 public comments were received, all in support of the Evidence-based Guidelines Subcommittee (EbGS) recommendation to cover immediate LARC placement in both the postpartum and postabortion setting. Nearly half of the commenters asked for coverage for the *Citizen/Alien-Waived Emergent Medical (CAWEM)* population which is beyond the scope of the coverage guidance. Those comments were noted in the "Other Considerations" section and staff forwarded the suggestion to the OHA's Health Systems Division.

In developing this coverage guidance, EbGS noted significant administrative barriers to implementation. A letter to CCO medical directors has been developed to accompany the Coverage Guidance that addresses some of these barriers, and includes a summary of solutions that other states around the US have developed to resolve those barriers.

Proposal

Livingston read through the GRADE-Informed Framework ([page 206](#)), noting that this issue affects all insurance payers.

Appointed experts Dr. Neilson and Dr. Rodriguez pointed out this guidance is one step in helping to fix the billing issues associated with providers being reimbursed for this product/service outside a global billing reimbursement for the delivery.

MOTION: To approve the proposed coverage guidance for Timing of Long-Acting Reversible Contraceptive (LARC) Placement as presented. Carries 12-0. (Absent: Williams)

MOTION: To approve the proposed Long-Acting Reversible Contraceptive (LARC) Placement guideline note for the Prioritized List as amended to include a web link to the accompanying letter to explain the administrative issues surrounding LARC placement. Carries 12-0. (Absent: Williams)

MOTION: To approve the letter from the HERC and EbGS chairs as drafted (As appears in Appendix A). Carries 12-0. (Absent: Williams)

Approved Coverage Guidance:

HERC Coverage Guidance

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

Changes for the Prioritized List of Health Services:

GUIDELINE NOTE 162 LONG-ACTING REVERSIBLE CONTRACEPTIVE (LARC) PLACEMENT

Line 6

Long-acting reversible contraceptives (implant or intrauterine device) are included on Line 6 in all settings, including (but not limited to) immediately postpartum and postabortion.

The development of this guideline note was informed by a HERC coverage guidance. See <http://www.oregon.gov/oha/herc/Pages/blog-long-acting-reversible-contraceptives.aspx>. HERC leadership added a letter (<http://www.oregon.gov/oha/herc/Documents/LARC-Implementation.pdf>) to Medical Directors regarding implementation issues, which references CMS requirements around contraceptive coverage and guidance on ways to implement effective LARC policy.

Review of Prioritization of Acute and Chronic Hepatitis C [Meeting materials](#) page 328

Dr. James Rickards, Oregon Health Authority's Chief Medical Officer, addressed the Commission with a request. Rickards said that, based on the Pharmacy & Therapeutics Committee's limited scope, OHA is asking HERC to re-evaluate the prioritization for the treatment of hepatitis C based on stage of disease.

Coffman, providing history, said the Commission (and its predecessor, the Health Service Commission) reviewed treatment of hepatitis C a number of times from 1999 to present. Most recently, in 2014, HERC focused on different treatments, not stage of disease. Some CCOs submitted testimony that they would prefer to manage the coverage criteria for these drugs themselves; others expressed support for HERC to determine coverage criteria for these medications. HERC elected not to pursue the topic and made no changes to the Prioritized List. Since then, fee-for-service and CCOs have managed coverage criteria for treatment with oversight from the OHA to ensure compliance with CMS guidance.

In November, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a letter to all state governments addressing treatment of hepatitis C, clearly stating the agency shared equal concerns about the budgetary impact to Medicaid programs and patient's access to needed care. In the letter, CMS urged states to take advantage of competition with pricing arrangements and/or supplemental rebates. Other points include:

- States retain discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes though limitations should not result in the denial of access to effective, clinically appropriate and medically necessary treatments for patients with chronic hepatitis C virus (HCV) infections.

- States should examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new direct-acting antiviral (DAA) HCV drugs.
- CCOs need to provide coverage no less than the amount, duration and scope of coverage by fee-for-service (FFS).

P&T has been reviewing this topic with some frequency, and at their September 29, 2016 meeting asked if HERC could be asked to review the current prioritization of hepatitis C. Current FFS prior authorization criteria covers hepatitis C treatments for patients with liver fibrosis stages F3-F4, and for those with stage fibrosis 2 as well as HIV co-infection. These criteria were created in consultation with hepatologists to define priority patients in 2014. The new review should consider prioritization of different fibrosis stages, including: prioritization methodology components, safety considerations (harms/reactivation of HBV/increased resistance), with cost as a clear reason for the review; if the cost threshold were lower, it wouldn't be such a strong consideration in ranking.

Livingston said of those who contract hepatitis C, 5-25% progress to cirrhosis. She suggested HERC stratify treatment based on disease severity/fibrosis staging and examine the potential benefits versus harms at each stage in determining how they should be prioritized. This approach would look at clinical evidence of benefit to patients in the early stages vs. later stages of the disease as well as cost effectiveness. Coffman said HERC may want to use the coverage guidance process as a framework for this review, but assign the topic directly to VbBS to take testimony/begin deliberations at 1/12/17 meeting and finish no later than the March meeting to incorporate it into the current biennial review of the Prioritized List.

Discussion centered on finding a way to review this topic using a shortened/hybrid coverage guidance process assigned to VbBS. Coffman said the review must be completed and adopted at the March 9, 2017 meeting for inclusion in the Biennial Report to go to the legislature in May. Since it has a potential fiscal impact the interim modification process is not appropriate. Missing this deadline could delay implementation of the findings for an additional two years. There is a possibility to amend the CCO contracts sooner, though the state does not generally like to do that.

Some members expressed their concern this topic requires more than a compressed review. Members settled on a two-step process: 1) complete a two-month review focused on the prioritization of stage 2 disease to meet the biennial review deadline, then a 2) full review of the remaining stages of the disease to follow.

Public Testimony:

BJ Cavnor, Executive Director for 1 in 4 Chronic Health, stated his organization receives money from the pharmaceutical industry, but they have not received any funds in past years from a company that has had a hepatitis C drug on the market. He said he is available as a resource to HERC as an advocate for patients to address questions. He went on to say that hepatitis C is a public health issue, affecting 10,000 persons in Oregon alone; with numbers growing due to patients seeking heroin when they are denied opioid medication, then using and sharing needles. The disease disproportionately affects people of color and Native Americans. Treating hepatitis C early may save costly treatment of other co-morbid conditions. It is expensive but the costs are going down: he has heard they are as low as \$15-30k per patient through the 340(b) program; they are now able to treat three people for the price it formerly cost to treat one person.

Sara Love, Policy Director of CCO Oregon, a nonprofit organization, also testified, stating no conflicts of interest other than stakeholders in her organization who pay dues. Dr. Love urged the Commission to address the need for an adequate provider network and robust case management using a biopsychosocial approach to achieve a high sustained viral response (SVR). She asked the Commission to take into account safety, clinical effectiveness and cost-effectiveness.

Public Comment

There was no other public comment at this time.

Adjournment

Meeting adjourned at 4:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, January 12, 2017 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon.

Appendix A



OFFICE FOR OREGON HEALTH POLICY & RESEARCH
Health Evidence Review Commission

Kate Brown, Governor



November 10, 2016

500 Summer Street NE, E-65
Salem, OR 97301
Voice (503) 373-1985
FAX (503) 378-5511

Dear Medical Directors:

In developing our Coverage Guidance on Timing of Long-Acting Reversible Contraceptive (LARC) Placement, we have become aware that administrative issues, rather than coverage policy per se, are discouraging the use of highly effective LARC devices (intrauterine devices and subdermal implants). While placement of LARC devices is already covered for most plans, administrative issues are preventing patients from receiving these devices at the point when they are most likely to achieve the objective of preventing unintended pregnancy. The LARC devices are safe and effective, and are more cost-effective than any other contraceptive method. For example, one cost-effectiveness analysis found that over 2 years, placement of a postpartum IUD was associated with a savings of \$282,540 per 1,000 women. They cannot be effective or cost-saving, however, unless they are placed.

In order for placement to occur, an appropriate device must be offered and placed at a time convenient to the woman desiring contraception, preferably when she is already receiving care for another condition. Best practices for timing of insertion include placement immediately following birth or abortion, as well as same-day placement in the outpatient setting. Currently, due to administrative barriers, women are often required to return for one or more visits in order to receive a LARC device. Many women do not return for follow up visits, including postpartum visits. Others may become pregnant before such a visit can occur. In order to offer immediate placement, providers must be confident that they and the facilities in which they work will be appropriately compensated for the devices and related care. We have heard reports of major hospital systems halting placement of these devices in the postpartum setting due to reimbursement issues and are aware of others that simply do not offer postpartum LARC placement unless funded through a grant for a very limited population.

As you implement the changes related to this coverage guidance, we urge you to address the following administrative barriers, if they are present in your plans and provider networks.

- Lack of reimbursement for the cost of these devices when provided after an in-hospital birth due to global DRG-based payment for delivery services
- Lack of reimbursement to professionals and facilities for the service of placing these devices in the inpatient setting
- Inadequate inventory of these devices to allow for their placement on a timely basis in all settings of care
- Lack of health system support for the uptake of policies and procedures supporting the immediate placement of LARC.
- Reimbursement rates to providers which are lower than the provider's cost of the devices
- Lack of providers able to perform postpartum placement of IUDs

Appendix A

- For devices provided through a pharmacy benefit, lack of a mechanism for providers to recoup the cost of the device if a device assigned to a particular woman is not placed
- Lack of provider reimbursement when LARC removal, replacement or re-insertion is required
- Any prior authorization requirements, which can delay or block placement of these devices
- Payer refusal to pay for two distinct services on the same day (e.g., a birth or the termination of pregnancy followed by LARC placement)

We have attached two documents to the coverage guidance from the Center for Medicaid and CHIP Services. The first (Appendix F) is an [Informational Bulletin from April, 2016](#) which outlines these issues as well as options other states have implemented to resolve them. Appendix G is a [State Health Official's Letter](#) outlining implementations option for same day LARC placement as well as other coverage requirements for state Medicaid programs, including limitations on prior authorization and applicability to managed care plans.

We hope that this information will help you as you work with your plan and contracted providers to ensure effective access to these important devices.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Saha'.

Somnath Saha, MD, Chair, Health Evidence Review Commission

A handwritten signature in black ink, appearing to read 'Wiley Chan'.

Wiley Chan, MD, Chair, Evidence-based Guidelines Subcommittee

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on November 10, 2016

*For specific coding recommendations and guideline wording, please
see the text of the 11/10/2016 VbBS minutes.*

RECOMMENDED CODE MOVEMENT (effective 1/1/17 unless otherwise noted)

- Delete residential mental health treatment from several inappropriate lines.
- Delete supportive employment and crisis intervention coders from the Prioritized List and place on the Ancillary File.
- Add the 2017 CPT and HCPCS codes to various lines and lists.
- Add the procedure code for sacroiliac joint fusion and the diagnosis code for sacroiliitis to an uncovered line with a new guideline note.
- Add coverage for diagnostic sacroiliac joint injections with a new guideline.
- Remove skin substitute codes from a deep open wound line.
- Add a dietary surveillance code to the obesity line.
- Add and delete various straightforward coding changes.

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- The federal definition of habilitative was not added to the Rehabilitative and Habilitative Services Guideline.
- Higher prioritization was considered for uncomplicated inguinal hernias, but no changes were made.
- Confirm ongoing noncoverage of pharmacotherapy for obesity.

RECOMMENDED GUIDELINE CHANGES (effective 1/1/17 unless otherwise noted)

- Update the non-prenatal genetic testing guideline to include the most current NCCN guidelines.
- Add a new guideline regarding repair of paravalvular leaks.
- Edit the preventive services guideline to clarify that USPSTF “D” recommendations are included on the uncovered lower preventive services line.
- Edit the back surgery guideline to clarify coverage, including coverage of spinal fusion with cervical decompression for spondylolisthesis.
- Edit the guideline on noninvasive testing for liver fibrosis to exclude 3 tests.
- Delete the guideline note on liver elastography, as it was superseded by the new guideline on noninvasive testing for liver fibrosis.
- Add a new guideline note on skin substitutes for chronic skin ulcers.
- Modify the guideline on obesity and overweight to clarify coverage of behavioral interventions and add specific detail about children.
- Add language to the guideline on obesity to clarify non-coverage of devices for obesity and add them to the Services Recommended for Non-Coverage Table.

- Add a new multisector intervention statement on the prevention and treatment of obesity.
- Update the ventral hernia guideline to clarify the current noncoverage of repair.
- Add a new guideline clarifying that long-acting reversible contraceptives are covered in the postpartum and postabortion setting.

DRAFT

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
November 10, 2016
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Susan Williams, MD, Vice-chair (by phone); David Pollack, MD; Mark Gibson; Irene Croswell, RPh; Holly Jo Hodges, MD (9:30 arrival); Vern Saboe, DC; Gary Allen, DMD.

Members Absent: None.

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

Also Attending: Jesse Little and Kim Wentz, MD, MPH, (Oregon Health Authority); Valerie King, MD MPH, Rachel Hackett, Craig Mosbaek, and Moira Ray, MD (OHSU Center for Evidence-based Policy); Duncan Neilson, MD; Maria Rodriguez, MD (via phone); Andy Kranenberg, MD (via phone); Jessie Payne; Margaret Olmon (Abbvie); Blair Elgren (Osiris); Grant Hamilton (SI-Bone); Duncan Neilsen, MD (Legacy Health Systems); Sara Love (CCO Oregon).

➤ **Roll Call/Minutes Approval/Staff Report**

The meeting was called to order at 8:00 am and roll was called. Minutes from the October 10, 2016 VbBS meeting were reviewed and approved. Staff pointed out edits to those minutes which were added after the packet was distributed, and these changes were considered appropriate.

Smits reviewed the errata; there was no discussion.

Coffman discussed the plan to have HERC review hepatitis C as a biennial review item. This topic was discussed in more detail at the later HERC meeting.

➤ **Topic: Genetics Advisory Panel (GAP) Report**

Discussion: Smits reviewed the GAP report. There was some discussion about breast cancer gene panel testing. GAP had recommended that HERC staff review NCCN guidelines; staff reviewed this guideline and found no strong guidance. After staff conferred with HERC leadership, staff determined that there is no clear guidance but that this is a rapidly evolving field. The plan is to have GAP review this at their meeting next year. Smits also reviewed concerns raised about access to genetic counseling in the state. Pollack discussed the shortage of training programs in Oregon for genetic counseling. Olson noted that

genetic counselors are not licensed by the state and therefore cannot bill directly for their services. Lack of licensing is a barrier in Oregon. The need is increasing rapidly. VbBS requested that HERC make a motion to the staff of the health workforce or health policy board to license genetic counselors and workforce training. Workforce shortage impedes HERC's ability to implement evidence based guidelines around genetic testing.

The non-prenatal genetic testing guideline required straightforward changes to update the references to the most current NCCN guidelines.

The recommendations for 2017 CPT code placements involving genetic testing were approved as part of the larger 2017 code placements later in the meeting.

Recommended Actions:

- 1) Modify Diagnostic Guideline D1 as shown in Appendix A.

MOTION: To approve the guideline changes as presented. CARRIES 7-0. (Absent: Hodges)

➤ **Topic: Behavioral Health Advisory Panel (BHAP) Report**

Smits reviewed the BHAP report. There was minimal discussion. All coding changes recommended by BHAP were considered appropriate. VBBS agreed with the BHAP recommendation to not add acupuncture as a treatment for depression and to not continue to consider higher prioritization of insomnia for any age group.

The recommendations for 2017 CPT code placements related to behavioral health services were approved as part of the larger 2017 code placements later in the meeting.

Recommended Actions:

- 1) Remove HCPCS H0018 (Behavioral health; short-term residential (non-hospital residential treatment program) from the following lines:
 - a. 153 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD
 - b. 216 NON-SUBSTANCE-RELATED ADDICTIVE BEHAVIORAL DISORDERS₂
 - c. 257 PSYCHOLOGICAL FACTORS AGGRAVATING PHYSICAL CONDITION (EG. ASTHMA, CHRONIC GI CONDITIONS, HYPERTENSION)₂
 - d. 394 SEPARATION ANXIETY DISORDER₂
 - e. 397 PANIC DISORDER; AGORAPHOBIA₂
 - f. 419 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED₂
 - g. 442 STEREOTYPY/HABIT DISORDER AND SELF-ABUSIVE BEHAVIOR DUE TO NEUROLOGICAL DYSFUNCTION₂
 - h. 466 OBSESSIVE-COMPULSIVE DISORDERS₂
 - i. 554 SOMATIC SYMPTOMS AND RELATED DISORDERS₂
- 2) Remove H2023 (Supported employment, per 15 minutes) from all lines on the Prioritized List.

- a. Advise HSD to place H2023 on the Ancillary File.
- 3) Remove H2011 (Crisis intervention service, per 15 minutes) from all lines on the Prioritized List.
 - a. Advise HSD to place H2011 on the Diagnostic Workup File.
- 4) Add ICD-10 F50.89 (Other specified eating disorder) to line 153 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD and line 635 PICA.
 - a. Add a coding specification to lines 153 and 635 as follows:

“ICD-10 F50.89 is included on lines 153 for avoidant/restrictive food intake disorder and on line 386 for psychogenic loss of appetite. ICD-10 F50.89 is included on line 635 for pica in adults and for all other diagnoses using this code.”
- 5) Remove the following coding specification from line 386:

~~“ICD-10 CM F50.8 is included on this line only for binge eating disorder. All other diagnoses using this code (i.e. pica in adults) are included on line 664 PICA.”~~

MOTION: To approve the coding changes as presented. CARRIES 7-0. (Absent: Hodges)

➤ **Topic: Straightforward/Consent Agenda**

Discussion: There was no discussion about the consent agenda items.

Recommended Actions:

- 1) Add CPT 29822 (Arthroscopy, shoulder, surgical; debridement, limited) to line 157 PYOGENIC ARTHRITIS.
- 2) Add CPT 29821 (Arthroscopy, shoulder, surgical; synovectomy, complete) to line 406 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS.
- 3) Add ICD-10 B69.0 (Cysticercosis of central nervous system) to line 338 BENIGN CEREBRAL CYSTS.
- 4) Add CPT 37212 (Transcatheter therapy, venous infusion for thrombolysis, any method, including radiological supervision and interpretation, initial treatment day) to line 51 DEEP ABSCESES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS.
- 5) Add CPT 38747 (Abdominal lymphadenectomy, regional, including celiac, gastric, portal, peripancreatic, with or without para-aortic and vena caval nodes) to line 321 CANCER OF PANCREAS.
- 6) Add CPT 15100 (Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children) to line 205 CANCER OF BONES.
- 7) Add CPT 67917 (Repair of ectropion; extensive (eg, tarsal strip operations)) to line 280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA.
- 8) Add CPT 21230 (Graft; rib cartilage, autogenous, to face, chin, nose or ear) and 21235 (Graft; ear cartilage, autogenous, to nose or ear (includes obtaining graft)) to line 280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA.
- 9) Add CPT 77293 (Respiratory motion management simulation) to line 321 CANCER OF PANCREAS.

- 10) Add CPT 43266 (Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)) to line 220 CANCER OF STOMACH.
- 11) Add CPT 31600 (Tracheostomy, planned) to line 205 CANCER OF BONES.
- 12) Add CPT 38720 (Cervical lymphadenectomy (complete)) and 38724 (Cervical lymphadenectomy (modified radical neck dissection)) to line 205 CANCER OF BONES.
- 13) Add CPT 38760 (Inguinofemoral lymphadenectomy, superficial, including Cloquet's node) to line 291 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS.
- 14) Add CPT 77789 (Surface application of low dose rate radionuclide source) to line 117 CANCER OF EYE AND ORBIT.
- 15) Add CPT 49203-49205 (Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors...) to line 219 CANCER OF KIDNEY AND OTHER URINARY ORGANS.
- 16) Add CPT 78816 (Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body) to line 117 CANCER OF EYE AND ORBIT.
- 17) Add Line 117 CANCER OF EYE AND ORBIT to Guideline Note (GN) 19 PET SCAN GUIDELINES.
- 18) Add CPT 21210 (Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)) to line 305 CLEFT PALATE AND/OR CLEFT LIP.
- 19) Remove ICD-10 M11.8 (Other specified crystal arthropathies) from line 663 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY and add to line 501 CALCIUM PYROPHOSPHATE DEPOSITION DISEASE (CPPD) AND HYDROXYAPETITE DEPOSITION DISEASE.
- 20) Add ICD-10 M13.87 (Other specified arthritis, ankle and foot) to line 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE.
- 21) Add ICD-10 M24.17 (Other articular cartilage disorders, ankle or foot) to lines 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE, 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS, and 467 OSTEOARTHRITIS AND ALLIED DISORDERS and remove from lines 392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS and 436 INTERNAL DERANGEMENT OF KNEE AND LIGAMENOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT.
- 22) Add ICD-10 M24.87 (Other specific joint derangements of ankle, not elsewhere classified) to lines 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE and 467 OSTEOARTHRITIS AND ALLIED DISORDERS and remove from line 545 DEFORMITIES OF FOOT.
- 23) Add ICD-10 M25.87 (Other specified joint disorders, ankle and foot) to lines 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE, 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS, and 467 OSTEOARTHRITIS AND ALLIED

DISORDERS and remove from line [530 DEFORMITIES OF UPPER BODY AND ALL LIMBS](#)⁵⁴⁵
~~DEFORMITIES OF FOOT~~

- 24) Add ICD-10 A04.9 (Bacterial intestinal infection, unspecified) to line 664.
GASTROINTESTINAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR
NO TREATMENT NECESSARY and remove from line 150 ENTERIC INFECTIONS AND
OTHER BACTERIAL FOOD POISONING.
- 25) Add ICD-10 K90.9 (Intestinal malabsorption, unspecified) to line 555 OTHER
NONINFECTIOUS GASTROENTERITIS AND COLITIS and remove from line 232 INTESTINAL
MALABSORPTION
- 26) Modify Guideline Note 24 as shown in Appendix A.

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 7-0.
(Absent: Hodges)

➤ **Topic: 2017 CPT/HCPCS Code Placements**

Discussion: There was no discussion about any of the CPT or HCPCS code placements with the following exceptions:

- 1) 58674 (Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency) was felt to not be experimental. However, the recommended placement on the Services Recommended for Non-Coverage was felt to be appropriate. The rationale for placement should be insufficient level of effectiveness.
- 2) 77065-77067 (Diagnostic and screening mammography with computer-aided-detection): The subcommittee determined that the computer aided detection guideline should be maintained, with wording altered to remove the CPT codes. This may allow value-based pricing by HSD, and serves as a statement of HERC's assessment of the evidence around CAD.
- 3) G9678 (Oncology care model (ocm) monthly enhanced oncology services (meos) payment for ocm enhanced services) was added to the Ancillary list rather than the chemotherapy/radiation therapy lines.

Recommended Actions:

- 1) 2017 CPT and HCPCS codes placements as shown in Appendix B.
- 2) Guideline note 106 was modified as shown in Appendix A.
- 3) Diagnostic Guideline D15 was modified as shown in Appendix A.
- 4) A new guideline was adopted regarding transcatheter repair of paravalvular leaks as shown in Appendix C

MOTION: To approve the amended recommendations for code placement and guideline changes and new guideline. CARRIES 8-0.

➤ **Topic: Rehabilitative and Habilitative Therapy Guideline**

Discussion: Smits reviewed the OHP medical director request to include the federal definition of habilitative in GN6. This definition is from federal rule and the subcommittee determined that it should not be included in the guideline. Therefore no changes should be made to the current guideline. HERC staff will direct health plans and providers with questions to the federal rule.

MOTION: To make no changes to the guideline. CARRIES 8-0.

➤ **Topic: Back Surgery Guideline**

Discussion: Smits introduced the summary document on back surgery guideline changes. Williams requested that the work “joint” be changed to “joints” in the criteria for spinal instability, as resection of one joint would not cause instability. - Hodges asked how spinal instability would be determined by a medical director for determination of coverage; Williams indicated that the surgeon should document existing or expected instability in the pre-operative note.

Recommended Actions:

- 1) GN37 was modified as shown in Appendix A

MOTION: To approve the guideline note changes as amended. CARRIES 8-0.

➤ **Topic: Non-invasive Tests for Liver Fibrosis**

Discussion: Livingston presented the issue summary which would add to the guideline note on noninvasive testing of liver fibrosis that 3 tests are not included on any line on the Prioritized List (real time tissue elastography, Hepascore® (FibroScore®), and FibroSure® (FibroTest®). Olson let the group know that Providence is newly using Fibrosure®. Hodges asked a clarifying question about the deletion of guideline note 76. Livingston stated it was superseded by language adopted from the Coverage Guidance box language.

Recommended Actions:

- 1) Modify GUIDELINE NOTE XXX DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE TREATMENT OF HEPATITIS C IN NON-CIRRHOTIC PATIENTS as shown in Appendix A.
- 2) Delete GUIDELINE NOTE 76, LIVER ELASTOGRAPHY as shown in Appendix D.

MOTION: To approve the guideline note changes. CARRIES 8-0.

➤ **Topic: SI Joint Fusion**

Discussion: Smits reviewed the discussion on this topic from August, and the interim work done by HERC staff, Vern Saboe and Susan Williams. This work included the development of a possible guideline in SI joint fusion was added to the Prioritized List.

Andy Kranenberg, MD (via phone) testified, noting that he receives reimbursement for teaching the surgical technique to other providers, but does not have financial interest in the company. His testimony summarized the handout he provided to members, and involved the need for the SI joint fusion procedure and the evidence supporting this procedure. SI joint pain is disabling and has large impact on quality of life (QOL), and surgery can improve QOL and allows patients to continue working. Projected savings are sizable for using this procedure. He is in support of coverage with a guideline note similar to proposed. He went through the importance of treatment and the evidence supporting efficacy of the SI joint fusion procedure.

Jessie Payne, a patient who had SI joint fusion surgery, testified about her experience with SI joint pain, and the impact of this condition on her quality of life. She did multiple treatments, including physical therapy, chiropractic, and acupuncture. After having the fusion done bilaterally as outpatient surgery, she was able to return to a high level of activity, and had a significant improvement in quality of life.

Pollack asked for further information on why the staff assessment of the evidence quality conflicts with the expert opinion on the evidence. Smits reviewed the evidence reviewed from August. Pollack asked if other experts such as physiatrists had been consulted. Staff indicated that no physiatrists had been consulted.

Saboe stated that the national chiropractic association review has found that the evidence does not support use. However, the evidence does show that a subset of individuals can benefit from surgery, and he thinks that the proposed guideline note would help define this group.

Olson summarized that the proposed guideline addresses the ability to accurately diagnose SI joint dysfunction and assists in identifying the subset of patients who could benefit from surgery.

Drs. Kranenberg and Williams indicated that SI joint anesthetic injection was an important part of the ability to correctly diagnose that SI joint dysfunction was the cause of the pain and that the North American Spine Association (NASS) guideline included a requirement for a good response to two separate anesthetic injections. They recommended including this clause in the guideline. Kranenberg indicated that the evidence does not support the use of corticosteroid injections as a stand along therapy for SI joint dysfunction, but the diagnostic injections are supported by evidence and expert guidelines. Staff indicated that the possible

CPT codes used for diagnostic SI joint injection were either Services Recommended for Non Coverage (i.e. 27096 Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed), or not on the back surgery line (i.e. 20610 Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance or 20552 Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)). Staff was directed to determine the most appropriate CPT code for this injection type, and to add this code to the diagnostic list with a new diagnostic guideline that would clearly state that only the diagnostic injection is included for diagnostic coverage; the therapeutic steroid injection is not covered.

There was discussion about whether this procedure should be on the covered or on the uncovered back surgery line. If on the unfunded line, what comorbid conditions should be allowed? The thought was that if the pain interfered with exercise for control of diabetes or similar types of comorbid conditions, then it should be considered. Back pain should not be considered for a comorbid condition that would allow coverage of the SI joint surgery. There was discussion about adding to the upper covered line and requiring there to be significant disability from the condition. Livingston reviewed the major diagnoses on the covered surgical line such as myelopathy and spinal instability. SI joint dysfunction was felt to be more appropriate to be prioritized with the conditions on the lower surgical line. The decision was made to add the procedure and diagnosis codes to the lower back surgery line.

The proposed guideline was reviewed. References to pain values on pain scales were removed as the subcommittee felt that the patient should have function issues to qualify for surgery rather than just pain. There was discussion about removing the clause not allowing surgery for patients with other generalized pain conditions such as fibromyalgia. This was not adopted as the subcommittee felt that the NASS guideline should be followed for this clause. An additional clause was added based on the NASS requirement for good response to the diagnostic SI joint injection.

Recommended Actions:

- 1) Add CPT 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device) to 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
- 2) Add ICD-10 M46.1 (Sacroiliitis, not elsewhere classified) to 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS and keep on line 407 CONDITIONS OF THE BACK AND SPINE
- 3) Adopt the a new guideline regarding sacroiliac joint fusion for line 532 as shown in appendix C
- 4) HERC staff to identify the correct CPT code(s) for diagnostic SI joint injection and place this/these code(s) on the Diagnostic List
- 5) Adopt a new diagnostic guideline regarding this diagnostic SI joint injection with HERC staff to determine the CPT code to place into this guideline as identified in #4 above. This guideline is shown in appendix C

Addendum: HERC staff identified the following codes as utilized for diagnostic SI joint injection:

- 1) 20610 Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance*
- 2) 27096 Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed*

CPT 20610 is on various lines on the Prioritized List and is not a candidate for the Diagnostic List. HERC staff, in consultation with HERC leadership, placed these codes on line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS. The new guideline initially approved as a diagnostic guideline was converted to a guideline attached to line 532 and merged with the SI joint fusion guideline. Minor wording changes were made to the text of this ~~is~~ guideline to improve clarity and allow this conversion.

MOTION: To approve the code changes and new guideline notes as modified and newly proposed. CARRIES 8-0.

➤ **Topic: Skin substitutes for chronic skin ulcers**

Discussion: Livingston presented the issue summary. There was minimal discussion. Olson asked for public comment. There was none. Williams asked for clarity around the reasons for not including brands of skin substitutes. Livingston addressed some of the issues with the rapidly evolving literature base. Hodges clarified that the paragraph at the end of the guideline note would be helpful in determining those with evidence and the least costly option.

Recommended Actions:

- 1) Remove skin substitute codes (CPT codes 15271-15278) from Line 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
- 2) Adopt a new guideline note on skin substitutes for chronic skin ulcers as shown in Appendix C.

MOTION: To approve the recommendations as stated in the issue summary. CARRIES 8-0.

➤ **Topic: Obesity Taskforce (Biennial Review)**

Discussion: Livingston presented the Obesity Task Force issue summaries on behavioral interventions for obesity, pharmacotherapy for obesity, and devices for obesity. There was minimal discussion. Mosbaek presented the evidence review on Multisector Interventions for Obesity. Pollack talked about the importance of having physicians in training having more experience with food and the social determinants of health. There was a discussion

about whether the multisector intervention statement should be specifically attached to the obesity and diabetes lines. Coffman discussed the issue with yoga coverage - that if there is a specific link to lines there may be unintended expectation that the multisector interventions are discretely covered services.

Staff was asked to see if there was a way to reference the obesity and diabetes line with multisector interventions.

Subcommittee members discussed that the audience of the multisector interventions is wider than the general Prioritized List changes. That the goal is to ensure public policy entities are aware of the evidence-based interventions. The group wondered about the public entities who may be interested in these topics and Olson discussed mentioning this further at HERC.

Recommended Actions:

- 1) Approve the Obesity Task Force Package on behavioral interventions, pharmacotherapy, and devices for overweight and obesity to the January, 2018 Prioritized List.
 - a. Add Z71.3 Dietary counseling and surveillance to Line 325
 - b. Delete the lower obesity line
 - c. Modify guideline note 5 on behavioral interventions for obesity and overweight as shown in Appendix A
 - d. Modify guideline note 5 to add language about intended noncoverage of devices for obesity as shown in Appendix A
 - e. Add an entry to the Services Recommended for Non-Coverage table for devices for obesity
 - f. Make no change to the current noncoverage of pharmacotherapy for obesity
 - g. Add a Multisector Intervention statement on the prevention and treatment of obesity to the Prioritized List as shown in Appendix C

MOTION: To approve the Obesity Task Force package. CARRIES 8-0.

➤ **Topic: Repair of inguinal and ventral hernias**

Discussion: Smits reviewed the literature update on the comparative effectiveness and harms of watchful waiting versus elective repair of asymptomatic or minimally symptomatic inguinal hernias. The subcommittee discussed whether the evidence of improvement in quality of life (QOL) with elective repair justified adding coverage for non-symptomatic inguinal hernias. There was discussion about whether to add coverage for non-incarcerated/non-obstructed inguinal hernias that affected function or ability to be employed. It was noted that elective hernia repair is among the most common elective surgeries performed. No evidence was found that surgery improves function, but likely this

is due to the fact that most surgery is performed for pain prior to functional impairment. Pain does not appear to be related to risk of complications such as incarceration or obstruction. The decision was to make no change in coverage for inguinal or ventral hernia.

MOTION: To not recommend changes to current coverage of inguinal or ventral hernias CARRIES 8-0.

➤ **Topic: Coverage Guidance— Long acting reversible contraceptives (LARC)**

Discussion: Ray reviewed the Draft Coverage Guidance on LARC, including the evidence, the policy landscape, and public comments. Gibson asked about the difference in expulsion rates in the studies versus in the community. Ray clarified that there may be overestimates of community expulsion rates and some of the differences depended on postpartum versus postabortion groups.

Neilson stated that the major concern about coverage of LARC is about the global OB payment. The cost of LARC is prohibitive for hospitals to build this in as a part of their global payment for a delivery.

Olson clarified intent is to cover LARC placement in these circumstances and that administrative barriers should not serve as barriers to prevent their use.

VbBS members agreed that they would like to endorse the attached letter from Dr. Saha and Dr. Chan about the implementation challenges associated with LARC placement.

Hodges asked about making the reference materials readily available to the medical directors. Subcommittee members discussed various ways that these reference materials (specifically the CMS summary of solutions state Medicaid agencies have identified) should be readily available to medical directors. Staff was given leeway to determine the most effective way to make these available as part of the guideline note.

Recommended Actions:

- 1) Adopt a new guideline note on LARC placement as shown in Appendix C
- 2) Endorse the letter written by Dr. Saha and Dr. Chan to the plan Medical Directors
- 3) Staff to determine how to make the reference materials (solutions to administrative barriers) readily available to medical directors and clear on the Prioritized List

MOTION: To approve the recommended changes to the Prioritized List based on the draft Timing of LARC Placement Coverage Guidance. CARRIES 8-0.

➤ **Public Comment:**

No additional public comment was received.

➤ **Issues for next meeting:**

No items were carried forward to the next meeting

➤ **Next meeting:**

January 12, 2017 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

➤ **Adjournment:**

The meeting adjourned at 1:10 PM.

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DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

- A) Genetic tests are covered as diagnostic, unless they are listed below in section F1 as excluded or have other restrictions listed in this guideline. To be covered, initial screening (e.g. physical exam, medical history, family history, laboratory studies, imaging studies) must indicate that the chance of genetic abnormality is > 10% and results would do at least one of the following:
 - 1) Change treatment,
 - 2) Change health monitoring,
 - 3) Provide prognosis, or
 - 4) Provide information needed for genetic counseling for patient; or patient's parents, siblings, or children
- B) Pretest and posttest genetic counseling is required for presymptomatic and predisposition genetic testing. Pretest and posttest genetic evaluation (which includes genetic counseling) is covered when provided by a suitable trained health professional with expertise and experience in genetics.
 - 1) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.
- C) A more expensive genetic test (generally one with a wider scope or more detailed testing) is not covered if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context.
- D) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history.
 - 1) Services are provided according to the Comprehensive Cancer Network Guidelines.
 - a) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal [V2.2016 \(9/26/16\)](#) ~~V.1.2015 (5/4/15)~~. www.nccn.org.
 - b) Breast and ovarian cancer syndrome genetic testing services (CPT 81162, 81211-81217) for women without a personal history of breast, ovarian and other associated cancers should be provided to high risk women as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and ovarian. [V1.2017 \(9/19/16\)](#). ~~V2.2015 (6/25/15)~~. www.nccn.org.

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- c) Breast and ovarian cancer syndrome genetic testing services (CPT 81162, 81211-81217) for women with a personal history of breast, ovarian, and other associated cancers and for men with breast cancer should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. [V1.2017 \(9/19/16\)](#). ~~V2.2015 (6/25/15)~~. www.nccn.org.
- d) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Colorectal Screening. [V2.2016 \(9/26/16\)](#) ~~V.1.2015 (5/4/15)~~. www.nccn.org.
- 2) Genetic counseling should precede genetic testing for hereditary cancer whenever possible.
 - a) Pre and post-test genetic counseling should be covered when provided by a suitable trained health professional with expertise and experience in cancer genetics. Genetic counseling is recommended for cancer survivors when test results would affect cancer screening.
 - i) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.
 - b) If timely pre-test genetic counseling is not possible for time-sensitive cases, appropriate genetic testing accompanied by pre- and post- test informed consent and post-test disclosure performed by a board-certified physician with experience in cancer genetics should be covered.
 - i) Post-test genetic counseling should be performed as soon as is practical.
- 3) If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT 81211) analyses is not. There is one exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).
- 4) Costs for rush genetic testing for hereditary breast/ovarian and colon/endometrial cancer is not covered.
- E) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
 - 1) CPT 81228, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.

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- 2) CPT 81229, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities; plus cytogenetic constitutional microarray analysis for single nucleotide polymorphism (SNP) variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder; only if (a) consanguinity and recessive disease is suspected, or (b) uniparental disomy is suspected, or (c) another mechanism is suspected that is not detected by the copy number variant test alone.
 - 3) CPT 81243, 81244, Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
 - 4) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.
- F) Related to other tests with specific CPT codes:
- 1) The following tests are not covered:
 - a) CPT 81225, CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
 - b) CPT 81226, CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN).
 - c) CPT 81227, CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
 - d) CPT 81287, MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme), methylation analysis
 - e) CPT 81291, MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
 - f) CPT 81330, SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal) (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)
 - g) CPT 81350, UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, *28, *36, *37)
 - h) CPT 81355, VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variants (eg, -1639/3673)
 - i) CPT 81417, re-evaluation of whole exome sequencing
 - j) CPT 81425-81427, Genome sequence analysis

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- k) CPT 81470, 81471, X-linked intellectual disability (XLID) genomic sequence panels
- l) CPT 81504, Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores
- 2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
 - a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
 - b) Diagnostic testing for cystic fibrosis (CF)
CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
 - c) Carrier testing for cystic fibrosis
 - i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered once in a lifetime.
 - d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg, male infertility): Covered only after genetic counseling.
 - e) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
 - f) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

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- g) CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.
- h) CPT 81221, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the alpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.
- i) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test
- j) CPT 81430-81431, Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.
- k) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.
- l) CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.

* American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories. 2008 Edition, Revised 3/2011 and found at <https://www.acmg.net/StaticContent/SGs/CFTR%20Mutation%20Testing.pdf>

DIAGNOSTIC GUIDELINE D15, COMPUTER-AIDED MAMMOGRAPHY

Computer-aided mammography (~~CPT code 77051 and 77052~~) is not intended to be a covered service.

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.

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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. [Neurologic impairment is defined as 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](#)

Otherwise, these diagnoses are included on Line 532. Only decompression surgery is included on these lines for spinal stenosis; spinal fusion procedures are not included on either line for ~~this diagnosis~~ [spinal stenosis unless:](#)

- 1) [the spinal stenosis is in the cervical spine OR](#)
- 2) [spondylolisthesis is present as above OR](#)
- 3) [there is pre-existing or expected post-surgical spinal instability \(e.g. degenerative scoliosis >10 deg, >50% of foraminal joints expected to be resected\)](#)

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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 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.](#)

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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.

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Line 3, 625

Included on ~~this~~ line 3 are the following preventive services as required by federal law:

1. US Preventive Services Task Force (USPSTF) “A” and “B” Recommendations
<http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/>
2. American Academy of Pediatrics (AAP) Bright Futures Guidelines:
<http://brightfutures.aap.org>. Periodicity schedule available at
http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity%20Schedule_FINAL.pdf.
3. **Health Resources and Services Administration (HRSA) Women’s Preventive Services - Required Health Plan Coverage Guidelines:**
<http://www.hrsa.gov/womensguidelines/>
4. Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP):
<http://www.cdc.gov/vaccines/schedules/hcp/index.html>

USPSTF “D” recommendations are included on line 625

Appendix B
2017 CPT Codes

Code	Description	Placement
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each inter	51 DEEP ABSCESES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS 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 205 CANCER OF BONES 259 CHRONIC OSTEOMYELITIS 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS 366 SCOLIOSIS 406 ENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS 482 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS 561 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete)	51, 154, 205, 259, 351, 366, 406, 482, 532, 561
22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary	51, 154, 205, 259, 351, 366, 406, 482, 532, 561

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22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level	Services recommended for non-coverage
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)	Services recommended for non-coverage
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level	Services recommended for non-coverage
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)	Services recommended for non-coverage
27197	Closed treatment of posterior pelvic ring fracture(s), dislocation(s), diastasis or subluxation of the ilium, sacroiliac joint, and/or sacrum, with or without anterior pelvic ring fracture(s) and/or dislocation(s) of the pubic symphysis and/or superior/inferior rami, unilateral or bilateral; without manipulation	187 FRACTURE OF PELVIS, OPEN AND CLOSED
27198	Closed treatment of posterior pelvic ring fracture(s), dislocation(s), diastasis or subluxation of the ilium, sacroiliac joint, and/or sacrum, with or without anterior pelvic ring fracture(s) and/or dislocation(s) of the pubic symphysis and/or superior/inferior rami, unilateral or bilateral; with manipulation, requiring more than local anesthesia (ie, general anesthesia, moderate sedation, spinal/epidural)	187 FRACTURE OF PELVIS, OPEN AND CLOSED
28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant	361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE

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28295	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal metatarsal osteotomy, any method	545 DEFORMITIES OF FOOT
31551	Laryngoplasty; for laryngeal stenosis, with graft, without indwelling stent placement, younger than 12 years of age	47 CLEFT PALATE WITH AIRWAY OBSTRUCTION 70 LARYNGEAL STENOSIS OR PARALYSIS WITH AIRWAY COMPLICATIONS 521 PARALYSIS OF VOCAL CORDS OR LARYNX
31552	Laryngoplasty; for laryngeal stenosis, with graft, without indwelling stent placement, age 12 years or older	47, 70, 521
31553	Laryngoplasty; for laryngeal stenosis, with graft, with indwelling stent placement, younger than 12 years of age	47, 70, 521
31554	Laryngoplasty; for laryngeal stenosis, with graft, with indwelling stent placement, age 12 years or older	47, 70, 521
31572	Laryngoscopy, flexible; with ablation or destruction of lesion(s) with laser, unilateral	210 SUPERFICIAL ABSCESES AND CELLULITIS 292 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX 377 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS 641 BENIGN POLYPS OF VOCAL CORDS
31573	Laryngoscopy, flexible; with therapeutic injection(s) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral	210 SUPERFICIAL ABSCESES AND CELLULITIS 367 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral	70 LARYNGEAL STENOSIS OR PARALYSIS WITH AIRWAY COMPLICATIONS 521 PARALYSIS OF VOCAL CORDS OR LARYNX
31591	Laryngoplasty, medialization, unilateral	70 LARYNGEAL STENOSIS OR PARALYSIS WITH AIRWAY COMPLICATIONS 521 PARALYSIS OF VOCAL CORDS OR LARYNX
31592	Cricotracheal resection	267 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS 377 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS

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33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supe	Services recommended for non-coverage
33390	Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; simple (ie, valvotomy, debridement, debulking, and/or simple commissural resuspension)	73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 86 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 110 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 190 RHEUMATIC MULTIPLE VALVULAR DISEASE 193 CHRONIC ISCHEMIC HEART DISEASE 228 DISEASES AND DISORDERS OF AORTIC VALVE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
33391	Valvuloplasty, aortic valve, open, with cardiopulmonary bypass; complex (eg, leaflet extension, leaflet resection, leaflet reconstruction, or annuloplasty)	73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 86 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 110 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 190 RHEUMATIC MULTIPLE VALVULAR DISEASE 193 CHRONIC ISCHEMIC HEART DISEASE 228 DISEASES AND DISORDERS OF AORTIC VALVE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
36456	Partial exchange transfusion, blood, plasma or crystalloid necessitating the skill of a physician or other qualified health care professional, newborn	Services recommended for non-coverage
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated	384 CHRONIC ULCER OF SKIN 519 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL 522 POSTTHROMBOTIC SYNDROME 643 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION

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36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition	384 CHRONIC ULCER OF SKIN 519 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL 522 POSTTHROMBOTIC SYNDROME 643 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION
36901	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report;	63 END STAGE RENAL DISEASE 131 ACUTE KIDNEY INJURY 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 344 CHRONIC KIDNEY DISEASE
36902	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty	63 END STAGE RENAL DISEASE 131 ACUTE KIDNEY INJURY 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 344 CHRONIC KIDNEY DISEASE

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36903	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment	63 END STAGE RENAL DISEASE 131 ACUTE KIDNEY INJURY 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 344 CHRONIC KIDNEY DISEASE
36904	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s);	63 END STAGE RENAL DISEASE 131 ACUTE KIDNEY INJURY 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 344 CHRONIC KIDNEY DISEASE
36905	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty	63 END STAGE RENAL DISEASE 131 ACUTE KIDNEY INJURY 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 344 CHRONIC KIDNEY DISEASE

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36906	Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis circuit	63 END STAGE RENAL DISEASE 131 ACUTE KIDNEY INJURY 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 344 CHRONIC KIDNEY DISEASE
36907	Transluminal balloon angioplasty, central dialysis segment, performed through dialysis circuit, including all imaging and radiological supervision and interpretation required to perform the angioplasty	63 END STAGE RENAL DISEASE 131 ACUTE KIDNEY INJURY 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 344 CHRONIC KIDNEY DISEASE
36908	Transcatheter placement of intravascular stent(s), central dialysis segment, performed through dialysis circuit, including all imaging radiological supervision and interpretation required to perform the stenting, and all angioplasty in the central dialysis segment	63 END STAGE RENAL DISEASE 131 ACUTE KIDNEY INJURY 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 344 CHRONIC KIDNEY DISEASE
36909	Dialysis circuit permanent vascular embolization or occlusion (including main circuit or any accessory veins), endovascular, including all imaging and radiological supervision and interpretation necessary to complete the intervention	63 END STAGE RENAL DISEASE 131 ACUTE KIDNEY INJURY 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 344 CHRONIC KIDNEY DISEASE

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37246	Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; initial artery	48 COARCTATION OF THE AORTA 74 CONGENITAL PULMONARY VALVE ANOMALIES 110 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 228 DISEASES AND DISORDERS OF AORTIC VALVE 240 LIMB THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR COMPLICATIONS 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 310 DISORDERS OF ARTERIES, OTHER THAN CAROTID OR CORONARY 354 NON-LIMB THREATENING PERIPHERAL VASCULAR DISEASE 452 ATHEROSCLEROSIS, AORTIC AND RENAL
37247	Transluminal balloon angioplasty (except lower extremity artery(ies) for occlusive disease, intracranial, coronary, pulmonary, or dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same artery; each additional artery	48 COARCTATION OF THE AORTA 74 CONGENITAL PULMONARY VALVE ANOMALIES 110 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 228 DISEASES AND DISORDERS OF AORTIC VALVE 240 LIMB THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR COMPLICATIONS 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 310 DISORDERS OF ARTERIES, OTHER THAN CAROTID OR CORONARY 354 NON-LIMB THREATENING PERIPHERAL VASCULAR DISEASE 452 ATHEROSCLEROSIS, AORTIC AND RENAL
37248	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein	83 PHLEBITIS AND THROMBOPHLEBITIS, DEEP 240 LIMB THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR COMPLICATIONS 285 BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 354 NON-LIMB THREATENING PERIPHERAL VASCULAR DISEASE

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37249	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; each additional vein (List separately in add	83 PHLEBITIS AND THROMBOPHLEBITIS, DEEP 240 LIMB THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR COMPLICATIONS 285 BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 354 NON-LIMB THREATENING PERIPHERAL VASCULAR DISEASE
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed	Services recommended for non-coverage
43285	Removal of esophageal sphincter augmentation device	428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency	Services recommended for non-coverage
62320	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance	75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
62321	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic, with imaging guidance (ie, fluoroscopy or CT)	75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance	75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS

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62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)	75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance	Ancillary
62325	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)	Ancillary
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance	Ancillary
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)	Ancillary
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar	Services recommended for non-coverage

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76706	Ultrasound, abdominal aorta, real time with image documentation, screening study for abdominal aortic aneurysm (AAA)	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS 625 PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS
77065	Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral	Diagnostic Procedures File
77066	Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral	Diagnostic Procedures File
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (eg, immunoassay); capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges) includes sample validation when performed, per	Diagnostic Procedures File
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (eg, immunoassay); read by instrument assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per d	Diagnostic Procedures File
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry eit	Diagnostic Procedures File
81327	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis	Services recommended for non-coverage
81413	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCN	Diagnostic Workup File

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81414	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1	Diagnostic Workup File
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood	Services recommended for non-coverage
81439	Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN	Diagnostic Workup File
81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score	Services recommended for non-coverage
84410	Testosterone; bioavailable, direct measurement (eg, differential precipitation)	Diagnostic Procedures File
87483	Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (eg, Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, human parechovirus, herpes si	Diagnostic Procedures File
90674	Influenza virus vaccine, quadrivalent (ccIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use	Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
90697	Diphtheria, tetanus toxoids, acellular pertussis vaccine, inactivated poliovirus vaccine, Haemophilus influenzae type b PRP-OMP conjugate vaccine, and hepatitis B vaccine (DTaP-IPV-Hib-HepB), for intramuscular use	Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

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92242	Fluorescein angiography and indocyanine-green angiography (includes multiframe imaging) performed at the same patient encounter with interpretation and report, unilateral or bilateral	100,117,143,159,171, 175, 179, 248, 249, 252, 270, 274, 278,284,301, 302, 304, 313, 315, 323, 324, 340, 341, 342, 353, 356, 359, 365, 370, 372, 375, 379, 388, 399, 410, 441, 445, 453, 455, 456, 464, 475, 476, 488, 499, 505, 564, 567, 572, 597, 630, 636, 644
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
96160	Administration of patient-focused health risk assessment instrument (eg, health hazard appraisal) with scoring and documentation, per standardized instrument	Diagnostic Procedures File
96161	Administration of caregiver-focused health risk assessment instrument (eg, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument	Diagnostic Procedures File
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection	All lines with chemotherapy
96936	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion (List separately in addition to code for primary procedure)	Services recommended for non-coverage
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements f	All lines with 97001 currently 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, 297, 306, 314, 317, 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, 512, 532, 558, 561, 574, 592, 611

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97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in	All lines with 97001 currently
97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures	All lines with 97001 currently
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment i	All lines with 97001 currently
97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An	All lines with 97003 currently 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, 297, 306, 314, 322, 346, 350, 351, 353, 360, 361, 364, 366, 381, 382, 392, 406, 407, 413, 421, 423, 427, 428, 436, 447, 467, 471, 482, 490, 512, 532, 558, 561, 574, 592, 611
97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or	All lines with 97003 currently
97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psych	All lines with 97003 currently

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97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in con	All lines with 97003 currently
97169	Athletic training evaluation, low complexity, requiring these components: A history and physical activity profile with no comorbidities that affect physical activity; An examination of affected body area and other symptomatic or related systems addressing	Services recommended for non-coverage
97170	Athletic training evaluation, moderate complexity, requiring these components: A medical history and physical activity profile with 1-2 comorbidities that affect physical activity; An examination of affected body area and other symptomatic or related syst	Services recommended for non-coverage
97171	Athletic training evaluation, high complexity, requiring these components: A medical history and physical activity profile, with 3 or more comorbidities that affect physical activity; A comprehensive examination of body systems using standardized tests an	Services recommended for non-coverage
97172	Re-evaluation of athletic training established plan of care requiring these components: An assessment of patient's current functional status when there is a documented change; and A revised plan of care using a standardized patient assessment instrument a	Services recommended for non-coverage
99151	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the m	Ancillary

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99152	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the m	Ancillary
99153	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the m	Ancillary
99155	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 min	Ancillary
99156	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; initial 15 min	Ancillary
99157	Moderate sedation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports; each additiona	Ancillary

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Code	DESCRIPTION	Placement
G0490	Face-to-face home health nursing visit by a rural health clinic (rhc) or federally qualified health center (fqhc) in an area with a shortage of home health agencies; (services limited to rn or lpn only)	Any line with 99374 and 99375 (Supervision of a patient under care of home health agency)
G0493	Skilled services of a registered nurse (rn) for the observation and assessment of the patient's condition, each 15 minutes (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment in the home health or hospice setting)	Ancillary
G0494	Skilled services of a licensed practical nurse (lpn) for the observation and assessment of the patient's condition, each 15 minutes (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment in the home health or hospice setting)	Ancillary
G0495	Skilled services of a registered nurse (rn), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes	Ancillary
G0496	Skilled services of a licensed practical nurse (lpn), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes	Ancillary
G0500	Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older (additional time may be reported with 99153, as appropriate)	Ancillary
G0501	Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lift, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient, evaluation and management visit (list separately in addition to primary service)	Ancillary
G0502	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies	Ancillary

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G0503	Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies; monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment	Ancillary
G0504	Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (list separately in addition to code for primary procedure); (use g0504 in conjunction with g0502, g0503)	Ancillary
G0505	Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home	Diagnostic Procedures File
G0506	Comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service)	Ancillary
G0507	Care management services for behavioral health conditions, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team	Ancillary
G0508	Telehealth consultation, critical care, initial , physicians typically spend 60 minutes communicating with the patient and providers via telehealth	Inpatient lines on Prioritized List
G0509	Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth	Inpatient lines on Prioritized List

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G9481	Remote in-home visit for the evaluation and management of a new patient for use only in the medicare-approved comprehensive care for joint replacement model, which requires these 3 key components: a problem focused history; a problem focused examination; and straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are self limited or minor. typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary
G9482	Remote in-home visit for the evaluation and management of a new patient for use only in the medicare-approved comprehensive care for joint replacement model, which requires these 3 key components: an expanded problem focused history; an expanded problem focused examination; straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of low to moderate severity. typically, 20 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary
G9483	Remote in-home visit for the evaluation and management of a new patient for use only in the medicare-approved comprehensive care for joint replacement model, which requires these 3 key components: a detailed history; a detailed examination; medical decision making of low complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate severity. typically, 30 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary
G9484	Remote in-home visit for the evaluation and management of a new patient for use only in the medicare-approved comprehensive care for joint replacement model, which requires these 3 key components: a comprehensive history; a comprehensive examination; medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 45 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary

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G9485	Remote in-home visit for the evaluation and management of a new patient for use only in the medicare-approved comprehensive care for joint replacement model, which requires these 3 key components: a comprehensive history; a comprehensive examination; medical decision making of high complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 60 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary
G9486	Remote in-home visit for the evaluation and management of an established patient for use only in the medicare-approved comprehensive care for joint replacement model, which requires at least 2 of the following 3 key components: a problem focused history; a problem focused examination; straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are self limited or minor. typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary
G9487	Remote in-home visit for the evaluation and management of an established patient for use only in the medicare-approved comprehensive care for joint replacement model, which requires at least 2 of the following 3 key components: an expanded problem focused history; an expanded problem focused examination; medical decision making of low complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of low to moderate severity. typically, 15 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary
G9488	Remote in-home visit for the evaluation and management of an established patient for use only in the medicare-approved comprehensive care for joint replacement model, which requires at least 2 of the following 3 key components: a detailed history; a detailed examination; medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 25 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary

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G9489	Remote in-home visit for the evaluation and management of an established patient for use only in the medicare-approved comprehensive care for joint replacement model, which requires at least 2 of the following 3 key components: a comprehensive history; a comprehensive examination; medical decision making of high complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 40 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary
G9490	Comprehensive care for joint replacement model, home visit for patient assessment performed by clinical staff for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and ensuring beneficiary connections to community and other services. (for use only in the medicare-approved cjr model); may not be billed for a 30 day period covered by a transitional care management code	Ancillary
G9678	Oncology care model (ocm) monthly enhanced oncology services (meos) payment for ocm enhanced services. g9678 payments may only be made to ocm practitioners for ocm beneficiaries for the furnishment of enhanced services as defined in the ocm participation agreement	Ancillary
G9686	Onsite nursing facility conference, that is separate and distinct from an evaluation and management visit, including qualified practitioner and at least one member of the nursing facility interdisciplinary care team	Ancillary
G9770	Peripheral nerve block (pnb)	Informational
S0285	Colonoscopy consultation performed prior to a screening colonoscopy procedure	3 PREVENTIVE SERVICES
S0311	Comprehensive management and care coordination for advanced illness, per calendar month	Ancillary
T1040	Medicaid certified community behavioral health clinic services, per diem	Ancillary
T1041	Medicaid certified community behavioral health clinic services, per month	Ancillary

Appendix C

NEW GUIDELINES

GUIDELINE NOTE XXX PERCUTANEOUS REPAIR OF PARAVALVULAR LEAKS

Line 290

Percutaneous transcatheter closure of paravalvular leak (CPT 93590-93592) is included on this line only for patients with

- 1) prosthetic heart valves with paravalvular leak AND
- 2) intractable hemolysis or NYHA class III/IV heart failure AND
- 3) who are at high risk for surgery and have anatomic features suitable for catheter-based therapy AND
- 4) when performed in centers with expertise in the procedure.

GUIDELINE NOTE XXX DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE TREATMENT OF HEPATITIS C IN NON-CIRRHOTIC PATIENTS

Line 203

If a fibrosis score of $\geq F2$ 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 $\geq F3$ 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 $\geq F2$ or $\geq F3$ only when at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminate results, a second one is similarly indeterminate, contraindicated or unavailable, and MRE is readily available.

Noninvasive tests are covered no more often than once per year.

The following tests are not included on this line (or any other line):

- Real time tissue elastography

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- 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>

GUIDELINE XXX, SACROILIAC JOINT FUSION

Line 532

Sacroiliac (SI) joint fusion (CPT 27279) is included on this line for patients who have all of the following:

1. Baseline score of at least 30% on the Oswestry Disability Index (ODI)
2. Undergone and failed a minimum six months of intensive non-operative treatment that must include non-opioid medication optimization and active therapy. Active therapy is defined as activity modification, chiropractic/osteopathic manipulative therapy, bracing, and/or active therapeutic exercise targeted at the lumbar spine, pelvis, SI joint and hip including a home exercise program. Failure of conservative therapy is defined as less than a 50% improvement on the ODI.
3. Typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SI joint, and consistent with SI joint pain.
4. Thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e. at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine) in the absence of tenderness of similar severity elsewhere (e.g. greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
5. Positive response to at least three of six provocative tests (e.g. thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test).
6. Absence of generalized pain behavior (e.g. somatoform disorder) and generalized pain disorders (e.g. fibromyalgia).
7. Diagnostic imaging studies that include ALL of the following:
 - a. Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g. tumor, infection), fracture, traumatic SI joint instability, or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion
 - b. Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology
 - c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain
 - d. Imaging of the SI joint that indicates evidence of injury and/or degeneration
 - e.

At least 75 percent reduction of pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular SI joint injection.SI

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NEW GUIDELINES

joint injections (CPT 20610 and 27096) are included on this line for diagnostic SI joint injections with anesthetic only, but not for therapeutic injections or corticosteroid injections. Injections are only included on this line for patients for whom SI joint fusion surgery is being considered.

Note: initially approved as a diagnostic guideline, but converted to a guideline attached to line 532 and merged with the other approved SI joint fusion guideline as discussed in the minutes above. Minor wording changes were made to the approved guideline wording to allow these changes

GUIDELINE NOTE XXX SKIN SUBSTITUTES FOR CHRONIC SKIN ULCERS

Line 384

Skin substitutes for chronic venous leg ulcers and chronic diabetic foot ulcers are included on this line when all of the following criteria are met:

- 1) FDA indications and contraindications are followed, if applicable
- 2) Wound has adequate arterial flow (ABI > 0.7), no ongoing infection and a moist wound healing environment
- 3) For patients with diabetes, Hba1c level is < 12
- 4) Prior appropriate wound care therapy (including but not limited to appropriate offloading, multilayer compression dressings and smoking cessation counseling) has failed to result in significant improvement (defined as at least a 50 percent reduction in ulcer surface area) of the wound over at least 30 days
- 5) Ongoing coverage requires significant improvement of the ulcer with skin substitute application over the preceding 6 week time period
- 6) Patients is able to adhere to the treatment plan
- 7) The use of skin substitutes is not included on this line for chronic skin ulcers other than venous leg ulcers and diabetic foot ulcers (e.g., pressure ulcers)

Note: There is no evidence supporting superiority of one skin substitute versus another and new studies are constantly being published. Decisions for specific products could be made based on at least one supportive randomized controlled trial, and those that involve fewer applications, and are lower cost.

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)

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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:

<http://www.oregon.gov/oha/herc/Pages/blog-obesityMSI.aspx>

GUIDELINE NOTE XXX LONG-ACTING REVERSIBLE CONTRACEPTIVE (LARC) PLACEMENT

Line 6

Long-acting reversible contraceptives (implant or intrauterine device) are included on Line 6 in all settings, including (but not limited to) immediately postpartum and postabortion.

The development of this guideline note was informed by a HERC coverage guidance. See <http://www.oregon.gov/oha/herc/Pages/blog-long-acting-reversible-contraceptives.aspx>.

HERC leadership added a letter (<http://www.oregon.gov/oha/herc/Documents/LARC-Implementation.pdf>) to Medical Directors regarding implementation issues, which references CMS requirements around contraceptive coverage and guidance on ways to implement effective LARC policy.

Appendix D

DELETED GUIDELINE NOTES

~~GUIDELINE NOTE 76, LIVER ELASTOGRAPHY~~

~~Line 203~~

~~Liver elastography (CPT 91200) is included on this line only when the non-invasive test would replace liver biopsy for determination of eligibility for medications for chronic hepatitis C. Performance of liver elastography more than twice per year or within six months following a liver biopsy is not included on this line.~~

MINUTES

Health Technology Assessment Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 210
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
December 1, 2016
1:00-4:00pm

Members Present: Som Saha, MD, MPH (Chair Pro Tempore); Derrick Sorweide, DO (Vice-Chair); Chris Labhart; Clyde Farris, MD; Vinay Prasad, MD, MPH; Leda Garside, RN, MPH; Mark Bradshaw, MD.

Members Absent: None

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

Also Attending: Adam Obley, MD, Val King MD, MPH & Craig Mosbaek (OHSU Center for Evidence-based Policy), Kari Thomas, MD, Legacy Health Systems (appointed expert); Lana Giacomelli (Women's Health Care Association); Cindy Fletcher (Susan B. Komen Foundation in Oregon and SW Washington).

1. CALL TO ORDER

Coffman welcomed new member Vinay Prasad. Staff and other members introduced themselves.

2. MINUTES REVIEW

Minutes from the September, 2016 meeting were reviewed and approved 7-0.

3. STAFF REPORT

Coffman reported that there is a revision in the Coverage Guidance monitoring process. In the future, there will not be any active monitoring of coverage guidances involving updated literature search. Instead, stakeholders can suggest a review and staff will perform a rescan if necessary. Rulemaking for this new process is underway.

4. DRAFT COVERAGE GUIDANCE: DIGITAL BREAST TOMOSYNTHESIS (3D MAMMOGRAPHY) FOR BREAST CANCER SCREENING IN AVERAGE RISK WOMEN

Obley presented a summary of the draft coverage guidance and reviewed the public comments received during the public comment period as well as the new studies found in the updated evidence search. He highlighted the separation of U.S. and European studies, as baseline recall rate differences between the U.S. and Europe were causing challenges in interpreting the findings.

The one systematic review of the observational data did show an improved cancer detection rate in the population with dense breasts. Thomas asked whether this finding included women with heterogeneously dense breasts (it does), and said that this would mean that the definition of dense breasts would include about 50 percent of a screening population.

In the broader population, Obley said there is no meta-analysis, but overall there is a consistent finding in the U.S. studies of a significant reduction in recall rate. For cancer detection rate, however, while all but one of the 11 U.S.-based studies showed a benefit, only five of these reached a level of statistical significance.

Obley also reviewed slides on the studies of economic analysis. They assume a reduced recall rate as well as increased cancer detection. He said there is considerable disagreement about the disutility of false positive mammograms, with estimates ranging from 5 to 10.5 percent for a period of several weeks. Cost-effectiveness is higher for younger women. Both analyses showed reasonable cost-effectiveness in some simulations but not in others, especially those using higher prices for DBT.

Saha summarized that, in the U.S., there is probably a lower recall rate for false positives in the range of 1 to 5 percent and there may be an increased cancer detection rate. Cost-effectiveness estimates appear to use reasonable assumptions. That said, the cost-effectiveness studies assume lower recall as well as higher cancer detection, though there are some mixed results in the clinical data on the latter outcome.

He invited Kari Thomas, MD, who works at Legacy Good Samaritan Hospital and OHSU, to comment. She said her center has provided uniform DBT in screening for some time. She has reviewed cancers from her center that were found on DBT images but not on the 2D images of the same breast. These tumors were all invasive breast cancers, and the institution hasn't seen any increase in detection of ductal carcinoma in situ (a less risky form of breast cancer).

Prasad said that invasive cancer is not necessarily 'important' cancer. Obley said that most studies published in the literature found an increase in detection of both invasive and noninvasive cancers; one found a decrease in overall cancer detection but not in invasive cancer detection. Saha said that even if one accepts that the cancers are, in fact, invasive, in order to show a benefit in cancer detection it would also need to be the case that there would be an incremental benefit in detecting these cancers before they grew enough to be detected on the next mammograph. Prasad agreed, and said that in order to reach the levels of incremental cost-effectiveness shown in the modelling studies, one would have to make assumptions of a benefit in terms of mortality from improved cancer detection. This assumption has not been substantiated.

Saha then turned discussion to differential outcomes for women with dense breasts. Is their benefit from the recall rate and cancer detection in this population? Obley said that based on one study, the recall rate benefit would fall within the range of benefit for the entire screening population.

Thomas said that there is a lot of variation in how radiologists classify breast density, so it would be difficult to set coverage criteria for digital mammography allowing it only for women who have dense breasts. The rule would need to be based on the most recent screen, and sometimes breast density can vary over time in the same woman. Further discussion clarified that in addition to the diagnostic ambiguity there is no way to distinguish whether a woman has breast density in administrative data.

There is a law in Oregon requiring special notice to women whose mammograms indicate dense breasts, but the notifications are made based on the radiologist's interpretation.

A member asked about radiation exposure. Thomas explained that currently, both a 2-dimensional and 3-dimensional image are constructed from a single exposure, so the radiation dose is the same whether or not DBT is performed.

Thomas said that more and more health plans are paying for DBT.

Livingston said that the U.S. Preventive Services Task Force recently reviewed this topic and found insufficient evidence to recommend it. The question is whether the new evidence available to this committee would be significant enough to lead to a coverage recommendation. Obley said that the new evidence mostly adds to the consistency in the finding of reduced recall rate. The confidence in the evidence for increased cancer detection remains low.

Garside said it would be good to know the number of mammograms performed on OHP women, along with the rate of false positives. Staff has not performed this analysis.

Members discussed the possibility of harm from overdiagnosis. Thomas said, that while there are no pathologic markers that predict which ductal carcinomas in situ will become problematic, she said it would be hard to argue this is the case for invasive cancer. Prasad said that overdiagnosis has actually been shown for invasive breast cancer, so there are possible harms from this technology. Obley said that there is controversy in the mammography literature about overdiagnosis but rates may be 10 to 20 percent with digital mammography. Overdiagnosis is not factored into the cost-effectiveness modelling.

Saha invited public testimony.

Lana Giacomelli from the Women's Health Care Association offered public comment. She said offering differential coverage based on breast density would be an administrative nightmare. Gingerich confirmed that there is no diagnosis code for a finding of dense breasts, only for an inconclusive mammogram (which could be for a variety of reasons).

Cindy Fletcher, Director of Programs for the Susan B. Komen Foundation in Oregon and Southwest Washington, asked a question. She said that in her organization's outreach work, they are hearing that 3D mammography is becoming standard of care at many breast centers. She asked what is happening to 2D mammography units and when will women no longer be able to get a standard mammogram.

Thomas explained that 3D mammography machines can also create a standard 2D image. Garside asked whether, in order to get the 3D mammography, the 3D mammography needs to be approved. Thomas said that her facility uses 3D mammography unless patients opt out. If insurance doesn't cover the 3D mammography portion, there is a consent process and the woman may receive an extra bill. In her practice, 98 percent of women receive 3D mammography. Gingerich clarified that a Medicaid recipient could not be billed for the additional cost of the service.

Garside asked when the data from the randomized trials is expected. Obley said he does not know, but some trials have already completed data collection. The larger trials will not complete data collection for another year or more. Garside asked what the process would be to update this topic. Coffman explained that the topic could be updated at any time if there is a game-changing trial and there would otherwise

be an opportunity to raise the need to update the coverage guidance once per year.

Saha took a straw poll of the subcommittee to determine which option was supported. There was mixed support for the option to cover 3D mammography and the option not to cover 3D mammography. Some members expressed interest in the option to cover it only for women with dense breasts, but thought the implementation issues previously identified would be significant. In addition, the stronger evidence related to women with dense breasts is about cancer detection rather than improvements in mortality or morbidity.

After additional discussion, most members of the subcommittee agreed that the evidence for incremental cancer detection is not sufficient to result in a coverage recommendation, since there is the possibility of no significant increased cancer detection, and the possibility of harm from overdiagnosis. The benefit in reduction in recall rate appears to be real, but DBT is not cost-effective for this outcome. The subcommittee also discussed the current randomized trials underway, which may lead to a new review in the relatively near future.

There was a motion to approve the draft coverage guidance with Option A presented in the meeting materials, recommending noncoverage. The motion carried 6-1 (Garside opposed).

Saha asked that the record reflect that this was not an easy decision and the subcommittee is hopeful about the technology but would like to wait for proof that the technology is beneficial enough to warrant the investment. The next step for this topic is for the draft coverage guidance to be reviewed by the Value-based Benefits Subcommittee and HERC on January 12, 2017.

Thomas reminded the subcommittee that the U.S. Congress recently acted to put the 2016 USPSTF mammography recommendations on hold until 2018. Saha acknowledged this, stating that the Commission needs to base its decision on public values and preferences, not political pressure.

DRAFT HERC COVERAGE GUIDANCE

Digital breast tomosynthesis for breast cancer screening in average risk women is not recommended for coverage (*weak recommendation*).

5. COVERAGE GUIDANCE TOPIC MONITORING

Gingerich reported that staff did not conduct a rescan for two of the topics that were up for rescan, due to resource limitations and the belief that a formal rescan would not likely show new evidence that would alter the current recommendations. The two topics are *Upper Endoscopy for Gastroesophageal Reflux Disease (GERD)* and *Knee Arthroscopy for Patients with Osteoarthritis*. The former topic's recommendation is based on red flag criteria more than firm evidence, and the latter is not recommended for coverage.

Farris, an orthopedist, said that he agrees that knee arthroscopy in patients with osteoarthritis does not benefit patients. Obley said that while no formal rescan was conducted, he is aware of more recent studies that support the recommendation for noncoverage. Staff recommends that these topics be put

on passive monitoring status per the new administrative rule.

Obley reviewed the rescanned topics.

For *Indications for Hyperbaric Oxygen Therapy*, the current coverage guidance was scoped for a variety of indications. Because such a wide scope would not be well suited to the new HERC process, scope was limited to wounds and burns. There were new guidelines and reviews, but they would not appear to change the current coverage guidance.

For *Artificial Disc Replacement*, there is emerging evidence about performing two-level cervical disc replacement, but many of the authors believe evidence to be insufficient at this point; on balance he would say the coverage guidance is up-to-date. In the future, there may be a need to update it regarding two-level cervical disc replacement. Saha asked Farris about this topic. Farris said he isn't a spine surgeon, though he's aware of other surgeons doing them. He doesn't believe the long-term results are there yet to be sure the outcomes warrant the expense.

For *Hip Resurfacing*, Obley reported on two new reviews, which found it less effective than hip replacement. One of these also found that it is not cost-effective. One found an increased risk of adverse events in women. On balance the evidence likely supports the current coverage recommendations, which recommend the service for a narrow population. Farris agreed they may be appropriate for a narrow population such as a laborer in his 40s or 50s. He said these surgeries aren't done very often.

For *Lumbar Discography*, Obley said that the updated evidence search continues to support the recommendation for noncoverage. Farris agreed, adding that he is reluctant to intervene on a healthy disc.

For *Viscosupplementation for Osteoarthritis of the Knee*, Obley said that some lower-quality evidence may show a benefit, but when you limit it to studies with placebo controls and double blinding there is no benefit. Farris agreed, saying there may be a placebo effect for this intervention. No rescan is recommended.

Obley said that for the next two topics of *Osteoporosis Screening by Dual-Energy X-ray Absorptiometry (DXA)* and *Osteoporosis Screening by Dual-Energy X-ray Absorptiometry (DXA)*, which were split from a prior coverage guidance covering both topics, new evidence supported the current coverage guidance. There is no additional evidence on frequency of screening or monitoring.

For *Hip Surgery Procedures for Femoroacetabular Impingement Syndrome*, the evidence base consists of case series which show an apparent benefit for younger patients who are athletes. Much of the literature is about surgical technique and favors an arthroscopic approach over open surgery, and labral reconstruction over labral debridement. Gingerich reminded the subcommittee that Dr. Herzka, the appointed expert for the last review, attended the last meeting and recommended consideration relaxing the restrictions on this surgery for adolescents. Obley said the new evidence did appear to show increased benefit for younger patients, but the evidence is noncomparative case series and there is concern about harms for skeletally immature individuals. Farris said he has referred several patients for this surgery, but none improved. Obley said there are some better-designed comparative trials underway in Canada.

For *Treatment of Sleep Apnea in Adults*, Obley said there is likely no evidence that would change the

current recommendation. However the literature has a lack of randomized trials. The one randomized trial that has been published showed a lack of improvement for cardiovascular outcomes with Continuous Positive Airway Pressure (CPAP) devices. Most studies look at blood pressure or apnea-hypopnea index rather than long-term patient outcomes. There is a little evidence showing that stimulants or corticosteroids may be beneficial compared to placebo (they were not compared to standard treatments). There is also a new guideline supporting the use of mandibular advancement devices in patients who can't tolerate CPAP. Shaffer said that the wording of the current coverage guidance differs slightly with regards to mandibular advancement devices. The guideline would allow mandibular advancement devices for patients who prefer them to CPAP.

The subcommittee voted 7-0 to recommend that HERC reaffirm the existing coverage guidances on the topics for which a new evidence search was performed.

- Indications for Hyperbaric Oxygen Therapy for Chronic Wounds and Burns
- Artificial Disk Replacement
- Hip Resurfacing
- Lumbar Discography
- Viscosupplementation for Osteoarthritis of the Knee
- Osteoporosis Screening by Dual-Energy X-ray Absorptiometry (DXA)
- Osteoporosis Monitoring by Dual-Energy X-ray Absorptiometry (DXA)
- Hip Procedures for Femoroacetabular Impingement Syndrome
- Treatment of Obstructive Sleep Apnea in Adults

6. NEXT TOPICS

Farris announced that he will resign from the subcommittee due to his retirement effective immediately. Shaffer said that for the next meeting, discussion will focus a new topic of *Breast Cancer Screening in Women at Above-Average Risk* and updating the existing coverage guidance on *Continuous Glucose Monitoring in Diabetes Mellitus*.

7. ADJOURNMENT

The meeting was adjourned at 4:00 pm. The next meeting is scheduled for February 16, 2017 from 1:00-4:00 pm in Room 210 of the Wilsonville Training Center of Clackamas Community College.

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
November 3, 2016
2:00-5:00 pm

Members Present: Wiley Chan, MD, Chair; Eric Stecker, MD, MPH (by phone, joined at 3:15 PM), Vice-Chair; Beth Westbrook, PsyD; Alison Little, MD, MPH; George Waldmann, MD.

Members Absent: Kim Tippens, ND, MSAOM, MPH.

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

Also Attending: Adam Obley, MD, Val King MD, MPH, and Craig Mosbaek (OHSU Center for Evidence-based Policy); Janna Friedly, MD.

1. CALL TO ORDER

Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:00 pm.

2. MINUTES REVIEW

No changes were made to the September 1, 2016 minutes as presented.
Minutes approved 4-0 (Stecker not present).

3. STAFF REPORT

Coffman reported that staff is working on a new “passive monitoring” process. HERC has approved this methodology and administrative rules are being updated to align with this. This means that once a year, in conjunction with the topic nomination/solicitation process, those who believe there is a need to update an existing coverage guidance can request a review. Staff would then review the requests, and determine the need for an updated evidence search related to the request. Then, HERC would decide whether a new review is warranted. This process is similar one used by the Washington Health Technology Assessment program.

Waldman said that sometimes there are requests to revise a Prioritized List guideline note for clarity or implementation issues and asked if these would require a full coverage guidance update. Coffman said

that these could be handled at VbBS through the Prioritized List process unless they required a new review of the evidence or substantial change in the coverage recommendation. Since updating a coverage guidance requires substantial resources, that process wouldn't begin for minor wording changes, but only for substantial new evidence. Chan observed that the draft rule does not require new evidence to be submitted. Gingerich said that when the original rule was drafted, a decision was made to include other factors for consideration such as context or rationale. Since the original rule was adopted we have not received any such requests.

Livingston explained a discrepancy between how HTAS and EbGS have weighed functional outcomes in recently-developed scope statements. In some cases, EbGS considered short-term function to be a critical outcome, while HTAS considered it an important outcome, with long-term function as critical. Chan explained that this is important because a critical outcome could, by itself, drive a coverage recommendation, while an important outcome would be less likely to. The subcommittee discussed this and decided that while in some cases the committees may come to different conclusion for specific topics, consistency is generally important. Waldmann suggested that staff work these issues with chairs. Little said that it might depend on the topic whether the outcome should be treated the same, especially with interventions in different areas.

4. Low Back Pain: Corticosteroid Injections

Coffman introduced Dr. Janna Friedly, who will serve as an ad hoc expert for this topic. Dr. Friedly is a board certified physiatrist and assistant professor in the Department of Rehabilitation medicine at the University of Washington. She is the medical director of the outpatient rehabilitation Medicine clinics and the Amputee Rehabilitation Program at Harborview Medical Center. She completed the Rehabilitation Medicine Scientist Training Program (RMSTP) K12 fellowship in 2008. Dr. Friedly conducts outcomes research related to back pain treatments in the Comparative Effectiveness, Cost and Outcomes Research Center at the University of Washington. She was a co-author on the Chou review published by AHRQ that serves as the basis for the coverage guidance. She has declared no conflicts of interest.

Dr. Tim Keenen, president of the Oregon Orthopedic Society, was also appointed as an expert for this topic but was not in attendance.

Obley summarized the draft coverage guidance as presented in the meeting materials. Livingston reviewed the resource allocation, values and preferences and other elements of the GRADE-informed framework.

Livingston asked for questions about the evidence. Little asked how "immediate function" was defined in the literature. Obley said that it was within two weeks. Waldmann asked how Washington Medicaid dealt with repeat injections. Obley said that they allow up to two injections. After that, there would need to be documented improvement and only two injections are allowed every three months. Waldmann asked how this was justified. Friedly said that she was present for the discussions in Washington and that the Washington group asked whether there was new evidence to change the prior recommendations. They were presented with a strong argument from the interventional pain group including case studies and observational data and decided to leave the status quo. Obley said the group may have given some deference to clinical guidelines.

Chan said one of the most challenging things is that the staff recommendations appear to be different than anyone else's. At the same time, he can't justify anything but a strong recommendation against based on the evidence presented. Livingston said the strong recommendation is based on low to moderate confidence of no benefit. She reviewed the rationales for each GRADE table.

Friedly offered a description of the controversy surrounding the Chou report including criticism from the interventional pain societies. They expressed concern about the lack of inclusion of observational studies and case studies, saying that it limits the conclusions, as there are noncontrolled studies which suggest that patients improve with injections. They also raised concerns that the report includes interventions done without imaging guidance, which do not reflect current practice. That said, the report separated these out and were not able to distinguish any differences in outcomes. They also had concerns about calling a local anesthetic injection or saline injection a placebo, as some consider anesthetics to be active controls. The biggest concern is that there are many subpopulations. It may be too broad to group patients who have radiculopathy together as there can be several etiologies and some may be inflammatory in origin. She said she and her colleagues have addressed these concerns many times.

Friedly said the study was also criticized because it looked at long-term outcomes, but these injections aren't expected to have long-term benefits. Long-term pain or long-term function may not be an appropriate outcome. Obley said that many of the trials included multiple injections and 12-24 month followup periods.

Little asked whether some studies used comparators other than anesthetics. Obley said that yes, some trials used saline. He said it would be analogous to a trial where Drug A plus a sugar pill would be compared to a combination of Drug A and Drug B, showing equivalent results. In that scenario few would recommend administering both drugs, even if there were no additional cost. Friedly said that regarding comparators, the gold standard trial pointed to by the interventional pain societies was a 2010 study, a 5-arm study included in the AHRQ report with 150 patients (30 randomized to each arm). The study was for herniated disc and radiculopathy and it showed short-term improvement in pain for corticosteroid injections compared to all of the other control groups. All four control groups (transforaminal lidocaine injections, intramuscular lidocaine injections, transforaminal saline injections and intramuscular saline injections) performed similarly. There is a lot of controversy about lidocaine as a control or active treatment since lidocaine performed the same as saline. This study was included in the AHRQ report along with other trials. Friedly said that after one month the study was unblinded and patients were allowed to receive other treatments. In addition, there are no functional results reported, only pain.

Friedly also shared concerns not reflected in the report that there may be systemic harms such as cortisol suppression with long-term sequelae from repeat corticosteroid injections. These harms are not reflected in the studies.

Waldmann asked whether commenters from the pain groups shared insights as to which patients are most likely to benefit. In his experience it works occasionally but mostly in younger, healthier patients rather than more typical back patients with comorbidities such as sedentary lifestyle, obesity and mental health problems. Friedly said most studies have not looked at that, but she participated in a trial of steroid injections with lidocaine versus lidocaine alone for patients with spinal stenosis. The only characteristics that predicted response (in both the control and intervention groups) were patients who

did not have depression, anxiety, catastrophizing and fear/avoidance. Obley said the review agreed with this conclusion based on his assessment.

Chan said that more and better research would be required to support this intervention. Obley said this is similar to skin substitutes in that better trials could be done, as these are common conditions.

Livingston also reviewed the title change shown in the meeting material, from *Low Back Pain: Epidural Steroid Injections* to *Low Back Pain: Corticosteroid Injections*. Based on the evidence of no benefit for epidural steroid injections and insufficient evidence regarding outcomes for sacroiliac joint injections, staff recommends a strong recommendation for noncoverage for all these interventions.

Friedly relayed a concern of many stakeholders in the Washington process that there is a lack of available effective interventions and that denying these injections could result in more opioid use. Evidence-based interventions for back pain such as psychological interventions and exercise are not widely available in the US healthcare system. She doesn't know whether there is data from Washington state, whether opioid use and surgery rates were affected when steroid injections were restricted. Chan and Waldmann said that this would of course be observational data, and you would need a long-term study. Obley said there were secular reductions in opioid prescribing in Washington during this time. Waldmann noted that marijuana availability may also impact opioid use and surgery rates. Livingston noted that the Oregon Health Plan has recently expanded coverage for behavioral and other back pain treatments. Little added that the Oregon Health Plan stopped covering epidural steroid injections for low back pain on July 1.

Chan invited public comments.

Tina Schiff, with Disabled Americans for Change, testified. She declared no conflicts of interests. She said she wanted to show the face behind these injections. She knows that it works, and she is aware of the increased coverage for conservative therapy. She said she couldn't lay on the yoga mat without an injection. She can go online and find evidence that these injections work, though not as well as surgery. Everyone is different, so you can't lump everyone together. It may not be a huge stack of evidence, but even if it provides 30 percent relief, the difference can allow her to do more activities and be a productive member of society versus having to take pain medication. She advocated for a variety of treatments being available for back pain. She said she knows of patients who would be ideal candidates, but are being denied. Would there be a way to allow this for patients who have tried a variety of other therapies? She delivered a letter from a member of her organization as well as a letter from that patient's doctor advocating for coverage.

Chan responded that he experienced a reduction in pain after corticosteroid injections years ago due to sciatica. He would have accepted immediate surgery had it been offered. He got immediate relief from the anesthesia and also got longer term relief. That said, looking at the evidence, it is possible that he would have ended up in a similar condition if his injections had been scheduled out six weeks. The evidence still doesn't show that these injections improve the health of the population in question. Despite his personal experience he would still say the evidence doesn't support epidural steroid injections.

A motion was made to post the draft coverage guidance for public comment. **Motion approved 4-0** (Stecker abstained as he was not present for the majority of the discussion).

Later in the meeting, Livingston asked the subcommittee to clarify whether short-term function should be a critical or important outcome. After brief discussion, the subcommittee voted to make short-term function an important outcome. **Motion approved 5-0.**

DRAFT COVERAGE GUIDANCE

Corticosteroid injections (including epidural, facet joint, medial branch, and sacroiliac joint) are not recommended for coverage for the treatment of low back pain (*strong recommendation*).

5. 2016 Coverage Guidance Rescan

Livingston reviewed the coverage guidance rescan process. In September, the EbGS approved scope statements for topics last reviewed in 2014. Based on these scope statements, the Center for Evidence-based Policy conducted an evidence search to see whether updated evidence would support a new review of the topics in question. In future years the Commission will move to passive monitoring, where stakeholders can request a review when they believe there is a reason to revisit a coverage guidance, with an active solicitation once every year in conjunction with the topic nomination process.

Obley reviewed the rescan document for each of the topics, and Livingston reviewed the rescan summaries.

- *Imaging for Low Back Pain* – There was no discussion. The staff recommendation is to affirm that the coverage guidance is up-to-date.
- *Low Back Pain: Non-Pharmacological Noninvasive Interventions* – Westbrook asked about different types of yoga and psychotherapy other than those previously recommended. Obley said that all the studies of psychotherapy were of cognitive behavioral therapy. The studies of yoga also showed effectiveness for ayengar yoga. Westbrook expressed concern that not adding coverage for the additional modalities may limit access to effective therapies. However, Gingerich observed that the Oregon Health Plan guideline note does not differentiate between types of yoga and that the billing codes do not differentiate between types of yoga or psychotherapy. Yoga is billed with a generic code for group exercise classes. Obley noted that Tai Chi has also shown effectiveness, as well as cognitive behavioral therapy delivered by tele-devices. He said recent evidence has cast some doubt on the effectiveness of massage therapy. The staff recommendation is to affirm that the coverage guidance is up-to-date, recognizing that there are some detailed recommendations which may change. Waldmann said that acupuncture, spinal manipulation and so forth are effective after four weeks, while the Oregon Health Plan's new coverage criteria allow these modalities earlier. Livingston said that the HERC's low back pain task force was aware of this coverage guidance when they made their recommendations, and even in the absence of evidence they recommended that certain treatments be available. Livingston also noted that with the new HERC methodology, each intervention would require an in-depth review (the previous methodology allowed HERC to reference trusted sources rather than perform an in-depth review of each intervention). The staff recommendation was to affirm that the coverage guidance is up-to-date. Gingerich said

that staff could add the rescan document to the coverage guidance blog. Waldmann asked about the evidence on TENS (transcutaneous electrical nerve stimulation). Obley said there was not much new evidence, though it is being advertised over-the-counter. The subcommittee agreed to recommend affirming that the coverage guidance is up-to-date.

- *Nonpharmacologic Interventions for Treatment-Resistant Depression* – There was minimal discussion. In response to a question about the two studies suggesting an update may be needed, Obley said there was some evidence questioning the clinical significance of the benefits of transcranial magnetic stimulation. Still, he suggested most patients would likely prefer a trial of transcranial magnetic stimulation prior to electroconvulsive therapy. Therefore, the staff recommendation was to affirm the existing coverage guidance.
- *Low Back Pain: Pharmacologic and Herbal Therapies* – Staff did not conduct an evidence search for this topic due to staff resource limitations. Livingston said staff determined that since the coverage guidance is about treatment strategies (rather than coverage/noncoverage), staff believes searching for new evidence may not be worthwhile. Coffman mentioned that there has been a lot of work related to opioids in Oregon, so adding a new coverage guidance may not be helpful. This coverage guidance cannot be affirmed as there has been no new evidence search, but it will be changed to passive monitoring status.
- *Neuroimaging for Mild Cognitive Impairment or Dementia* – This topic was also not rescanned, as clinical use of this technology has remained low (though research is ongoing) and an updated coverage guidance would be unlikely to impact practice. Staff's recommendation is to let the topic go to passive monitoring status. There was minimal discussion.
- *Planned Cesarean Birth* – Staff recommendation is to let this topic go to passive monitoring, as no evidence search has been conducted. The Center for Evidence-based Policy (CEBP) staff recommendation was not to dedicate resources to rescanning this topic as there has not been a significant change in the evidence for this procedure.
- *Routine Ultrasound in Pregnancy* – Staff recommendation is to let this topic go to passive monitoring, as no evidence search has been conducted. The CEBP staff recommendation was not to dedicate resources to rescanning this topic as there has not been a significant change in the evidence for this procedure.
- *Prenatal Genetic Testing* – Staff recommends retiring this coverage guidance as it includes a variety of tests, which would be cumbersome to update in our new coverage guidance process. In addition, this field is rapidly changing with new genetic tests being released and expanded indications. The Prioritized List guideline notes on Prenatal and Non-prenatal genetic testing would remain in place and be updated as necessary through the Value-based Benefits Subcommittee. There was brief discussion.
- *Low Back Pain: Minimally Invasive and Non-Corticosteroid Percutaneous Interventions* – This topic is already planned for review by EbGS, beginning in February.
- *Chronic Otitis Media with Effusion in Children* – Livingston reviewed current coverage criteria, which do not allow for adenoidectomy alone or at the time of first pressure equalization tube

insertion. Obley said new evidence appears to indicate that adenoidectomy may be effective under these circumstances, particularly for children over the age of 4. Members asked about the new evidence regarding antibiotics. Obley clarified that it indicates that antibiotics are effective at resolving effusion by two or three months. The persistence of effusion may not be significant unless it is persistent and accompanied by speech and language delays. None of these interventions are terribly effective for long-term outcomes. Chan said that the alternative is to allow VbBS to revise the guideline note without updating the entire coverage guideline. Livingston said that if this occurs, the Commission might consider retiring the coverage guidance if it is not considered up-to-date. Little asked whether there was a concern about staff resources if this coverage guidance were to be updated. Livingston said she was not sure how this topic would be prioritized in the coverage guidance nomination process. She also noted that for the Oregon Health Plan, this diagnosis is not funded, though these procedures are frequently requested. After brief additional discussion the subcommittee initially decided to affirm the existing coverage guidance since the new evidence is of fairly low quality. Stecker questioned whether the current approach requiring periodic evaluations is safe. Obley said that a combined guideline from the AAFP and AAP is the basis for this. Based on the limitations of the new evidence, the subcommittee ultimately decided not to reaffirm the coverage guidance, but to leave it on passive monitoring so that it can be updated if further evidence develops that would be more likely to have a significant impact on coverage.

Summary of decisions:

- Retire the coverage guidance on Prenatal Genetic Testing
- Reaffirm coverage guidances on Imaging for Low Back Pain; Low Back Pain: Non-Pharmacological Noninvasive Interventions; and, Nonpharmacologic Interventions for Treatment-Resistant Depression
- Move the following topics to passive monitoring status: Low Back Pain: Pharmacologic and Herbal Therapies; Neuroimaging for Mild Cognitive Impairment or Dementia; Planned Cesarean Section; Routine Ultrasound During Pregnancy; and, Chronic Otitis Media with Effusion in Children
- Low Back Pain: Minimally Invasive and Non-Corticosteroid Percutaneous Interventions will be updated beginning in February

There was a motion to approve the recommendations as indicated above. **Motion approved 5-0.**

6. ADJOURNMENT

Gingerich noted that the topic nomination process is now open. Members suggested a couple of coverage guidance topics, including social support for patients with bipolar disorder, stem cell injections for cartilage disorders, and genetic tests for selecting drugs for psychiatric conditions. Staff will forward the nomination form to the subcommittee so all topics can be considered.

Topics at the next meeting will include a review of public comment on *Low Back Pain: Corticosteroid Injections* as well as a new draft coverage guidance on *Low Back Pain: Minimally Invasive and Non-Corticosteroid Percutaneous Interventions*.

The meeting was adjourned at 4:15 pm. The next meeting is scheduled for February 2, 2017 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 Evidence Review Commission's Oral Health Advisory Panel (OHAP)

Clackamas Community College
Wilsonville Training Center, Room 210
November 28, 2016
10:00 AM – 1:00 PM

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

Members Absent: Mike Plunkett, DMD

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH

Also Attending: Kellie Skenandore, OHA; Kathleen Olesitse, CareOregon Dental (via phone); Lori McKeane, AllCare; Heather Simmons, Pacificsource (via phone), Dayna Steringer, DK Stat/ Advantage Dental.

➤ **Roll Call/Minutes Approval/Staff Report**

The meeting was called to order at 10:02 am and roll was called. The minutes from the September, 2016 meeting were reviewed and minor corrections made. Coffman reviewed the purpose of the meeting.

➤ **Topic: Multisector intervention: Early Childhood Caries Prevention**

Cat Livingston introduced the concept of multisector interventions and reviewed the draft scope statement for the multisector intervention statement for *Early Childhood Caries Prevention*. Schwarz recommended looking at motivational interviewing/anticipatory guidance. Loy wondered whether the question should include children up to age 6; she felt that it should be limited to younger children (pre-school and younger). It was clarified that children under age 6 means children 5 and younger. Schwarz pointed out that much of the literature on early childhood caries examines children age 3 and younger. The group was generally okay with children up to their 6th birthday; the term used should be consistent in the report.

The group discussed breaking out pregnant women as a separate report, looking at all interventions to improve dental health in pregnant women. Livingston discussed that

multisector interventions can include interventions outside of typical (child-targeted, clinical) interventions and thus xylitol in pregnancy would be appropriate to include as well as other types of interventions such as community-oriented ones. Allen suggested clarifying that the counseling would also include counseling of pregnant women as well as parents of small children. Schwarz recommended looking at extending coverage of dental care beyond the immediate postpartum period as another intervention. Loy mentioned that there is an oral health in pregnancy consensus statement that has already been prepared by the National Maternal and Child Oral Health Policy Center. It was noted to be available on the Oregon Oral Health Coalition website. Shirtcliff noted that the consensus statement is evidence based and has references to all of the literature reviewed.

The panel discussed that the dental group has done an extensive evidence review of early childhood caries several years ago. Livingston reviewed that a multisector intervention would become part of the Prioritized List and would be available to the CCOs and other audiences larger than the dental community. It could result in interventions outside of the typical ICD-10/CPT code pairings or CDT codes. Schwarz expressed reservations about the actual strength of evidence behind many dental interventions.

Livingston discussed creating a report that lists interventions with good evidence to support them. There was some discussion about those interventions, like fluoride toothpaste, which may not be studied because they are so obviously helpful. Livingston noted this and will consider how to present this type of intervention in the report.

Simmons wondered about having codes to implement the multisector interventions. Livingston clarified that many of the multisector interventions are unlikely to have codes, and CCOs and others would choose whether or not to invest discretionary spending in these types of interventions. The tobacco multisector intervention was discussed again as a menu of evidence-based options for CCOs to help achieve their performance metric.

Schwarz talked about addressing early childhood caries through a multisector intervention statement as having value for Oregon. Five to seven other states have their own guidelines (e.g. California, Michigan, and New York). Also, a multisector intervention statement is a key linkage to the public health world. The group agreed it was worth proceeding.

Livingston clarified that toothbrushing and flossing are not in the scope of this statement; in contrast, toothbrushing programs (with or without fluoridated toothpaste) would be included within the scope. Len asked whether including unfluoridated toothpaste within toothbrushing programs was appropriate, and others clarified that programs showing differential effectiveness based on the use of fluoridated versus unfluoridated toothpaste could be helpful, and could potentially result in a recommendation against unfluoridated toothpaste campaigns. Livingston asked whether she should look at prescription strength fluoridated toothpaste and the group did not think this would be useful.

The group reviewed the proposed outcomes. They felt that caries as an outcome was insufficient, and identified more important outcomes of being “cavity-free” and reducing the rate of cavities. They also clarified that dmfs should be used instead of DMFS.

The group turned to a discussion of “overall visits” as an outcome measure. The goal is to prevent certain types of preventable visits (e.g., hospitalization, dental surgery under anesthesia). Barozzini discussed that dental visits should go up and Shirtcliff discussed that there should be a general increase in visits that result in prevention, regardless of where the patient shows up. The group decided to eliminate the outcome of dental visits and focus on the undesirable visits (i.e., ED visits, dental hospitalizations, and oral surgeries).

Loy raised the issue of targeting siblings at the time of oral surgery or hospitalization. Many siblings of kids with cavities will also be at high risk, and studies show intervening can help.

The group discussed whether or not to add the use of antibiotics and opioids to the outcomes. Schwarz said that the studies are going to be older and there will be no evidence about opioids. The group directed staff to look at these only if they were to show up in the harms.

Schwarz raised that Key Question 2e did not accurately capture the intent, and they struck the bullet.

Barozzini raised the issue of making sure that breastfeeding was not discouraged as part of early childhood caries prevention. The group talked about the importance of baby bottle tooth decay and not having constant sugary drink consumption in bottles. Barozzini discussed that breastfeeding helps to prevent this, and the group decided to amend the scope statement to include this.

Contextual question 2 discusses risk assessment tools, and the group clarified the mostly useful one of these would be for risk assessment outside of the dental office.

The age range was again discussed and the group chose to stay with under 6 because it mirrors what is in the OARs, but given the ongoing concern about the language, Livingston offered to add 5 and under parenthetically for greater clarity.

Livingston said she would revise the scoping statement and send it out to the group. The evidence review will be completed internally by HERC staff. The review will not be ready for the February 2017 OHAP meeting and will be reviewed at a future OHAP meeting in 2017.

Recommended Actions:

- 1) Livingston will send out the revised PICO and key questions via email to the group for review
- 2) Livingston to work on the multisector intervention evidence review and bring it back to a 2017 OHAP meeting for further review and discussion

➤ **Topic: Guideline Note 17: Preventive Dental Care**

Smits reviewed the request to clarify “high risk” in GN17. The OHAP members had received several documents with information about dental risk. Shirtcliff brought up the new CDT risk codes (D0601-D0603), which were introduced to assist in identifying high risk patients. The group felt that high risk should be defined as CDT D0603 (Caries risk assessment and documentation with a finding of high risk) in a billing statement. If D0603 appears on a bill for fluoride or prophylactic care, then a higher frequency of claims for that patient should be allowed. Kellie Skenandore will look into whether D0603 can be used as a secondary code for billing. Shirtcliff noted that DCOs would still need to do chart audits to determine whether they were coded correctly as high risk. This was acknowledged. Allen felt this change would be helpful, and that the use of D0603 should be encouraged.

Recommended Actions:

- 1) No change to GN17
- 2) Skenandore will look into operationalizing the use of D0603 as a secondary code to allow identification of high risk patients

➤ **Topic: Guideline Note 34: Oral Surgery**

Smits reviewed the topic summary. The OHAP members felt the revised guideline was much improved. Loy suggested that OHAP might look at old HSD rules that defined severe dental pain. She believed the old rules included such items as: not responsive to OTC meds, keeps you up at night, etc. An “or” was added to clause #2 to clarify that a patient only needed one of the three entries to qualify for impacted third wisdom tooth removal. It was noted that non-impacted wisdom teeth could be removed if they met criteria for extraction of any other tooth (i.e. multiple caries, infection, etc.).

Recommended Actions:

- 1) GN34 was modified as shown below:

GUIDELINE NOTE 34, ~~ORAL SURGERY~~ EXTRACTION OF IMPACTED WISDOM TEETH

Line 349

~~Treatment only for symptomatic dental pain, infection, bleeding or swelling (D7220, D7230, D7240, D7241, D7250).~~

Extraction of impacted wisdom teeth (D7220, D7230, D7240, D7241, D7250) is only included on this line when there is:

- 1) evidence of pathology. Such pathology includes unrestorable caries, non-treatable pulpal and/or periapical pathology, cellulitis, abscess and osteomyelitis, internal/external resorption of the tooth or adjacent teeth, fracture of tooth, disease of follicle including cyst/tumor, tooth/teeth impeding surgery or reconstructive jaw surgery, and when a tooth is involved in or within the field of tumor resection OR

- 2) two or more episodes of pericoronitis OR
- 3) severe pain directly related to the impacted tooth that does not respond to conservative treatment.
 - a. extraction for pain or discomfort related to normal tooth eruption or for non-specific symptoms such as “headaches” or “jaw pain” is not considered medically or dentally necessary for treatment.

➤ **Topic: 2018 Biennial Review: Dental Implant Removal**

Smits reviewed the summary document regarding possible addition of coverage for some or all dental implant CDT codes. Shirtcliff and Parker both supported coverage for the removal of infected implants. Allen pointed out that the CDT code for implant removal (CDT D6100 IMPLANT REMOVAL, BY REPORT) is currently on an uncovered line. Parker and Allen reported that their DCOs are covering implant removal as a needed services, even if they are not reimbursed for it. Loy cautioned that adding coverage for removal of an implant is a slippery slope that might add costs to the DCOs that are more appropriately borne by the medical plans. Nolan suggested that if implant removal is covered, then the DCO rates should be reassessed. Shirtcliff reflected that OHAP should consider coverage for implant placement as well, as current OHP policy results in patients being made edentulous to allow dentures when some teeth could have been saved if implants were covered. Other OHAP members felt that implant placement should be covered only after crowns are covered, as crowns are a more important service. There was general agreement that implant removal should be covered, but not placement. Debridement of implants was discussed, but this was felt to be covered with general scaling of the other teeth. Specific treatment of implants is problematic in terms of what dental professional is responsible (the placing oral surgeon, the treating dentist, etc.). There was consensus that the addition of implant removal should be a biennial review change, to allow the normal rate review process to occur. Implementation of this benefit would then be January 1, 2018. There was also consensus that a guideline for when implant removal would be covered should be drafted, to follow similar situations to the newly adopted guideline for removal of impacted third molars.

Recommended Actions:

- 1) 2018 Biennial review change:
 - a. Add CDT D6100 (IMPLANT REMOVAL, BY REPORT) to line 349 DENTAL CONDITIONS (EG. SEVERE CRIES, INFECTION) Treatment: ORAL SURGERY (I.E. EXTRACTIONS AND OTHER INTRAORAL SURGICAL PROCEDURES)
 - b. Smits and Allen to draft a guideline for when implant removal is included on that line and send to OHAP members for review
 - c. Further discussion of the guideline will occur at the February, 2017 OHAP meeting

➤ **Topic: 2018 Biennial Review: Oral Health**

HERC staff reviewed that the 2018 biennial review was currently underway. The dental lines with all codes had been included in the meeting packet for members to review. Staff asked if there was any suggestions for oral health biennial review topics to take up, other than the addition of implant removal.

There was some discussion regarding the counseling CDT codes (D9311, D9991-D9994) that were discussed at the last meeting and added to the HSD Ancillary File. There was a question about adding these to lines to allow more visibility and utilization. The discussion about this centered around lack of clarity in what these codes will be used for, the provider types that can use these codes, etc. The decision was to wait and re-evaluate these codes at a later date once these questions are answered.

Allen brought up possibly adding coverage for immediate partial dentures (CDT D5221-D5222), based on provider request for the addition of this service. Currently, standard and interim partial dentures are covered on line 457. The discussion centered on how to define immediate. The members questioned whether there were any issues with immediate dentures, such as less durability than an interim denture which can last 5 years. Allen thought that an immediate partial denture would be a longer term solution than an interim denture. One of the issues is that dentists feel it is unethical to code for a standard partial denture (not immediate) when an immediate partial denture was actually provided. There were concerns about lack of allowed healing if immediate partial dentures were fitted very soon after an anterior tooth extraction. Some DCO plans are paying for an interim partial denture and then a standard partial denture, while others are only covering one or the other every 5 years. Cost are about the same for immediate and interim partial dentures.

The consensus was that immediate partial dentures should be added to line 457, where interim and standard partial dentures CDT codes already are placed. The DCOs and/or HSD could make rules about whether an immediate partial denture could be followed by a standard partial denture placement, and other utilization rules.

There was discussion that adding immediate partial dentures may add significant cost, and this change was best done as a biennial review change, effective January 1, 2018.

One last biennial review topic was brought up by Barozzini. He would like to clarify coverage of D9110 PALLIATIVE (EMERGENCY) TREATMENT OF DENTAL PAIN-MINOR PROCEDURES. There was some discussion about whether palliative emergency treatment would include prescribing antibiotics. It was unclear what services were allowed with this code. This code will be considered at a later time if there are continued questions or issues.

HERC staff let the members know that biennial review topics can be nominated for consideration at the planned February OHAP meeting. All topics to be nominated must be to HERC staff by 12/30/16.

Recommended Actions:

- 1) 2018 Biennial review: add D5221-D5222 (Immediate partial denture – resin base) to line 457 DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS (E.G. FULL AND PARTIAL DENTURES, RELINES) and removed from line 594 DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH) Treatment: ADVANCED RESTORATIVE-ELECTIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS).
- 2) HSD to determine rules about how often any type of partial denture can be covered and in what situations immediate partial dentures would be covered (i.e. anterior tooth extraction).

➤ **Topic: Tooth Extraction for Severe Caries**

Approved with minimal discussion.

Recommended Actions:

- 1) Add K02 series (Dental caries) to line 349 DENTAL CONDITIONS (EG. SEVERE CARIES, INFECTION) Treatment: ORAL SURGERY (I.E. EXTRACTIONS AND OTHER INTRAORAL SURGICAL PROCEDURES)
- 2) Add D7210 (SURGICAL REMOVAL OF ERUPTED TOOTH REQUIRING REMOVAL OF BONE AND/OR SECTIONING OF TOOTH, AND INCLUDING ELEVATION OF MUCOPERIOSTEAL FLAP IF INDICATED) to line 349

➤ **Public Comment:**

No additional public comment was received.

➤ **Issues for Next Meeting:**

- Guideline for implant removal
- Any other oral health biennial review topics
- Multisector intervention for early childhood caries prevention (post-February meeting)

➤ **Next Meeting:**

- TBD

Meeting was adjourned at 12:45 PM.

Section 2.0

Coverage Guidances

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: DIGITAL BREAST TOMOSYNTHESIS (3D MAMMOGRAPHY) FOR BREAST CANCER SCREENING IN AVERAGE RISK WOMEN

For VbBS/HERC Meeting Materials 1/12/2017

HERC Coverage Guidance

Digital breast tomosynthesis for breast cancer screening in average risk women is not recommended for coverage (*weak recommendation*).

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.

The 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 health care 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 the 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 digital breast tomosynthesis (DBT) be recommended for coverage for breast cancer screening?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
All-cause mortality (Critical outcome)	No data	Based on Medicare fee-for-service fee schedules, DBT increases the cost of mammography by 41%. While the cost of DBT in addition to DM is relatively modest at an individual level, this would add significant costs at the population level due to the large number of people electing breast cancer screening. If DBT+DM leads to lower rates of recall and/or detects	Women would strongly value having a test that is precise in that it detects cancer that will impact future morbidity and mortality, but would also decrease their risk of unnecessary worry and procedures. If a test is much more likely to pick up a cancer, they would strongly favor it if they know it will affect their long-term outcomes. There would be significant variability in	
Breast cancer morbidity (Critical outcome)	No data			
Test performance characteristics (Important outcome)	<u>Sensitivity for Breast Cancer:</u> <u>Italian study</u> DBT+DM: 0.85 (95% CI 0.74 to 0.92) DM: 0.54 (95% CI 0.42 to 0.65) <u>U.S. study</u> DBT+DM: 0.90⁹⁶ DM: 0.90⁶⁹ OR for improved sensitivity 1.03 (95% CI 0.57 to 1.89)			

Coverage question: Should digital breast tomosynthesis (DBT) be recommended for coverage for breast cancer screening?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
	<i>Specificity for Breast Cancer:</i> <u>Italian study</u> DBT+DM: 0.97 (95% CI 0.96 to 0.98) DM: 0.96 (95% CI 0.95 to 0.97) <u>U.S. study</u> DBT+DM: 0.913 DM: 0.897 OR for improved specificity 1.22 (95% CI 1.16 to 1.28) ●○○○ (Very low confidence) <i>Cancer Detection Rate:</i> DBT+DM: 4.6 to 8.9 per 1,000 DM: 3.5 to 6.3 per 1,000 <i>Incremental cancer detection rate with DBT in U.S.-based studies:</i> -0.8 to 1.9 per 1,000 (11 studies, 5 with statistically significant increases in incremental cancer detection rate) ●●○○ (Low confidence) <i>For women with dense breasts, incremental cancer detection rate with DBT:</i> 1.4 per 1,000 (95% CI 0.9 to 2.0) in retrospective studies and 3.9 per 1,000 (95% CI 2.7 to 5.1) in prospective studies ●●○○ (Low confidence)	cancer at an earlier stage, leading to improved outcomes, these costs could be offset.	how women would value an increased risk of a false-positive test and the subsequent need for biopsy or recall compared to a possible missed cancer diagnosis, but we assume that many women would have a strong preference to avoid a missed cancer diagnosis.	

Coverage question: Should digital breast tomosynthesis (DBT) be recommended for coverage for breast cancer screening?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
Breast cancer stage at diagnosis (Important outcome)	No data			
Recall rate/False-positive rate (Important outcome)	Recall rate: DBT+DM: 36 to 136 per 1,000 DM: 42 to 162 per 1,000 Change in recall rate with DBT in U.S.-based studies: -1.2% to -7.2% (11 studies, all with statistically significant results) Biopsy rate: DBT+DM: 12 to 27 per 1,000 DM: 14 to 22 per 1,000 PPV Recall: DBT+DM: 4.6% to 29.1% DM: 3.0% to 28.5% PPV Biopsy: DBT+DM: 22.7% to 50% DM: 16.7% to 30.2% ●●○○ (Low confidence)			

Coverage question: Should digital breast tomosynthesis (DBT) be recommended for coverage for breast cancer screening?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
	For women with dense breasts: Recall reduction with DBT of 23.3 per 1,000 (95% CI 16.8 to 29.9) ●●○○ (Low confidence)			
Balance of benefits and harms: There may or may not be a benefit in terms of cancer detection rate. There does appear to be an improvement in the recall rate. There are no clear harms, unless the possible increased cancer detection rate is mostly due to the detection of indolent and non-invasive lesions.				
Rationale: ~~We are uncertain of the effectiveness of DBT+DM versus DM based on the absence of studies evaluating the critical outcomes, and have very low confidence on the impact of DBT on the important outcomes (based on studies with conflicting results). Adding DBT to standard DM adds cost, with insufficient evidence that it improves any outcome. Additionally, randomized controlled trials are currently underway that should help with greater understanding of the risks and benefits of DBT+DM. The recommendation against coverage is a weak recommendation because further evidence could change the recommendation.~~ <u>Based on observational studies performed in the US, it is likely that DBT decreases recall rates as compared with DM alone. We have low confidence that DBT improves cancer detection rates. We are also not confident that any improvement in cancer detection rates with DBT, if clearly demonstrated, would result in cancers being detected at earlier stages, leading to earlier intervention that improve clinical outcomes. Adding DBT to standard DM adds cost, and we are not confident that DBT is cost-effective, based on current analysis. Additionally, randomized controlled trials are currently underway that should help with greater understanding of the risks and benefits of DBT+DM, including the critical issue of whether DBT improves clinical outcomes. The recommendation against coverage is a weak recommendation because further evidence could change the recommendation.</u>				
Recommendation: Digital breast tomosynthesis for breast cancer screening is not recommended for coverage (<i>weak recommendation</i>).				

Note: GRADE framework elements are described in Appendix A. The Quality of Evidence rating was assigned based on the GRADE Evidence Profile found in Appendix B.

EVIDENCE OVERVIEW

Clinical Background

Approximately 1 in 8 (12%) women in the United States develop invasive breast cancer during their lifetime, making breast cancer the second most common cancer (following skin cancer) in American women (American Cancer Society [ACS], 2016c). In 2013, there were 230,815 breast cancer diagnoses and 40,860 breast cancer deaths in women in the United States (Centers for Disease Control and Prevention [CDC], 2016a). In men, breast cancer is relatively rare, accounting for an additional 2,109 breast cancer diagnoses and 464 breast cancer deaths in 2013.

Trends in breast cancer incidence and mortality reveal health disparities across race and ethnicity. The rate of breast cancer diagnoses has remained stable in white women over the last decade, while increasing slightly in African American women (ACS, 2016c). The breast cancer mortality rate overall has steadily declined since 1989, but this trend disproportionately represents a larger decrease in breast cancer deaths among white women compared to other races and ethnicities (CDC, 2012). African American women are 40% more likely to die of breast cancer than white women, which reflects the need for more timely follow-up and improved access to high-quality treatment following a positive screening in this population.

Indications

The declining breast cancer mortality rate in the United States is partially attributed to greater screening efforts and thus earlier detection, in addition to fewer women using hormone therapy after menopause and improved quality of treatment (ACS, 2016c). Screening technology, such as mammography, can identify cancer at an earlier stage, before an individual experiences symptoms (ACS, 2016b). When detected early, abnormal tissue or cancer is easier to treat and patients have better outcomes. Women diagnosed with breast cancer in earlier stages have higher relative five-year survival rates (ACS, 2016a). The five-year survival rate for women with Stage 0 or Stage I breast cancer in the United States is almost 100%, compared to 22% for women with Stage IV breast cancer.

A systematic review and meta-analysis of randomized controlled screening trials for breast cancer completed in 2016 to inform the U.S. Preventive Services Task Force (USPSTF) concluded that screening mammography reduces breast cancer mortality, but not all-cause mortality (Nelson et al., 2016b). The absolute reduction in breast cancer mortality afforded by screening mammography varies by age group; for women 39-49 years old screening prevents 3 breast cancer deaths per 10,000 women over 10 years (a finding that was not statistically significant), while in women aged 60-69 years screening prevent 21 deaths per 10,000 women screened over 10 years. The review also concluded that the rate of false-positive recall from screening mammography is high: the cumulative rate of false-positive recalls over 10 years was 61% among women undergoing annual screening and 42% for women receiving biennial screening. On the basis of this review, the USPSTF offered a B recommendation to biennial mammography for average risk women between the ages of 50-74 years and a C recommendation for screening mammography for women 40-49 years old. The USPSTF issued an I recommendation to digital breast tomosynthesis.

The benefits of screening generally increase with age: the greatest benefit is for women aged 50 to 74 (U.S. Preventative Services Task Force, 2016). However, screening recommendations vary by individual case and risk level. Multiple factors contribute to individual risk aside from being female, including age, genetic mutations, denser breasts, family history of breast cancer, physical inactivity, and alcohol consumption (CDC, 2016b).

Advocates of DBT+DM generally recommend it to reduce false-positives and increase cancer detection rate.

Technology Description

Digital breast tomosynthesis (DBT), sometimes referred to as three-dimensional (3-D) mammography, is a breast cancer screening technique that was developed to improve detection and characterization of abnormal tissue in the breasts, especially in women with denser breasts (Helvie, 2011). DBT provides multiple X-ray images of thin breast sections, which can potentially reveal cancers concealed by normal tissue. An X-ray tube moves in an arc around a patient's compressed breast, which allows exposures from different angles to create a series of images. The image dataset is reconstructed into multiple images using mathematical algorithms and then reviewed by a radiologist. This process is distinct from standard (two-dimensional or 2-D) digital mammography (DM), in which only one image of overlapping tissue is produced. The first DBT system was approved by the U.S. Federal Drug Administration (FDA) on February 11, 2011 (U.S. FDA, 2015).

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 DBT as a primary screening modality in women referred for breast cancer screening?
2. Does the comparative effectiveness of DBT vary by the following characteristics:
 - a. Age
 - b. Race or ethnicity
 - c. Breast density
3. In a screening population, how do the test characteristics of 3-D/2-D mammography compare to those of standard 2-D mammography?
4. What are the harms of 3-D/2-D mammography compared to standard 2-D mammography alone?
5. If DBT is used as a primary screening modality, what is the optimal screening interval, and does that interval vary according to the characteristics listed in Key Question 2?

Critical outcomes selected for inclusion in the GRADE table are all-cause mortality and breast cancer morbidity. Important outcomes selected for inclusion in the GRADE table are test performance characteristics, cancer stage at diagnosis, and recall rate/false-positive test results.

Evidence Review

No randomized controlled trials of DBT have been published, although several are currently underway. Staff identified four recent, high-quality systematic reviews of observational trials of DBT combined with DM compared to DM alone. The included systematic reviews are summarized in Table 1.

DRAFT

Table 1. Summary of Included Systematic Reviews

Citation, Study Details	Center QA	# of Studies (k), Population (n)	Study Summary and Findings	Comments
Melnikow (2016a) <u>Search Dates</u> January 2000 to October 2015 <u>Included Study Designs</u> Prospective cohort	Good	k = 1 total n = 7,292 <i>SR's quality assessment of individual study:</i> Good	<u>Comparators</u> DBT + DM vs. DM <u>Outcomes</u> <i>Sensitivity for Breast Cancer:</i> 0.85 (95% CI, 0.74 to 0.92) vs. 0.54 (95% CI, 0.42 to 0.65) <i>Specificity for Breast Cancer:</i> 0.97 (95% CI, 0.96 to 0.98) vs. 0.96 (95% CI, 0.95 to 0.97)	<u>Included studies</u> Ciatto et al., (2013), Houssami et al. (2014) (2 reports from the same study - STORM) <u>Summarized in evidence tables¹</u> Destounis et al., (2014), Friedewald et al., (2014), Greenberg et al., (2014), Haas et al., (2013), Lang et al., (2015), McCarthy et al., (2014), Rose et al., (2013), Skaane et al., (2013a)
Nelson (2016a) <u>Search Dates</u> Through December 2014 <u>Included Study Designs</u> SRs, RCTs, observational studies	Good	k=5 total n = 517,011 <i>SR's quality assessment of individual studies:</i> Poor	<u>Comparators</u> DBT + DM vs. DM <u>Outcomes</u> <i>Recall Rate:</i> Significantly lower for DBT+ DM vs. DM across studies One U.S. study reported 16 fewer recalls per 1,000 screens (p<0.001) (Friedewald et al., 2014)	<u>Included studies</u> Ciatto et al., (2013), Friedewald et al., (2014), Haas et al., (2013), Rose et al., (2013), Skaane et al., (2013a) Evidence limited by lack of RCTs, comparability of results not reported, and outcomes not reported uniformly

¹ These studies did not meet the inclusion criterion of describing test performance characteristics, but were included in evidence tables to illustrate more proximal outcomes.

Citation, Study Details	Center QA	# of Studies (k), Population (n)	Study Summary and Findings	Comments
			<i>Biopsy Rate</i> : Increase of 1.3 biopsies per 1,000 screens for DBT+ DM compared to DM ($p < 0.001$) (Friedewald et al., 2014)	
WA HTA (2014) <u>Search Dates</u> January 1990 to November 2014 <u>Included Study Designs</u> Observational studies	Good	k = 9 total n = 313,298 <i>SR's quality assessment of individual studies</i> : Poor	<u>Comparators</u> DBT+ DM vs. DM <u>Outcomes*</u> <i>Cancer Detection Rate (CDR)</i> : 4 to 6 / 1,000 vs. 3 to 5/1,000 <i>Recall Rate</i> : 80 to 140/1,000 vs. 100 to 160/1,000 <i>Biopsy Rate</i> : 12 to 27/1,000 vs. 14 to 22/1,000 <i>PPV Biopsy</i> : 25 to 30% vs. 20 to 25% *Meta-analysis not performed for outcomes, significance not reported	<u>Included studies</u> Ciatto et al., (2013), Destounis et al., (2014), Friedewald et al., (2014), Greenberg et al., (2014), Haas et al., (2013), Lourenco et al., (2014), McCarthy et al., (2014), Rose et al., (2013), Skaane et al., (2013a), Skaane et al., (2013b) All included articles were rated by the review authors as poor quality due to insufficient follow-up in all but one study, and a 20% dropout rate in the study with 12-month follow-up (Destounis et al., 2014) Some of the studies had possible selection bias Authors reported a moderate to high degree of uncertainty in recall rate, biopsy rate, and CDR There is a low to moderate degree of uncertainty for the PPV of biopsy

Citation, Study Details	Center QA	# of Studies (k), Population (n)	Study Summary and Findings	Comments
Melnikow (2016b) <u>Search Dates</u> January 2000 to July 2015 <u>Included Study Designs</u> Observational studies	Good	k = 4 total n = 30,195 <i>SR's quality assessment of individual studies: Fair</i>	<u>Comparators</u> DBT+DM vs. DM for screening women with dense breasts <u>Outcomes*</u> <i>Cancer Detection Rate (CDR): 5.4 to 6.9 / 1,000 vs. 4.0 to 5.2 / 1,000</i> <i>Recall Rate: 7% to 11% vs. 9% to 17%</i> *Reported ranges, meta-analysis not performed	<u>Included studies</u> Ciatto et al., (2013), Haas et al., (2013), McCarthy et al., (2014), Rose et al., (2013) The 3 U.S. studies were single-site retrospective designs, and one study included women at above-average risk
Houssami (2016) <u>Search Dates</u> January 200 to July 2016 <u>Included Study Designs</u> Retrospective and prospective cohorts	Good	k = 8 total n = 291,232	<u>Comparators</u> DBT+DM vs. DM for screening women with dense breasts <u>Outcomes</u> <i>Incremental Cancer Detection Rate (CDR): 1.4 to 3.9 more cancers detected per 1,000 with DBT+DM</i> <i>Recall Rate Reduction: 23.3 fewer recalls per 1,000 with DBT+DM</i>	Ciatto, et al., (2013), Lang, et al., (2016), Bernardi, et al., (2016), Tagliafico, et al., (2016), Rose, et al., (2013), McCarthy, et al., (2014), Conant, et al., (2016), Rafferty, et al., (2016)

EVIDENCE SUMMARY

Key Questions 1 and 3

What is the comparative effectiveness of digital breast DBT as a primary screening modality in women referred for breast cancer screening?

In a screening population, how do the test characteristics of 3D/2D mammography compare to those of standard 2D mammography?

Melnikow et al., 2016a

A good-quality systematic review of DBT for breast cancer screening conducted for the Agency for Health Research and Quality (AHRQ) was published in January 2016 (Melnikow et al., 2016a). The systematic review included articles published between January 2000 and October 2015 that reported on the test performance of DBT in a screening population (asymptomatic women 40 years of age or older) compared to a comprehensive reference standard that was applied to all test results. The authors of the systematic review required that studies report one year of clinical follow-up after the initial imaging in order to ascertain interval breast cancers that were not detected during screening.

Only a single study met the inclusion criteria. That study, known as the Screening with Tomosynthesis OR standard Mammography (STORM) trial (Houssami et al., 2014), included a prospective cohort of more than 7,000 women aged 48 years or older from northern Italy. These women had both DM and DBT performed at the time of screening. Sequential reading was performed by eight radiologists who read the DM first, then interpreted the combined DM and DBT images. Median follow-up after screening was approximately 20 months. Among this cohort, 63 women were diagnosed with 65 breast cancers during the follow-up period. The authors of the AHRQ review reported the test characteristics from the single-reader analysis because they considered it the most consistent with the practice in the United States. DBT combined with DM (DBT+DM) was more sensitive than DM alone (85% vs. 54%). The two tests had similar specificity (97% for DBT+DM vs. 96% for DM). Overall cancer detection rates were 7.4 per 1,000 for DBT+DM compared to 4.8 per 1,000 for DM. Overall recall rates were 3.6% for DBT+DM compared to 4.2% for DM alone.

The authors of the AHRQ review summarized the results of eight additional screening cohort studies that did not report on test performance, but did report on cancer detection rates, recall rates, and biopsy rates. The authors did not methodologically assess the additional studies, and the results were only summarized in an included evidence table. Overall, the authors concluded that in most studies DBT was associated with increased cancer detection rates, reduced recall rates, and higher positive predictive value for initial recall. The results from the additional trials were mixed with respect to detection of invasive cancers and biopsy rate.

Nelson et al., 2016

A good-quality systematic review of the harm of breast cancer screening, including a comparison of the harms associated with different screening modalities, was published in 2016 to inform the deliberations of the U.S. Preventive Services Task Force (Nelson et al., 2016). The authors included cohort studies performed in asymptomatic populations. The authors assessed the overall quality of the evidence for differential harm by screening modality as poor, noting the absence of randomized trials, the failure to report group characteristics at baseline, and inconsistency in the reporting of outcomes including biopsy rate. Four of the five trials found lower recall rates with DBT+DM compared to DM, and the fifth trial found no significant difference. Only one of the trials reported on biopsy rate and found a statistically significant difference of 1.3 fewer biopsies per 1,000 for DM compared with DBT+DM.

Washington Health Technology Assessment, 2014

A good-quality systematic review of DBT for breast cancer screening was included in a Washington Health Technology Assessment (WA HTA) report released in December 2014 (WA HTA, 2014). The authors included nine studies reported in 10 articles and deemed all of the included studies to be of poor methodological quality. Issues of study heterogeneity prevented a formal meta-analysis, but the authors provided estimations of the cancer detection rate, recall rate, biopsy rate, and positive predictive value of biopsy between the DM and DBT+DM groups. Those results are summarized in Table 2.

Table 2. Summary Comparison of DM and DBT+DM from the WA HTA report

Outcome	DM	DBT+DM	Uncertainty
Cancer detection rate (per 1,000)	3–5	4–6	Moderate-high
Recall rate (per 1,000)	100–160	80–140	Moderate-high
Biopsy rate (per 1,000)	14–22	12–27	Moderate
Positive predictive value of biopsy	20–25%	25–30%	Low-moderate

Melnikow et al., 2016b

A good-quality systematic review of supplemental breast cancer screening for women with dense breasts, including DBT, was published in 2016 (Melnikow et al., 2016b). The authors included four fair-quality studies of DBT+DM compared to DM alone in women with dense breasts. The three U.S. studies were single retrospective cohorts comparing outcomes before and after implementation of DBT. None of the included studies reported on test performance characteristics. Three of the studies reported on cancer detection rate (4.0–5.2 per 1,000 for DM compared to 5.4–6.9 per 1,000 for DBT+DM); one of the studies reported that the rate of invasive cancers was the same between the two groups. Among the three U.S. studies included, recall rates were lower for DBT+DM (7%–11%) compared to DM (9%–17%). The authors noted that there is no reference standard by which to measure the accuracy of BI-RADS density determinations and that reclassification of breast density on sequential exams is common.

Results from individual studies included in the systematic reviews or submitted in public comments are summarized in Table 3, and Table 4 summarizes the U.S.-based studies.

Table 3. Results from Individual Studies Included in the Systematic Reviews or Submitted in Public Comment

Author (Year) Study Size Location	Source QA	Study Design and Population Characteristics	CDR per 1,000 women (% invasive)	Recall Rate (%)	PPV Recall	PPV Biopsy	Comments
Ciatto (2013) n = 7,292 Italy	Poor (WA HTA, 2014)	Prospective cohort (one arm) Population-based screening centers Mean age: 58 Test: Selenia Dimensions, Hologic	DBT+DM: 8.1 DM: 5.3 (p<0.0001)	DBT+DM: 4.3% DM: 5% (NS)	NR	NR	No long-term follow-up; one abnormal read-flagged recall
Destounis (2014)	Poor (WA HTA, 2014)	Retrospective cohort (two arm)	DBT+DM: 5.4 (33%) DM: 3.8 (50%)	DBT+DM: 4.2% DM: 11.4%	NR	DBT+ DM: 50.0% DM: 16.7%	One-year follow-up; 80% completion rate

Author (Year) Study Size Location	Source QA	Study Design and Population Characteristics	CDR per 1,000 women (% invasive)	Recall Rate (%)	PPV Recall	PPV Biopsy	Comments
DBT = 524 DM = 524 New York		Community breast clinic Mean age: 59 Test: Selenia Dimensions, Hologic SecurView, Hologic	(sig. NR)	(p<0.0001)		(sig. NR)	Selection bias likely due to baseline risk factors for breast cancer or abnormal imaging in the DBT group; some participants had a personal history of breast cancer
Friedewald (2014) DBT+DM exams = 173,663 DM exams = 281,187 U.S., multistate	Poor (WA HTA, 2014)	Retrospective cohort (two arm): Pre-post 13 academic medical centers and breast diagnostic/screening centers Mean age: 56.2 for DBT+DM; 57.0 for DM Test: Selenia Dimensions, Hologic	DBT+DM: 5.5 (75%) DM: 4.3 (67%) (p<0.001)	DBT+DM: 8.9% DM: 10.6% (p<0.001)	DBT+DM: 6.1% DM: 4.1% (p<0.0001)	DBT+DM: 29.2% DM: 24.2% (p<0.001)	Insufficient follow-up Pre-post design No individual-level data to stratify populations The biopsy rate was higher for DBT+DM group: 1.9% vs. 1.8% (p=0.004)
Greenberg (2014)	Poor (WA HTA, 2014)	Retrospective cohort (two arm)	DBT+DM: 6.3 (74%) DM: 4.9 (62%)	DBT+DM: 13.6% DM: 16.2% (p<0.0001)	DBT+DM: 4.6% DM: 3.0% (p=0.0003)	DBT+DM: 22.7% DM: 21.5% (NS)	No follow-up Volunteer bias possible

Author (Year) Study Size Location	Source QA	Study Design and Population Characteristics	CDR per 1,000 women (% invasive)	Recall Rate (%)	PPV Recall	PPV Biopsy	Comments
DBT+DM exams = 20,943 DM exams = 38,674 Washington, D.C.		Community-based multisite radiology practice Mean age: 59.5 Test: Selenia Dimensions, Hologic	(p=0.035)				May have overlap with Friedewald (2014) DBT+DM group had higher biopsy rate (2.6% vs. 2.1%, p=0.0003)
Haas (2013) DBT+DM = 6,100 DM = 7, 058 Connecticut	Poor (WA HTA, 2014)	Retrospective cohort (two arm) Mean age: 56 Test: Selenia Dimensions, Hologic	DBT+DM: 5.7 (69%) DM: 5.2 (68%) (NS)	DBT+DM: 8.4% DM: 12.0% (p<0.01)	DBT+DM: 6.8% DM: 4.3% ²	NR	No follow-up Women in DBT group had increased risk factors for breast cancer at baseline
Houssami (2014) n = 7,292	Good (Melnikow, 2016a)	Prospective cohort (one arm)	DBT+DM: 7.4 DM: 4.8 (p<0.001)	DBT+DM: 3.6% DM: 4.2% (NS)	DBT+DM: 21% DM: 11% ³	NR	Follow-up 13 months or greater Screen positive if one of two readers

² Center staff calculated this by dividing cancers detected by the product of the recall rate and the number of exams, significance not reported.

³ Drawn from AHRQ (2016) report; PPV not reported in original study. Significance not recorded.

Author (Year) Study Size Location	Source QA	Study Design and Population Characteristics	CDR per 1,000 women (% invasive)	Recall Rate (%)	PPV Recall	PPV Biopsy	Comments
Italy		Population screening program Median age: 58 Test: Selenia Dimensions, Hologic					interpreted DM or DBT as abnormal
Lourenco (2014) DBT exams = 12,921 DM exams = 12,577 U.S.	Poor (WA HTA, 2014)	Retrospective cohort (two arm) Single breast imaging center Mean age: 55.3 DBT, 54.6 DM Test: Selenia Dimensions, Hologic	DBT: 4.6 DM: 5.4 (NS)	DBT: 6.4% DM: 9.3% (p<0.00001)	DBT: 7.2% DM: 5.8% (NS)	DBT: 23.8% DM: 30.2% (sig. NR)	Insufficient follow-up Pre-post design Biopsy rate 1.7% DBT+DM vs. 1.6% DM (stat dif NR)
McCarthy (2014) DBT+DM exams = 15,571	Poor (WA HTA, 2014)	Cohort (two arm) One academic medical center Mean age: 57	DBT+DM: 5.5 (71%) DM: 4.6 (69%) (NS)	DBT+DM: 8.8% DM: 10.4% (p<0.001)	DBT+DM: 6.2% DM: 4.4% (p=0.05)	DBT+DM: 25.7% DM: 24.7% (NS)	Insufficient follow-up Overlap with Friedewald (2014) Pre-post design

Author (Year) Study Size Location	Source QA	Study Design and Population Characteristics	CDR per 1,000 women (% invasive)	Recall Rate (%)	PPV Recall	PPV Biopsy	Comments
DM exams = 10, 728 Pennsylvania		Test: Selenia Dimensions, Hologic					Biopsy rate for DBT+ DM 2.0% vs. 1.8%, for DM (NS)
Rose (2013) DBT+DM exams = 9,499 DM exams = 13,856 Texas	Poor (WA HTA, 2014)	Cohort (two arm) Multisite, community- based Mean age: NR Test: Selenia Dimensions, Hologic	DBT+DM: 5.4 (80%) DM: 4.0 (70%) (NS)	DBT+DM: 5.5% DM: 8.7% (p<0.001)	DBT+DM: 10.1% DM: 4.7% (p<0.001)	DBT+DM: 39.8% DM: 26.5% (p=0.06)	No follow-up Pre-post design Biopsy rate 1.1% DBT + DM vs. 1.5% DM (NS)
Skaane (2013a) n = 12, 621 exams Norway	Poor (WA HTA, 2014)	Prospective cohort (one arm) Citywide screening program	DBT+DM: 8.0 (80%) DM: 6.1 (73%) (p=0.001)	DBT+DM: 6.1% DM: 6.7% (p<0.001)	DBT+DM: 29.1% DM: 28.5% (NS)	NR	Incomplete follow-up Independent double- reading with

Author (Year) Study Size Location	Source QA	Study Design and Population Characteristics	CDR per 1,000 women (% invasive)	Recall Rate (%)	PPV Recall	PPV Biopsy	Comments
		Mean age: NR Test: Selenia Dimensions, Hologic					arbitration prior to recall CDR and recall rate calculated for each image prior to arbitration
Skaane (2013b) n = 12, 621 exams Norway	Poor (WA HTA, 2014)	Prospective cohort (one arm) Citywide screening program Mean age: 59.3 Test: Selenia Dimensions, Hologic	DBT+DM: 9.4 DM: 7.1 (p<0.001)	DBT+DM: 3.7% DM: 2.9% (p<0.001)	DBT+DM: 24.7% DM: 25.5% (NS)	NR	Incomplete follow-up Independent double- reading with arbitration prior to recall

Author (Year) Study Size Location	Source QA	Study Design and Population Characteristics	CDR per 1,000 women (% invasive)	Recall Rate (%)	PPV Recall	PPV Biopsy	Comments
Sharpe (2016) n = 85,852 exams United States	Poor	Retrospective cohort Single center Mean age: 57.6 Test: Selenia Dimensions, Hologic	DBT+DM: 5.4 DM: 3.5 (p<0.001) Invasive CDR DBT+DM: 2.81 DM: 2.46 (NS)	DBT+DM: 6.1% DM: 7.5% (p<0.001)	NR	NR	Baseline differences between cohorts Less experienced readers were excluded from recall rate analysis
Rose (2014) n = 10,878 United States	Poor	Retrospective reading study Single practice Mean age: NR Test: Selenia Dimensions, Hologic	DBT+DM: 5.4 (81%) DM: 3.5 (76%) (p<0.001)	DBT+DM: 5.4% DM: 8.2% (p<0.001)	NR	NR	Retrospective reading may influence interpretation

Author (Year) Study Size Location	Source QA	Study Design and Population Characteristics	CDR per 1,000 women (% invasive)	Recall Rate (%)	PPV Recall	PPV Biopsy	Comments
McDonald (2016) n = 44,468 United States	Poor	Retrospective cohort study Single center Mean age: 56.8 Test: Selenia Dimensions, Hologic	DBT+DM: 5.5 to 6.1 DM: 4.6 (NS)	DBT+DM: 8.8 to 9.2% DM: 10.4% (p<0.001)	DBT+DM: 6.2% to 6.7% DM: 4.4% (p=0.02)	Reported as not statistically significantly different (p=0.37)	
Lang (2016) n = 7,500 Sweden	Fair	Prospective cohort (one arm) Citywide screening program Mean age: 56 Test: Mammostat Inspiration, Siemens	DBT: 8.9 DM: 6.3 (p<0.0001)	DBT: 3.8% DM: 2.6% (p<0.0001)	DBT: 24% DM: 24% (NS)	NR	

Author (Year) Study Size Location	Source QA	Study Design and Population Characteristics	CDR per 1,000 women (% invasive)	Recall Rate (%)	PPV Recall	PPV Biopsy	Comments
Conant (2016) n = 142,883 United States	Poor	Retrospective cohort Three centers in the Northeast U.S. Mean age: NR Test: NR	DBT+DM 5.9 DM: 4.4 (p=0.0026) Invasive CDR DBT+DM: 4.4 DM: 3.3 (p=0.0449)	DBT+DM: 8.7% DM: 10.4% (p<0.0001)	DBT+DM: 6.4% DM: 4.1% (p<0.001)	NR	Baseline differences between cohorts
Bernardi (2016) n = 9,672 Northern Italy	Fair	Prospective double- reading study Population-based screening program in Italy Mean age: 58 Test: Selenia Dimensions, Hologic	DBT+DM: 8.8 DM: 6.3 (p<0.0001)	False-positive recall rate: DBT+DM 4.45% DM: 3.42% (p<0.0001)	NR	NR	Double reading model is uncommon in the U.S. Inadequate follow-up to detect interval cancers

Table 4. Incremental Cancer Detection Rate and Change in Recall Rate for DBT+DM over DM alone in U.S.-based studies

Study	Incremental Cancer Detection Rate	Change in Recall Rate
Haas (2013)	0.5 per 1,000 (NS)	-3.6%
Rose (2013)	1.4 per 1,000 (NS)	-3.2%
Destounis (2014)	1.6 per 1,000 (NR)	-7.2%
Friedewald (2014)	1.2 per 1,000	-1.7%
Greenberg (2014)	1.4 per 1,000	-2.6%
Lourenco (2014)	-0.8 per 1,000 (NS)	-2.9%
McCarthy (2014)	0.9 per 1,000 (NS)	-1.6%
Rose (2014)	1.9 per 1,000	-2.8%
Conant (2016)	1.5 per 1,000	-2.3%
McDonald (2016)	1.5 per 1,000 (NS)	-1.2%
Sharpe (2016)	1.9 per 1,000	-1.4%

All observed differences were statistically significant except where noted by NS (not significant) or NR (test of statistical significance not reported). For additional details, see Table 3.

Critical Outcome: All-cause mortality

None of the identified studies reported on the effects of DBT on all-cause mortality.

Critical Outcome: Breast cancer morbidity

None of the identified studies reported on the effects of DBT on breast cancer morbidity.

Important Outcome: Test performance characteristics

Only a single study from the included systematic reviews was designed to allow estimation of the test performance characteristics in a screening population (Houssami et al., 2014). In this prospective study of single-reader breast cancer detection that followed women for a median of nearly 20 months to detect interval cancers, the sensitivity of DBT+DM (0.85, 95% CI 0.74 to 0.92) was superior to that of DM (0.55, 95% CI 0.42 to 0.65). Specificity for DBT+DM was 0.97 (95% CI 0.96 to 0.98) compared to 0.96 (95% CI 0.95 to 0.98) for DM. As the AHRQ review authors noted, the observed sensitivity for DM in this study was well below that reported in other studies.

All 11 of the studies included in the systematic reviews reported on cancer detection rate. Five studies found significantly higher cancer detection rates for DBT+DM compared to DM. Four studies found no

significant differences in cancer detection rate, and one study did not report a test of statistical significance for the outcome.

Important Outcome: Cancer stage at diagnosis

None of the identified studies reported on the effects of DBT on cancer stage at diagnosis. Seven of the studies included in the systematic reviews reported on the percentage of detected cancers that were deemed invasive. For DBT+DM, 33% to 80% of the detected cancers were invasive compared to 50% to 74% for DM alone. Most of these studies reported similar or slightly higher rates of invasive disease among the cancers detected by DBT+DM compared to DM.

Important Outcome: Recall rate/false-positive test results

Among 11 studies included in the systematic reviews, nine found statistically significantly lower recall rates with DBT+DM compared to DM, and two found no difference. The reported recall rates ranged from 3.6% to 13.6% for DBT+DM and 4.2% to 16.2% for DM. The summary estimate of recall rates provided in the WA HTA report was 80–140 per 1,000 for DBT+DM and 100–160 per 1,000 for DM. The WA HTA report also found similar biopsy rates between the two groups (12–27 per 1,000 for DBT+DM vs. 14–22 per 1,000 for DM alone). In the WA HTA report, the estimate of the positive predictive value of biopsies indicated by DBT+DM was higher than that for biopsies indicated by DM alone (25–30% vs. 20–25%).

In the STORM study (Ciatto et al., 2013), the overall false-positive recall rate was 5.5%, with a significantly greater number of false-positive recalls attributable to DM (n=141) compared to DBT+DM (n=73). In the Oslo study (Skaane et al., 2013a), the overall false-positive recall rate for DBT+DM was lower than that of DM (5.3% vs. 6.1%, $p<0.01$).

Among the studies included in the systematic reviews, four studies found statistically significant increases in the positive predictive value of recall for DBT+DM compared to DM; three studies (two of which were conducted in Europe where overall recall rates are lower and the positive predictive value of recall is higher) found no significant differences in the positive predictive value of recall, and four studies either did not report on that outcome or did not report tests of statistical significance.

Key Question 2

Does the comparative effectiveness of DBT vary by the following characteristics:

- a. Age
- b. Race or ethnicity
- c. Breast density

The STORM study (Ciatto et al., 2013) reported on cancer detection rate by age group and breast density. The incremental cancer detection rate of DBT+DM compared to DM was 1.7 per 1,000 among women under age 60 compared to 4.0 per 1,000 in women aged 60 years or older. The incremental cancer detection rate was similar among women with lower breast density (2.8 per 1,000) and higher breast density (2.5 per 1,000), although the authors cautioned that the small number of women with higher breast density limits the comparison.

In the retrospective study by Haas and colleagues (2013), DBT+DM was associated with statistically significant reductions in recall rates for women in all age groups with the exception of those women 70 years of age or older. The authors also reported statistically significant reductions in recall rates for women with any breast density classification other than predominantly fatty.

The systematic review by Melnikow and colleagues on screening for women with dense breasts (2016b) found that in three studies the cancer detection rate was superior with DBT+DM (5.4–6.9 per 1,000) compared to DM (4.0–5.2 per 1,000), with one study also demonstrating equivalent proportions of invasive cancers in both groups. The reported recall rates were also lower with DBT+DM (range 7% to 11%) compared to DM (9% to 17%).

Key Question 4

What are the harms of 3-D/2-D mammography compared to standard 2-D mammography alone?

Overdiagnosis occurs when noninvasive or indolent cancers that would not cause morbidity are identified during screening. Estimates of the percentage of breast cancers that represent overdiagnosis range from approximately 10% to 20% based on randomized controlled trials of mammography (Nelson et al., 2016a). None of the included studies of DBT specifically reported on overdiagnosis, although as noted above, the studies that reported on invasive cancers found similar proportions between DM and DBT+DM groups.

False-positive results have been associated with higher levels of breast-cancer worry and distress in three fair- to good-quality systematic reviews, but the effects of false-positive tests on screening reattendance, anxiety, and depression were mixed (Nelson et al., 2016). As noted above, the overall recall rate for DBT+DM is similar to, or slightly lower than, the recall rate for DM alone. Four studies found statistically significant improvements in the positive predictive value of initial recall with DBT+DM while two studies found no significant difference.

Estimates of the incidence of radiation-induced cancer death from mammography vary based on age and screening interval, but range from 2 per 100,000 to 11 per 100,000 (Nelson et al., 2016). DBT and DM require similar doses of radiation. When DBT and DM images are acquired separately, the dose of radiation is effectively doubled (Melnikow et al., 2016a). Technology that became available in 2013 allows reconstruction of two-dimensional images, thus limiting the radiation dose to that required for a single examination.

Key Question 5

If DBT is used as a primary screening modality, what is the optimal screening interval, and does that interval vary according to the characteristics listed in Key Question 2?

Because none of the studies followed participants beyond one year or through subsequent rounds of screening with DBT, the optimal screening interval with DBT cannot be established from the existing evidence.

Additional Studies

Sharpe et al., 2016

This is a single center retrospective cohort study of 85,852 examinations for asymptomatic women presenting for breast cancer screening between 2011 and 2014. In the overall cohort, there were 5,703 DBT+DM examinations (6.6%) and 80,149 DM examinations. Nearly all of the examinations (89%) were interpreted by 10 radiologists specializing in breast imaging; the remaining 11% were interpreted by lower volume general radiologists and these examinations were excluded from the recall rate analysis. There were baseline differences in patient characteristics between the DBT cohort and DM cohort. In the DBT cohort there were greater proportions of women with extremely dense breasts, family history of breast cancer, personal history of breast cancer, and a history of breast biopsy with benign findings compared to the DM cohort.

The cancer detection rate in the DM cohort was 3.5 per 1,000 (95% CI 3.1 to 3.9) compared to 5.4 per 1,000 (95% CI 3.7 to 7.8), resulting in an incremental cancer detection rate of 1.9 per 1,000 ($p < 0.0018$). However, the invasive cancer detection rate was 2.46 per 1,000 in the DM cohort and 2.81 per 1,000 in the DBT+DM cohort, a difference that was not statistically significant ($p = 0.61$). The detection rate for carcinoma in situ was 1.04 per 1,000 in the DM cohort and 2.63 per 1,000 in the DBT+DM cohort ($p < 0.0006$).

The overall recall rate was statistically significantly lower in the DBT+DM cohort (6.10%) compared to the DM cohort (7.51%) ($p < 0.0001$). Subgroups in which there were statistically significant differences in the recall rate (in favor of DBT) included women with heterogeneously or extremely dense breasts and women in their fifth and seventh decades. However, in a mixed-effects logistic regression model intended to account for other factors associated with differences in recall rates, the authors found that there was no association between the type of study and the risk of recall after the other factors were accounted for ($p = 0.7459$).

Rose et al., 2014

This is a retrospective reading study in which seven radiologists from a single practice retrospectively interpreted the full-field DM images obtained from 10,878 DM+DBT examinations that had been prospectively interpreted by radiologists in a clinical setting. The retrospective readers interpreted the DM images at least 120 days after the examination was performed, and they were blinded to the original clinical interpretations and subsequent clinical course.

Of the 10,878 DBT+DM examinations that were prospectively interpreted, there were 588 recalls (5.4%) and 59 cancers detected (5.4 per 1,000, 81% invasive). In the retrospective reading of DM images alone, there would have been 888 recalls (8.2%) and 38 cancers detected (3.5 per 1,000, 76% invasive). For examinations that were indicated for recall only by retrospective review of the DM images, a third radiologist performed arbitration, and only 3 of these women were ultimately given a late recall; one of the late recalls resulted in a diagnosis of infiltrating lobular carcinoma and one resulted in a diagnosis of ductal carcinoma in situ. Of the 362 instances in which recall was indicated by DBT+DM but not by DM alone, there were 21 cancers detected, of which 19 were invasive. In the overall group, there was one case of breast cancer that was not screen detected over the course of one year of follow-up.

McDonald et al., 2016

This is a single center retrospective cohort study of 44,468 screening examination in 23,958 unique asymptomatic women between 2010 and 2014. In the first year (September 2010 to September 2011), 10,728 screening exams were performed using DM (denoted DM0 cohort). Between October 2011 and October 2014, 33,740 screening exams were performed using DBT (denoted DBT1, DBT2, or DBT3 cohorts based on the year the exam was performed). Information about the clinical course was taken from the medical record and the Pennsylvania State Cancer Registry (to assess the rate of interval cancers). There were no differences in the baseline patient characteristics between the DM0 and DBT3 cohorts.

The cancer detection rate was 4.6 per 1,000 in the DM0 cohort compared with 5.5 per 1,000 in the DBT1, 5.8 per 1,000 in the DBT2, and 6.1 per 1,000 in the DBT3 cohorts; none of the differences between the cancer detection rate in the DM0 cohort and each of the DBT cohorts were statistically significant. Similarly, there was no statistically significant difference in the rate of invasive cancer detection between the DM0 cohort and any of the DBT cohorts.

The recall rate in the DM0 cohort was 104 per 1,000 compared to 88 per 1,000, 90 per 1,000, and 92 per 1,000 in the DBT1, DBT2, and DBT 3 cohorts respectively. The difference in the recall rate was statistically significant between the DM0 cohort and each of the DBT cohorts. The overall biopsy rate was about 2% and did not differ between the cohorts. Notably, the recall rate for the most recent screening for women receiving serial rounds of DBT screening fell with each additional exam (78 per 1,000 in women who received two screenings and 59 per 1,000 in women who received three screenings).

The positive predictive value of recall (the number of cancers diagnosed per patients recalled to undergo biopsy, abbreviated PPV1) was 4.4% in the DM0 cohort, 6.2% in the DBT1 cohort, 6.5% in the DBT2 cohort, and 6.7% in the DBT3 cohort; the differences in PPV1 between the DM0 and DBT2 or DBT3 cohorts were statistically significant. The number of cancers per biopsy recommended (PPV2) and the number of cancers per biopsy performed (PPV3) were not statistically significantly different in comparing any of the cohorts. The interval cancer rate during the DM0 year was 0.7 per 1,000 compared to 0.5 per 1,000 in the DM1 year, a difference that was not statistically significant.

Lang et al., 2016

This is a prospective population-based single-arm screening cohort of asymptomatic Swedish women between the ages of 40 and 74 years. Among all women presenting to the screening program, 7,500 were randomly selected to undergo one-view DBT and two-view DM with independent, blinded double reading of the exams (double reading is a common practice in much of Europe). Six experienced readers interpreted all of the examinations; if either of the studies (DBT or DM) was interpreted as positive by one reader, that study was referred for arbitration by two other readers who made a final decision on recall. All of the follow-up evaluation for recalled patients was done at the same center. The average age of participating women was 56 years, and about 20% were undergoing their first screening examination; 34% had heterogeneously dense breasts and 8% had dense breasts.

Cancer was identified in 67 women in the DBT reading arm and 47 in the DM reading arms; 46 of the cancers were detected by both modalities, meaning that 21 cancers were detected only by DBT and one cancer was detected only by DM. The overall cancer detection rate was 8.9 per 1,000 (95% CI 6.9 to 11.3) for DBT and 6.3 per 1,000 (95% CI 4.6 to 8.3) for DM. The authors state that DBT offered a statistically significant increase in cancer detection of 43% over DM (95% CI 21% to 68%, $p < 0.0001$). In contrast to most studies that involve sequential interpretation of DBT and DM images, in this study all of the cancers found in the DBT reading arm were identified by DBT images alone.

There were more recalls in the DBT reading arm (3.8%, 95% CI 3.3% to 4.2%) compared to the DM reading arm (2.6%, 95% CI 2.3% to 3.0%). The authors stated that DBT resulted in a statistically significant increase in the recall rate over DM of 43% (95% CI 26% to 62%, $p < 0.0001$). The positive predictive value of recall was the same in both groups (24%). Of the 21 cancers detected in the DBT reading arm but not in the DM reading arm, 81% were invasive. There were no statistically significant differences in the cancer type, histologic grade, tumor size, or lymph node status between the cases detected only in the DBT reading arm and those detected in the DM reading arm, although the study was inadequately powered to detect such differences.

Conant et al., 2016

This is a retrospective cohort study involving 142,883 DM exams and 55,998 DBT exams performed at three centers in the Northeast U.S. between 2011 and 2014. The results from one of these centers were previously reported in part (Sharpe et al., 2016). At the second center, DBT+DM was offered based on availability and patient preference; at the third center, DBT+DM was used at the request of patients or providers or was targeted to women with dense breasts, baseline exams, or no previous imaging. Among the entire cohort, a smaller subset (25,268 DBT+DM exams and 113,061 DM exams) had at least 12 months of follow-up that allowed calculation of the overall cancer rate (derived from data from statewide cancer registries) and the sensitivity and specificity of the exams.

There were important baseline differences between the women in the DBT+DM cohort and the DM cohort with respect to age distribution (more younger women in the DBT cohort), race/ethnicity (more black women in the DBT cohort), breast density (more women with heterogeneously dense breasts in the DBT cohort), and first-time screening (more first-time screening exams in the DBT cohort). Additionally, nearly all of the women in the DM cohort came from two of the three study centers. The authors applied a prior logistic regression model meant to account for the differences in age, breast density, first-time screening, and research center.

Recall rates and biopsy rates were calculated for the overall cohort. The recall rate was 8.7% in the DBT+DM group compared to 10.4% in the DM group (odds ratio [OR] for recall in the adjusted analysis 0.68, 95% CI 0.65 to 0.71). The biopsy rate was 2% in the DBT+DM group compared to 1.8% in the DM group, but in the adjusted analysis the odds ratio for biopsy was lower in the DBT+DM group (OR 0.85, 95% CI 0.77 to 0.93). The reduction in recall for DBT+DM was greatest in women between age 40 and 49 and in women with dense breasts, but all subgroups showed a reduction in recall.

The cancer outcomes were calculated in the smaller cohort for individuals for whom at least 12 months of follow-up was available. The observed cancer rate was higher in the DBT+DM group (6.5 per 1,000)

than the DM group (4.9 per 1,000). The invasive cancer rate was 4.7 per 1,000 in the DBT+DM group and 3.7 per 1,000 in the DM group. The cancer detection rate was 5.9 per 1,000 in the DBT+DM group compared with 4.4 per 1,000 in the DM group ($p=0.0026$). The invasive cancer detection rate was 4.2 per 1,000 in the DBT+DM group and 3.3 per 1,000 in the DM group ($p=0.0449$). The false-negative rate was 0.60 per 1,000 in the DBT+DM group and 0.46 per 1,000 in the DM group ($p=0.347$). The positive predictive value of recall was 6.4% in the DBT+DM group and 4.1% in the DM group ($p<0.0001$). There was no difference in the sensitivity of the two exams (90.6% vs. 90.9%, $p=1.00$), but the specificity was higher for DBT+DM (91.3%) than for DM (89.7%) ($p<0.0001$).

Bernardi et al., 2016

This is a prospective double-reading study in which 9,672 asymptomatic women over the age of 49 in Northern Italy underwent both DM and DBT. There were two reading strategies. In the first strategy, two independent, experienced breast radiologists sequentially interpreted the separately acquired DM images and then the combined separately acquired DM+DBT images. In the second strategy, two independent, experienced breast radiologists sequentially interpreted synthetic DM images derived from DBT acquisition and then the combined synthetic DM+DBT images. A screening was deemed positive and recall initiated if either reader interpreted either one of the sequential images as positive. Screening detected 90 cancers in 85 women; 76 of the cancers detected were invasive. Of the 76 invasive cancers, 46 were detected by both standard DM alone and by the integrated screenings (DM+DBT and synthetic DM+DBT), and 28 were detected only by the integrated screening.

The cancer detection rate was 6.3 per 1,000 (95% CI 4.8 to 8.1) for DM alone compared with 8.5 per 1,000 (95% CI 6.7 to 10.5) for integrated DM+DBT and 8.8 per 1,000 (95% CI 7.0-10.8) for integrated synthetic DM+DBT. The improvements in the cancer detection rate for integrated strategies over DM alone were more pronounced in women under the age of 60 and women with heterogeneously or extremely dense breasts.

Compared to both of the integrated strategies, DM alone had a lower false-positive recall rate (3.42% vs. 3.97% for DM+DBT and 4.45% for synthetic DM+DBT.) The lower false-positive recall rate for DM alone was most pronounced among women with heterogeneously or extremely dense breasts.

The trial did not follow women in order to determine the rate of interval cancers that were not detected by screening.

Houssami & Turner, 2016

This is a rapid review and meta-analysis of cancer detection and recall rates for DBT in women with dense breasts. The authors divided the trials into prospective studies that compared screening detection in the same subjects between DM and DBT (Ciatto, 2013; Lang 2016; Bernardi, 2016; Tagliafico 2016), and retrospective studies that compared screening detection in different groups of subjects (Rose, 2013; McCarthy, 2014; Conant, 2016; Rafferty 2016). It should be noted that in one of the included trials (Tagliafico, 2016), the patients had been referred for adjunctive screening after a negative digital mammogram. In the meta-analysis of prospective studies, the incremental cancer detection rate was 3.9 additional cancers identified per 1,000 screens with DBT (95% CI 2.7 to 5.1). In the meta-analysis of the retrospective studies, the incremental cancer detection rate was 1.4 additional cancers identified per

1,000 screens with DBT (95% CI 0.9 to 2.0). Pooled estimates for the difference in recall rates could only be estimated from the retrospective trials; in that analysis, DBT resulted in 23.3 fewer recalls per 1,000 screens compared to DM (95% CI -29.9 to -16.8).

Summary of Additional Studies

Among the additional studies submitted during public comment or identified through searches:

- Five found increases in the cancer detection rate with DBT compared to DM (Sharpe, 2016; Rose, 2014; Lang, 2016; Conant, 2016; Bernardi, 2016), whereas one found no statistically significant difference (McDonald, 2016). However, in one of these trials (Sharpe, 2016), there was no statistically significant difference in the rate of invasive cancer detection, and the rate of recall did not differ between DBT and DM after accounting for other factors that influence recall in the mixed-effects logistic regression model.
- Four found decreases in the recall rate for DBT compared to DM (Sharpe, 2016; Rose, 2014; McDonald, 2016; Conant, 2016), one study found an increase in the recall rate (Lang, 2016), and one found an increase in the false-positive recall rate (Bernardi, 2016).
- A rapid review and meta-analysis of trials with subgroups of women with dense breasts found an increase in the cancer detection rate and a decrease in the recall rate with DBT compared to DM (Houssami & Turner, 2016).

Economic Analyses

Kalra et al., 2016

This is a cost-effectiveness analysis of annual screening using DBT from the federal payer perspective over a lifetime horizon. The clinical inputs were derived from Friedewald et al.'s 2014 study that showed a 1.2 per 1,000 screenings increase in cancer detection rate and 16 per 1,000 screenings decrease in the recall rate with DBT over DM. Costs were determined from the 2015 Medicare reimbursement values and the costs, utilities, and disutility associated with invasive and noninvasive cancers were derived from published literature. The authors noted that there is no reference standard for the disutility associated with false-positive recall. The standard 3% annual discounting was applied. Across all age groups in the base-case scenario, DBT resulted in a net gain of 0.04 quality-adjusted life-years (QALYs) over DM; the cost per QALY gained over DM was estimated at \$20,300. In the probabilistic sensitivity analysis (in which inputs are varied to create 10,000 simulations), DBT was cost-effective compared to DM at a willingness-to-pay threshold (WTP) of \$100,000 per QALY in 63.2% of the scenarios. In the deterministic sensitivity analyses, DBT remains cost-effective (at a WTP of \$100,000 per QALY) as long as the recall rate is reduced by at least 1 per 1,000 screens and the cost of DBT does not exceed \$250 more than the cost of DM alone. One limitation of this analysis was "an inability to capture the downstream costs of work-up for false positive cases" and the authors noted that their model accounted only for radiologic biopsies, not costlier surgical biopsies. Additionally, the clinical inputs were derived from large academic practices with uncertain congruence to community practices.

Bonafede et al., 2015

This is an economic modeling study designed to estimate the cost impact of full conversion from DM to DM+DBT in a hypothetical commercial managed care plan. The critical input pertaining to the use of

follow-up diagnostic services for people undergoing DM+DBT is based on unpublished proprietary market research data furnished by Truven Health Analytics. Additionally, the model assumes that DM+DBT would shift the distribution of diagnosed breast cancers toward earlier stages, an assumption that is not clearly supported in the literature (cf. Lang, 2016). In the base-case analysis, the conversion from DM to DBT+DM would save \$0.20 per member per month (PMPM) with a range (depending on the assumed rate of follow-up services for DBT+DM) of \$0.37 PMPM to \$0.03 PMPM.

Lee et al., 2014

This is a cost-effectiveness analysis comparing the biennial screening with DBT+DM to biennial screening with DM alone among women aged 50 to 74 with dense breasts from a federal payer perspective over a lifetime horizon. The operating characteristics of DBT+DM compared with DM for all women (not exclusive to women with dense breasts) were derived from the Oslo screening trial (Skaane, 2013); those operating characteristics were assumed to be the best-case scenario and the base-case scenario relied on more modest estimates of the performance of DBT+DM. The authors assumed an additional cost of \$50 for DBT+DM over the cost of DM alone, but because of uncertainty in that estimate they used a wide range of costs in the sensitivity analysis. In the base case analysis, DBT+DM resulted in a gain of 0.007 QALYs over DM with an incremental cost per QALY gained of \$53,893. In the sensitivity analysis, the best-case scenario for DBT performance, the incremental cost per QALY gained was \$26,107 and \$792,264 in the worst case scenario for DBT performance. Assuming a WTP of \$100,000 per QALY, DBT+DM remains cost-effective up to an added cost of \$87 over the cost of DM. A probabilistic sensitivity analysis was not performed.

Conclusions

The evidence for using DBT for breast cancer screening is limited to observational studies, most of which have methodological limitations and inadequate follow-up periods. Thus, the effects of DBT on all-cause mortality, breast cancer morbidity, and breast cancer stage at diagnosis are unknown. Two studies with adequate follow-up to ascertain interval cancer rates and thereby permit calculation of sensitivity and specificity reached differing conclusions; one of these trials showed increased sensitivity and similar specificity with DBT+DM, and the other study showed identical sensitivity and improved specificity with DBT+DM. Some of the conflicting results may be accounted for by differences in reading models and recall patterns between the United States and Europe. There is low-quality evidence with mixed results that DBT+DM improves cancer detection rates. There is low-quality evidence that DBT+DM reduces recall rates and increases the positive predictive value of recall compared to DM alone, particularly when limited only to studies that were performed in the United States. Among the U.S.-based studies, reduction in recall rate is the most consistent finding (see Table 4). However, with the exception of the population of women with dense breasts, there are no meta-analytic estimates available for any of the outcomes.

POLICY LANDSCAPE

Quality measures

No quality measures related to DBT specifically were identified when searching the [National Quality Measures Clearinghouse](#).

Payer coverage policies

Coverage policies were assessed for [Aetna](#), [Cigna](#), [Moda](#), and [Regence](#). Aetna, Moda, and Regence do not cover DBT because of insufficient evidence for its effectiveness. Although Cigna did not cover DBT for routine breast cancer screening under its previous policy, Cigna revised its coverage policy on August 23, 2016, to permit DBT for routine breast cancer screening based on recent guidance from the National Comprehensive Cancer Network (Cigna, 2016).

The [Washington Medicaid program covers DBT](#) when performed with a screening mammography for patients aged 40 to 74 who are candidates for screening mammography. Prior authorization is required for mammograms with or without DBT for patients age 39 or younger.

For Medicare, no National Coverage Determinations or Local Coverage Determinations related to DBT were identified.

Professional society guidelines

The U.S. Preventive Services Task Force issued an I recommendation for DBT in 2016, concluding that there was insufficient evidence to assess the benefits and harms of DBT for screening (USPSTF, 2016), based on the AHRQ systematic review (Melnikow et al., 2016a). Furthermore, the USPSTF also issued an I recommendation for adjunctive or supplemental screening, including DBT, for women with dense breasts.

Similarly, the American Congress of Obstetricians and Gynecologists (ACOG), American Cancer Society (ACS), American College of Physicians (ACP), and American Academy of Family Physicians (AAFP) all considered DBT in their breast cancer screening guidelines, but concluded that current evidence is insufficient to assess its effectiveness (ACOG, 2011; Oeffinger et al., 2015; Wilt, Harris, & Qaseem, 2015; AAFP, 2016).

Although the American College of Radiology (ACR) did not address DBT in its previous 2010 breast cancer screening recommendations (Lee et al., 2010), it released a position statement in November 2014, which states that DBT is no longer investigational and has demonstrated improvement in outcomes compared to digital mammography. The ACR (n.d.) summarizes its own position statement as follows:

“The ACR position on DBT is that it is no longer investigational. Tomosynthesis has been shown to improve key screening parameters compared to digital mammography.” The College applauds the decision by the Centers for Medicare and Medicaid Services (CMS) to facilitate access to these exams by covering beneficiaries for tomosynthesis and urges private payers to do the same.

Under its recommendation for an annual screening mammogram for average risk women aged 40 and over, the National Comprehensive Cancer Network (NCCN) recently added, “Consider tomosynthesis” (p. 7, 2016).

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APPENDIX A. GRADE INFORMED FRAMEWORK – ELEMENT DESCRIPTIONS

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
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 in the absence of likely cost offsets—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 issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences, and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences, and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences, and other factors, but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome⁴

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 estimate of effect: 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

⁴ Includes risk of bias, precision, directness, consistency, and publication bias.

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.

Low: The subcommittee's confidence in the estimate of effect 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 estimate of effect: 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.

DRAFT

APPENDIX B. GRADE EVIDENCE PROFILE

Quality Assessment (Confidence in Estimate of Effect)							
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	NA
Breast cancer morbidity							
0	NA	NA	NA	NA	NA	NA	NA
Test performance characteristics/Cancer detection rate (CDR)							
17 (for CDR) 2 (for sensitivity and specificity)	Mix of observational studies	Low to moderate	Not serious	None	Not serious	Sparse data for sensitivity and specificity	Low for CDR ●●○○ Very low for sensitivity and specificity ●○○○
Stage at diagnosis							
0	NA	NA	NA	NA	NA	NA	NA
Recall rate/False-positive rate							
16	Mix of observational studies	Low to moderate	Not serious	None	Not serious	NA	Low ●●○○

APPENDIX C. METHODS

Scope Statement

Populations

Women between the ages of 40 and 74 years referred for breast cancer screening

Population scoping notes: *Excludes women with a personal history of breast cancer, clinically significant BRCA gene mutations, Li-Fraumeni syndrome, Cowden syndrome, hereditary diffuse gastric cancer or other familial breast cancer syndromes, high-risk lesions (ductal or lobular carcinoma in situ, atypical ductal or lobular hyperplasia), or previous large doses of chest radiation therapy (≥ 20 Gy) before age 30 years.*

Interventions

DBT (3-D mammography) in conjunction with standard 2-D digital mammography

Intervention exclusions: *None*

Comparators

Standard 2-D mammography with or without computer-aided diagnosis

Considered but not selected: No screening, MRI, ultrasound

Outcomes

Critical: All-cause mortality, breast cancer morbidity

Important: Test performance characteristics, cancer stage at diagnosis, recall rate/false-positive test results

Considered but not selected for the GRADE table: Cancer-specific mortality, radiation exposure, PPV for recalls, PPV for biopsies

Key Questions

KQ1: What is the comparative effectiveness of digital breast DBT as a primary screening modality in women referred for breast cancer screening?

KQ2: Does the comparative effectiveness of DBT vary by the following characteristics:

- a. Age
- b. Race or ethnicity
- c. Breast density

KQ3: In a screening population, how do the test characteristics of 3-D/2-D mammography compare to those of standard 2-D mammography?

KQ4: What are the harms of 3-D/2-D mammography compared to standard 2-D mammography alone?

KQ5: If DBT is used as a primary screening modality, what is the optimal screening interval, and does that interval vary according to the characteristics listed in Key Question 2?

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 Digital Breast Tomosynthesis and 3-dimensional (3-D) mammography. Searches of core sources were limited to citations published in the past five years.

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 conducted to identify systematic reviews, meta-analyses, and technology assessments published in the past five years. A MEDLINE® search was then conducted to identify randomized control trials and cohort studies that would have been included in the identified systematic reviews except for being published after the search dates of the systematic reviews.

Searches for clinical practice guidelines were limited to those published since 2011. 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, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, or clinical practice guidelines.

APPENDIX D. APPLICABLE CODES

CODES	DESCRIPTION
ICD-10 Diagnosis Codes	
Z12.31	Encounter for screening mammogram for malignant neoplasm of breast
CPT Codes	
77051	Computer-aided detection with further physician review for interpretation; diagnostic mammography
77052	Computer-aided detection with further physician review for interpretation; screening mammography
77055	Mammography; unilateral
77056	Mammography; bilateral
77057	Screening mammography; bilateral
77061	Digital breast tomosynthesis; unilateral
77062	Digital breast tomosynthesis; bilateral
77063	Screening digital breast tomosynthesis; bilateral (in addition to primary screening mammography procedure)
HCPCS Level II Codes	
G0202	Screening mammography; producing direct digital image, bilateral, all views
G0204	Diagnostic mammography, producing direct digital image, bilateral, all views
G0206	Diagnostic mammography, producing direct digital image, unilateral, all views
G0279	Diagnostic digital breast tomosynthesis; unilateral or bilateral

Note: Inclusion on this list does not guarantee coverage.

Digital Breast Tomosynthesis (3D Mammography)
for Breast Cancer Screening in Average Risk Women

Question: Should digital breast tomosynthesis (DBT) be included on the preventive services line for average risk women?

Question source: HTAS

Issue: HTAS has developed a coverage guidance addressing digital breast tomosynthesis. Based on the evidence, HTAS has issued a weak recommendation that digital breast tomosynthesis should not be covered for breast cancer screening in average risk women.

Rationale for decision: There is no data, utilizing DBT for screening in average risk women, related to the critical outcomes of all-cause mortality and breast cancer morbidity. However, recognizing that data on long-term effects take time to accrue, HTAS also included important outcomes related to the operating characteristics of DBT.

Based on observational studies performed in the US, it is likely that DBT decreases recall rates as compared with digital mammography (DM) alone. We have low confidence that DBT improves cancer detection rates, due to low quality evidence with mixed results. We are also not confident that any improvement in cancer detection rates with DBT, if clearly demonstrated, would result in cancers being detected at earlier stages, leading to earlier intervention that improves clinical outcomes. Adding DBT to standard DM adds cost, and we are not confident that DBT is cost-effective, based on current analysis. Additionally, randomized controlled trials are currently underway that should help with greater understanding of the risks and benefits of DBT+DM, including the critical issue of whether DBT improves clinical outcomes. The recommendation against coverage is a weak recommendation because further evidence could change the recommendation.

This HTAS coverage guidance only addresses the use of DBT in population screening of average risk women and does not address the use of DBT as a diagnostic test. In addition, breast cancer screening for above average risk women will be addressed in a subsequent HTAS coverage guidance.

Current Prioritized List status:

CPT code	Code Description	Placement
77063	Screening digital breast tomosynthesis; bilateral (in addition to primary screening mammography procedure)	Services Recommended for Non-Coverage

HERC staff recommendation:

- 1) Make no change in the placement of digital breast tomosynthesis
 - a. Keep CPT 77063 on the Services Recommended for Non-Coverage

DIGITAL BREAST TOMOSYNTHESIS FOR BREAST CANCER SCREENING IN AVERAGE RISK WOMEN

Coverage Guidance for VbBS/HERC Consideration

January 12, 2017

Background

- 1 in 8 women (12%) develop invasive breast cancer during their lifetime
- Breast cancer death rate has steadily declined in last 15 years; decline in breast cancer mortality attributed to
 - Screening efforts leading to earlier cancer detection
 - Fewer women using hormone therapy after menopause
 - Improved quality of treatment

Background

- Systematic review and meta-analysis of randomized controlled trials of screening for breast cancer, conducted by Nelson et al. (2016) for USPSTF:
 - Screening mammography reduces breast cancer mortality, but not all-cause mortality
- USPSTF recommendations for mammography:
 - Grade “B” recommendation for biennial mammography for average risk women 50-74 years old
 - Grade “C” recommendation for mammography for average risk women 40-49 years old

Background

- Digital breast tomosynthesis (DBT), sometimes referred to as three-dimensional (3-D) mammography:
 - Multiple X-ray images of thin breast sections, compared to one image from conventional digital mammography (DM)
 - First DBT system was approved by the U.S. Federal Drug Administration in 2011
 - DBT seeks to improve mammography by improving cancer detection and reducing false-positive rate
 - In September, HTAS requested an evidence search for newer observational trials concurrent with public comment period

Scope Statement

- Population: Women between the ages of 40 and 74 years referred for breast cancer screening. Excludes women with history of:
 - Breast cancer
 - Clinically significant BRCA gene mutations
 - Li-Fraumeni syndrome
 - Cowden syndrome
 - Hereditary diffuse gastric cancer or other familial breast cancer syndromes
 - High-risk lesions (ductal or lobular carcinoma in situ, atypical ductal or lobular hyperplasia)
 - Previous large doses of chest radiation therapy (≥ 20 Gy) before age 30 years

Scope Statement

- Intervention: DBT (3-D mammography) in conjunction with standard 2-D digital mammography
- Comparator: Standard 2-D mammography with or without computer-aided diagnosis
- Outcomes:
 - All-cause mortality (critical outcome)
 - Breast cancer morbidity (critical outcome)
 - Test performance characteristics (important outcome)
 - Cancer stage at diagnosis (important outcome)
 - Recall rate/false-positive test results (important outcome)

Public Comments

- Comment: There are new observational trials and economic analyses since last systematic review
 - *New observational trials added to the evidence considered in the Coverage Guidance*
- Comment: Recall rates are lower in Europe than the U.S., so it is most appropriate to consider only U.S. studies to understand effects on recall rates
 - *Location of studies was specified in the Coverage Guidance, and a table with only U.S. studies was added*

Public Comments

- Comment: Evidence of reduced all-cause mortality or breast cancer morbidity should not be required to show that DBT is improvement over 2-D mammogram
 - *DBT's use as a primary screening modality should be subject to the normal evidentiary standards for screening tests; large-scale screening trials often report on all-cause and cancer-specific mortality*

Evidence Sources

- 4 recent, high-quality systematic reviews of observational trials of DBT+DM compared to DM alone
- 6 observational trials published since that last systematic review
- 3 economic analyses published recently
- No randomized controlled trials of DBT have been published, although several are currently underway

Evidence Review

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>
All-cause mortality <i>(Critical outcome)</i>	No data
Breast cancer morbidity <i>(Critical outcome)</i>	No data
Breast cancer stage at diagnosis <i>(Important outcome)</i>	No data

Evidence Review

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>
Test performance characteristics <i>(Important outcome)</i>	<i>Sensitivity for Breast Cancer</i> <u>Italian study</u> DBT+DM: 0.85 (95% CI 0.74 to 0.92) DM: 0.54 (95% CI 0.42 to 0.65) <u>U.S. study</u> DBT+DM: 0.909 DM: 0.906 OR for improved sensitivity 1.03 (95% CI 0.57 to 1.89) ●○○○ (<i>Very low confidence</i>)

Evidence Review

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>
Test performance characteristics <i>(Important outcome)</i>	<i>Specificity for Breast Cancer</i> <u>Italian study</u> DBT+DM: 0.97 (95% CI 0.96 to 0.98) DM: 0.96 (95% CI 0.95 to 0.97) <u>U.S. Study</u> DBT+DM: 0.913 DM: 0.897 OR for improved specificity 1.22 (95% CI 1.16 to 1.28) ●○○○ (<i>Very low confidence</i>)

Evidence Review

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>
Test performance characteristics <i>(Important outcome)</i>	<i>Cancer Detection Rate</i> <i>DBT+DM: 4.6 to 8.9 per 1,000</i> <i>DM: 3.5 to 6.3 per 1,000</i> <i>Incremental cancer detection rate with DBT in U.S.-based studies:</i> <i>-0.8 to 1.9 per 1,000 (11 studies, 5 with statistically significant increases in incremental cancer detection rate)</i> ●●○○ <i>(Low confidence)</i>

Evidence Review

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>
Test performance characteristics (Important outcome)	<i>Cancer Detection Rate</i> <i>For women with dense breasts</i> Incremental cancer detection rate with DBT: 1.4 per 1,000 (95% CI 0.9 to 2.0) in retrospective studies 3.9 per 1,000 (95% CI 2.7 to 5.1) in prospective studies ●●○○ (Low confidence)

Evidence Review

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>
Recall rate/False-positive rate <i>(Important outcome)</i>	Recall rate DBT+DM: 36 to 136 per 1,000 DM: 42 to 162 per 1,000 Change in recall rate with DBT in U.S.-based studies: -1.2% to -7.2% (11 studies, all with statistically significant results) <i>For women with dense breasts</i> Recall reduction with DBT of 23.3 per 1,000 (95% CI 16.8 to 29.9) ●●○○○ (<i>Low confidence</i>)

Evidence Review

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>
Recall rate/False-positive rate <i>(Important outcome)</i>	Biopsy Rate <i>DBT+DM: 12 to 27 per 1,000</i> <i>DM: 14 to 22 per 1,000</i> PPV Recall <i>DBT+DM: 4.6% to 29.1%</i> <i>DM: 3.0% to 28.5%</i> PPV Biopsy <i>DBT+DM: 22.7% to 50%</i> <i>DM: 16.7% to 30.2%</i> ●●○○ (Low confidence)

Evidence Review

DBT+DM over DM alone in U.S.-based studies

Study	Incremental Cancer Detection Rate	Change in Recall Rate
Haas (2013)	0.5 per 1,000 (NS)	-3.6%
Rose (2013)	1.4 per 1,000 (NS)	-3.2%
Destounis (2014)	1.6 per 1,000 (NR)	-7.2%
Friedewald (2014)	1.2 per 1,000	-1.7%
Greenberg (2014)	1.4 per 1,000	-2.6%
Lourenco (2014)	-0.8 per 1,000 (NS)	-2.9%
McCarthy (2014)	0.9 per 1,000 (NS)	-1.6%
Rose (2014)	1.9 per 1,000	-2.8%
Conant (2016)	1.5 per 1,000	-2.3%
McDonald (2016)	1.5 per 1,000 (NS)	-1.2%
Sharpe (2016)	1.9 per 1,000	-1.4%

Evidence Summary

- Evidence for DBT is limited to observational studies, most of which have methodological limitations and inadequate follow-up periods
- Effects of DBT on all-cause mortality, breast cancer morbidity, and breast cancer stage at diagnosis are unknown
- Two studies with adequate follow-up to ascertain interval cancer rates reached differing conclusions
 - One study showed increased sensitivity and similar specificity
 - One study showed identical sensitivity and improved specificity

Evidence Summary

- Low-quality evidence with mixed results that DBT+DM improves cancer detection rates
- Low-quality evidence that DBT+DM reduces recall rates, particularly when limited to U.S.-based studies
- There are no meta-analytic estimates available for any of the outcomes, except for women with dense breasts

Guidelines

- U.S Preventive Services Task Force (2016):
 - Grade “I” statement for DBT, concluding that there was insufficient evidence to assess the benefits and harms of DBT
 - Grade “I” statement for adjunctive or supplemental screening, including DBT, for women with dense breasts

Guidelines

- Current evidence is insufficient to assess effectiveness of DBT:
 - American Congress of Obstetricians and Gynecologists
 - American Cancer Society
 - American College of Physicians
 - American Academy of Family Physicians
- National Comprehensive Cancer Network: recently added, “consider tomosynthesis”
- American College of Radiology: DBT is no longer investigational and has demonstrated improvement in outcomes compared to DM

Policy Landscape

- Washington Medicaid covers DBT when performed with screening mammography for patients aged 40 to 74 who are candidates for screening mammography
- Reviewed four private payers:
 - Aetna, Moda, and Regence do not cover DBT because of insufficient evidence for its effectiveness
 - Cigna covers DBT

HTAS Decision on Coverage Guidance

Digital breast tomosynthesis for breast cancer screening in average risk women is not recommended for coverage (*weak recommendation*).

HTAS Rationale

- It is likely that DBT decreases recall rates as compared with DM alone, based on observational studies performed in the US
- We have low confidence that DBT improves cancer detection rates.
- We are not confident that any improvement in cancer detection rates with DBT, if clearly demonstrated, would result in cancers being detected at earlier stages, leading to earlier intervention that improves clinical outcomes.

HTAS Rationale

- Adding DBT to standard DM adds cost, and we are not confident that DBT is cost-effective, based on current analysis.
- Randomized controlled trials are currently underway that should help with greater understanding of the risks and benefits of DBT+DM, including the critical issue of whether DBT improves clinical outcomes.
- The recommendation against coverage is a weak recommendation because further evidence could change the recommendation.

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

Disposition of Public Comments

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Discussion Table

IDs/#s	Summary of Issue	Subcommittee response
A1, A3, C1, E1	Additional evidence and guidelines to be considered	The newly submitted studies and guidelines have been incorporated into the coverage guidance.
A2, B1, D1	Concerns pertaining to the selection of all-cause and cancer-specific morbidity and mortality as critical outcomes	HERC strives to select outcomes that are most appropriate to the intervention under consideration and reflect patient-important results that would influence decisions regarding coverage. Large-scale population screening trials frequently examine and report on the effects of screening on all-cause and cancer-specific mortality. Rigorously designed screening trials are necessary to avoid common and well-described pitfalls of observational screening trials, including lead-time bias and length-time bias, and to account for possible overdiagnosis and other harms of screening. However, recognizing that data on long-term effects take time to accrue, HERC also included outcomes related to the operating characteristics of DBT.

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

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Commenters

Identification	Stakeholder
A	Legacy Health <i>[Submitted September 30, 2016]</i>
B	Diane Coady, R.T.R.M. <i>[Submitted October 12, 2016]</i>
C	John Griffith <i>[Submitted October 14, 2016]</i>
D	Sheven Thorson <i>[Submitted October 14, 2016]</i>
E	Kari A. Thomas, MD <i>[Submitted October 14, 2016]</i>

Public Comments

ID/#	Comment	Disposition
A1	Legacy is concerned that the HERC draft recommendation regarding digital breast tomosynthesis (DBT) has overlooked recent data that directly addresses the specific concerns of the HERC regarding DBT efficacy, as well as pertinent cost analysis. Due to the omission of these relevant studies from the HERC’s literature review, we feel the panel’s recommendations are not fair to the evidence, which is a disservice to our patients, and for all women in Oregon. For nearly four years, Legacy physicians and patients have experienced the advantage of increased cancer detection rates and decreased recall rates afforded by the early adoptions of DBT technology in our breast centers. In our experience, the additional cancers detected by DBT are primarily invasive; introduction of DBT into our practice has not significantly increased in situ cancer detection. The HERC review appears to have only considered studies that were included in previous systematic reviews by the USPSTF and the Washington HTA, which are incomplete and outdated. As a result, while the HERC review included eleven studies, it does not include the six important clinical publications listed below. Collectively, these publications report the findings of more than 350,000 mammograms: 1. Conant 2016	<i>Thank you for your comments. The listed studies, along with other recent observational studies, have been added as evidence sources in the coverage guidance.</i>

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women Disposition of Public Comments

ID/#	Comment	Disposition
	2. Bernardi 2016 3. McDonald 2016 4. Sharpe 2015 5. Lang 2015 6. Rose 2014 In particular, Conant 2016 is important because it comprises results of almost 200,000 exams in the United States. We respectfully request that the panel consider the results of these studies and amend the recommendation to cover DBT accordingly. Each of the six studies listed above showed a statistically significant increase in cancer detection. Taken together with the five additional studies noted by the HERC, the statistically significant increase in cancer detection from DBT is made clear by the results of nearly 900,000 mammograms. In contrast, the four studies noted by the HERC which showed no statistically significant increase in cancer detection only report the results of just over 88,000 mammograms. The evidence is clear and consistent: tomosynthesis has a higher cancer detection rate than digital mammography alone. The HERC review states that there is “very low confidence” in recall rate estimates. Recall rates are lower in Europe than in the US, as noted by the HERC. If only US-based data are considered, there are eleven studies showing a statistically significant reduction in recall rate with DBT, and NONE that find no change. The evidence is clear and consistent: tomosynthesis has a lower recall rate than digital mammography alone in the US.	

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

Disposition of Public Comments

ID/#	Comment	Disposition
A2	Regarding outcomes, to require evidence of reduced all-cause mortality and/or breast cancer morbidity is unnecessary for an improved mammogram. This type of evidence was not required when digital mammography became an acceptable alternative to film mammography and should NOT be required for DBT to become an acceptable alternative to digital mammography. As detailed above by more recent literature, DBT improves the benefits provided by digital mammography alone by having a higher cancer detection rate, while reducing the harms of false positive recalls.	<i>Thank you for your comments. While one might consider DBT merely to be an “improved mammogram,” its use as a proposed primary screening modality should be subject to the normal evidentiary standards for screening tests. Large-scale population screening trials frequently examine and report on the effects of screening on all-cause and cancer-specific mortality. Rigorously designed screening trials are necessary to avoid common and well-described pitfalls of observational screening or diagnostic accuracy studies including lead-time bias, length-time bias, and to account for possible overdiagnosis and other harms of screening. However, recognizing that data on long-term effects take time to accrue, HERC also included outcomes related to the operating characteristics of DBT.</i>
A3	Regarding cost, 2016 comparative effectiveness data that is not included in the HERC literature review shows the benefits outweigh the DBT cost, and debunks the hypothesis that the cost of DBT would negatively impact the system at a population level.	<i>Thank you for your comments. Additional economic studies have been included as evidence sources in the coverage guidance—see C1 below.</i>
A4	Also of note, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for 2016 issued a Category 1 recommendation for DBT, meaning this applies to all	<i>Thank you for your comments. We have added the NCCN guidelines to the coverage guidance.</i>

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

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	populations for annual screening mammography. This is the highest recommendation NCCN awards. The NCCN is a leader in defining and advancing high-quality, high-value oncology care.	
A5	Time and again, Legacy patients have benefitted from DBT—many invasive breast cancers would not have been detected otherwise, and fewer patients have been unnecessarily recalled for additional imaging. If the aim of the HERC is to improve patient care, population health, and the cost-effectiveness of health care in Oregon and across the country, approval for coverage of DBT is critical.	<i>Thank you for your comments.</i>
B1	I believe the HERC is inadvertently holding DBT to an unfair standard to provide coverage. Digital mammography never had to prove such a strict standard of endpoints when it surpassed film mammography, and DBT is so much more superior to 2D in the published studies than 2D was to film, it is astounding to those of us in the breast imaging community that you would recommend non-coverage in your draft. I have found a similarity to CT colonography to help explain my point. Regarding the use of all-cause mortality as a “critical outcome” for diseases where screening is recommended, the need to demonstrate that a test with superior accuracy also improves all-cause mortality is unnecessarily restrictive and results in an unnecessary delay in access to improved screening. Using all-cause mortality as a critical outcome for an improved breast cancer screening test is also inconsistent with the approach taken for colon cancer. New colon cancer screening tests, such as CT colonography and fecal immunochemical testing, are considered as acceptable screening strategies based on performance characteristic studies alone. The latest USPSTF review did not identify any studies which evaluate the all-cause mortality of these tests, yet the USPSTF found sufficient evidence that are acceptable alternatives to traditional colonoscopy. Since you rely heavily on the USPSTF in your draft review, I thought this was relevant. This same approach should be taken for mammography. The evidence clearly demonstrates that breast tomosynthesis detects more cancers (increased sensitivity) with fewer false positives (increased specificity) when compared to traditional 2D mammography. If 2D mammography is	<i>Thank you for your comments. See A2 above. Additionally, it is common for HERC to consider patient-important outcomes and other factors when examining the evidence for any intervention, including screening interventions. HERC would most likely apply the same standards to CT colonography were it being considered for a coverage guidance.</i>

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

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	acceptable, breast tomosynthesis should also be an option for women who undergo breast cancer screening.															
C1	I urge you to reverse your position of non-payment for breast tomosynthesis based on sound medical evidence that it is cost-effective. Three economic analyses of breast tomosynthesis have been published in peer-reviewed journals. These studies are summarized below. <table><tr><th>Study</th><th>Analysis Type</th><th>Patient population</th><th>Incremental QALY*</th><th>Incremental costs</th><th>ICER**</th><th>Conclusion</th></tr><tr><td>Lee 2014</td><td>Cost-effectiveness</td><td>Routine biennial screening of women with dense breasts age 50-74</td><td>0.007</td><td>\$349</td><td>\$53,893</td><td>“Biennial combined digital mammography and tomosynthesis screening for US women aged 50–74 years with dense breasts is likely to be cost-effective if priced appropriately (up to \$226 for combined examinations vs. \$139 for digital</td></tr></table>	Study	Analysis Type	Patient population	Incremental QALY*	Incremental costs	ICER**	Conclusion	Lee 2014	Cost-effectiveness	Routine biennial screening of women with dense breasts age 50-74	0.007	\$349	\$53,893	“Biennial combined digital mammography and tomosynthesis screening for US women aged 50–74 years with dense breasts is likely to be cost-effective if priced appropriately (up to \$226 for combined examinations vs. \$139 for digital	<i>Thank you for your comments. The listed studies have been added as evidence sources in the coverage guidance.</i>
Study	Analysis Type	Patient population	Incremental QALY*	Incremental costs	ICER**	Conclusion										
Lee 2014	Cost-effectiveness	Routine biennial screening of women with dense breasts age 50-74	0.007	\$349	\$53,893	“Biennial combined digital mammography and tomosynthesis screening for US women aged 50–74 years with dense breasts is likely to be cost-effective if priced appropriately (up to \$226 for combined examinations vs. \$139 for digital										

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

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ID/#	Comment							Disposition
							mammography alone) and if reported interpretive performance metrics of improved specificity with tomosynthesis are met in routine practice.”	
	Bonafede 2015	Budget Impact	Routine screening of women age 40-74	N/A	\$28.53 saved per screening exam	N/A	“The results of this study demonstrate clinical and economic favourability of DBT for breast cancer screening among commercially insured US women. Wider adoption of DBT mammography presents an opportunity to deliver value-	

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

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							based care in the US health care system.”	
	Kalra 2016	Cost-effectiveness	Routine annual screening of women age 40-79	0.04	\$812	\$20,230	“Addition of annual screening tomosynthesis to 2D mammography beginning at the age of 40 years was cost-effective compared with 2D mammography alone in our analysis. Three times greater net monetary benefits were found in women 40–49 years old compared with those 50–59 years old.”	
	* QALY: Quality-Adjusted Life Years; ** ICER: Incremental Cost-Effectiveness Ratio.							

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

Disposition of Public Comments

ID/#	Comment	Disposition
D1	With regard to your approach of evaluating outcomes data including recall rate, biopsy rate, and cancer detection, I believe there are some fundamental issues considering this is a screening technology not a pharmaceutical drug or other therapy. I do not disagree with the approach, in general, but I do disagree with the position that this is the type of outcome data the HERC should look for when evaluating a screening or diagnostic technology. The National Institute of Health articulates this position very clearly in its publication “Fundamental Concepts for Health Technology Assessments”: <i>“Beyond technical performance of screening and diagnostic tests, their effect on health outcomes or health-related quality of life is often less immediate or direct than for other types of technologies. The impacts of most preventive, therapeutic, and rehabilitative technologies on health outcomes can be assessed as direct cause-and-effect relationships between interventions and outcomes. However, the relationship between the use of screening and diagnostic tests and health outcomes is typically indirect, given intervening decisions or other steps between the test and health outcomes. Even highly accurate test results may be ignored or improperly interpreted by clinicians. Therapeutic decisions that are based on test results can have differential effects on patient outcomes. Also, the impact of those therapeutic decisions may be subject to other factors, such as patient adherence to a drug regimen...”</i> It is a fact that better detection of invasive cancer improves outcomes—a study with DBT is not necessary to prove this point. Furthermore, it is unlikely such a study will ever be conducted because it would be considered unethical and inhumane to allow breast cancer to progress to more advanced stages and eventual death in the control group, not to mention that it would take 10-20 years to compile meaningful data. DBT improves cancer detection and PPV for biopsy and reduces recall rates compared to digital mammography alone. To boil this down, if you believe in mammography as a screening tool (which I assume you do since your policy supports it today) then there should be no question for you to add coverage of DBT, considering that all exams include a 2D, and it is therefore impossible for DBT to ever perform	<i>Thank you for your comments. See A2 above. Additionally, we would interpret the points made by the NIH regarding the indirectness of test operating characteristics as ultimately favoring stronger study designs meant to demonstrate that in real-world practice a screening test actually leads to patient-important outcomes. Furthermore, the improvement in invasive cancer detection is not uniform across the studies included in the coverage guidance and the effects on recall are similarly mixed. Lastly, several randomized controlled trials of DBT as a screening modality are currently underway.</i>

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

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ID/#	Comment	Disposition
	worse than 2D alone. Beyond logic, the published studies show that DBT enhances mammography screening compared to 2D alone. On the other hand, if you don't believe in mammography as a screening tool, then it will be very difficult for you to ever find a reason to cover DBT, and logically you should actually remove coverage of 2D because it wouldn't even pass the criteria bar you have set for DBT in this analysis. In my opinion, the HERC is treating the DBT analysis like it would a drug or therapeutic treatment. Instead, it needs to step back and look at DBT for what it is: a screening technology that enhances 2D mammography, reduces recalls, improves PPV for biopsy and finds cancer earlier, end of story. Thus its impacts long-term outcomes and economics for the state in a positive way. I am asking that you not simply fall in line with the outdated USPSTF review or the outdated WA TEC assessment like your draft guidance appears to do. Instead, evaluate the published US studies and if you determine that DBT enhances performance over 2D alone, add it to coverage.	
E1	The HERC draft recommendation does not accurately characterize the overall quantity, quality, and consistency of the evidence. Quantity of Evidence There are 11 major clinical trials (7 US, 4 European) which compare breast cancer screening with digital breast tomosynthesis (DBT) to screening with digital mammography (DM) alone. The HERC draft review only included 6 of these studies. The following studies, which evaluate a total of 347,579 exams, should be included in the review: Rose 2014, Lang 2015, Sharpe 2015, McDonald 2016, Conant 2016. The draft review also incorrectly evaluates five “secondary” manuscripts as if they are independent of their “primary” manuscript, which also appears in the review. For example, the review appears to characterize the Greenberg 2014, Haas 2013, and McCarthy 2014 manuscripts as unique studies. In reality, these manuscripts report single center data from the Friedewald 2014 multicenter study, which is already included in the review. While these “secondary” studies do	<i>Thank you for your comments. The listed studies, along with other recent observational studies and a new rapid review and meta-analysis, have been added as evidence sources in the coverage guidance. We have also delineated which studies were performed in the United States and which were performed in other countries.</i> <i>In GRADE methodology, observational trials begin as low-quality evidence. None of the other factors applied to observational trials would be sufficient to upgrade the evidence (large magnitude of effect, plausible confounding in the</i>

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

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	include some endpoints not presented in primary manuscript, the cancer detection and recall results are duplicative of those included in the Friedewald 2014 manuscript. A complete list of the 11 studies which contain a significant number of unique exams is provided in the table below. Quality of Evidence While all 11 studies evaluating DBT are observational and may be considered lower quality evidence than randomized controlled trials, the panel should separately consider studies which evaluate DBT and DM exams which were contemporaneously acquired in the same population. Observational studies are subject to selection bias due to potential population differences in the experimental and control groups. Such selection bias is not possible in five of the DBT screening trials (Ciatto 2013, Skaane 2013, Rose 2014, Lång 2015, Bernardi 2016) because these studies evaluated DBT and DM in the same patient population, and thus patients served as their own controls. Therefore, these studies should be considered as a higher level of evidence than studies which evaluate two different population groups. Consistency of evidence While each of the 11 DBT screening studies has a lower quality observational design, the panel should consider the volume and consistency of the evidence when evaluating multiple studies. In total, the 11 DBT screening studies evaluated more than 850,000 examinations and consistently demonstrated that the use of DBT increases the rate of cancer detection while reducing the recall/false positive rate. <u>Breast Cancer Detection</u> Eight of the 11 DBT screening trials reported that DBT detects breast cancer at a significantly greater ($p < 0.001$) rate than DM alone. These studies evaluated a total of 787,556 exams and reported a 27-55% relative increase in the rate of cancer detection. All five of the higher quality	<i>direction of effectiveness, or dose-response relationship)</i> .

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

Disposition of Public Comments

ID/#	Comment	Disposition
	studies in which patients served as their own controls demonstrated a statistically significant increase in cancer detection. Three smaller studies evaluating a total of 71,014 exams found no statistically significant increase in cancer detection. While a formal meta-analysis would be difficult due to differences in study design and patient population, there is a clear trend toward increased cancer detection when all 11 studies are considered together. In total, the 11 studies evaluated 330,522 DBT exams which detected 1,727 total cancers (5.23 cancers/1000 exams) and 576,021 DM exams which detected 2,340 cancers (4.06 cancers/1000 exams). Using this approach, the three studies which did not show a statistically significant increase in cancer detection did demonstrate an overall trend towards increased cancer detection. In these studies, there were 229 total cancers detected in 47,185 total DM+DBT exams (4.9 cancers/1000 exams) and 92 total cancers detected in 23,829 total DM alone exams (3.9 cancers/1000 exams). <u>Recall/False Positive Rates</u> Nine of the 11 DBT trials reported that DBT resulted in a statistically significant decrease in recall/false positive rate. These studies evaluated a total of 840,398 exams and reported a 13-63% relative decrease in the recall/false positive rate. Both studies which demonstrated an increase in recall rate with DBT were conducted in Europe, and one of these studies included a significant bias because DBT information was used during arbitration for all cases. As double reading is common in Europe (unlike the US), and recall rates are significantly lower in Europe than the US, it is most appropriate to consider US studies to understand the impact of DBT on recall in the US. All 7 studies conducted in the US demonstrated a statistically significant reduction in recall rate.	

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

Disposition of Public Comments

References Provided by Commenters

ID/#	References
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C	Bonafede, M. M., Kalra, V. B., Miller, J. D., & Fajardo, L. L. (2015). Value analysis of digital breast tomosynthesis for breast cancer screening in a commercially-insured US population. <i>ClinicoEconomics and Outcomes Research</i>, 7, 53-63. DOI: 10.2147/ceor.s76167. Kalra, V. B., Wu, X., Haas, B. M., Forman, H. P., & Philpotts, L. E. (2016). Cost-Effectiveness of Tomosynthesis in Annual Screening Mammography. <i>American Journal of Roentgenology</i>, 1-4. DOI: 10.2214/ajr.15.14487.

HERC Coverage Guidance – Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women Disposition of Public Comments

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E	Conant, E. F., Beaber, E. F., Sprague, B. L., Herschorn, S. D., Weaver, D. L., Onega, T., ... Barlow, W. E. (2016). Breast cancer screening using tomosynthesis in combination with digital mammography compared to digital mammography alone: A cohort study within the PROSPR consortium. <i>Breast Cancer Research and Treatment</i>, 156(1), 109-116. DOI: 10.1007/s10549-016-3695-1. Lang, K., Andersson, I., Rosso, A., Tingberg, A., Timberg, P., & Zackrisson, S. (2016). Performance of one-view breast tomosynthesis as a stand-alone breast cancer screening modality: Results from the Malmo Breast Tomosynthesis Screening Trial, a population-based study. <i>European Radiology</i>, 26(1), 184-190. DOI: 10.1007/s00330-015-3803-3. McDonald, E. S., Oustimov, A., Weinstein, S. P., Synnestvedt, M. B., Schnall, M., & Conant, E. F. (2016). Effectiveness of digital breast tomosynthesis compared with digital mammography: Outcomes analysis from 3 years of breast cancer screening. <i>JAMA Oncology</i>, 2(6), 737-743. DOI: 10.1001/jamaoncol.2015.5536. Rose, S. L., Tidwell, A. L., Ice, M. F., Nordmann, A. S., Sexton, R., Jr., & Song, R. (2014). A reader study comparing prospective tomosynthesis interpretations with retrospective readings of the corresponding FFDM examinations. <i>Academic Radiology</i>, 21(9), 1204-1210. DOI: 10.1016/j.acra.2014.04.008. Sharpe, R. E., Jr., Venkataraman, S., Phillips, J., Dialani, V., Fein-Zachary, V. J., Prakash, S., ... Mehta, T. S. (2016). Increased cancer detection rate and variations in the recall rate resulting from implementation of 3D digital breast tomosynthesis into a population-based screening program. <i>Radiology</i>, 278(3), 698-706. DOI: 10.1148/radiol.2015142036.

Section 3.0

VbBS Report

Errata
January 2017

- 1) CPT 19357-19380 (Breast reconstruction) are not included in the gender dysphoria line but these codes appear in the gender dysphoria guideline. The intent was not to include these codes for gender dysphoria as they are used for post-mastectomy reconstruction and not appropriate for this line. The CPT codes were removed from the gender dysphoria guideline
 - a. Relevant excerpt from GN127
 - i. Mammoplasty (CPT 19316, 19324-19325, 19340, 19342, 19350, ~~19357-19380~~) is only included on this line when 12 continuous months of hormonal (estrogen) therapy has failed to result in breast tissue growth of Tanner Stage 5 on the puberty scale OR there is any contraindication to, intolerance of or patient refusal of hormonal therapy.
- 2) Add CPT 64905 (Nerve pedicle transfer; first stage) to line 70 LARYNGEAL STENOSIS OR PARALYSIS WITH AIRWAY COMPLICATIONS
 - a. This code is the correct CPT code for laryngeal re-innervation, which was added as a covered benefit effective October 1, 2016.
- 3) The negative pressure wound therapy guideline contains 2 HCPCS codes that are no longer valid and were removed.

GUIDELINE NOTE 62, NEGATIVE PRESSURE WOUND THERAPY

Lines 8,30,51,84,210,212,240,290,384,428

Negative pressure wound therapy (CPT 97605-97608, ~~HCPCS G0456, G0457~~) is included on these lines only for patients who:

- Have wounds that are refractory to or have failed standard therapies;
- Are not suitable candidates for surgical wound closure; or,
- Are at high risk for delayed or non-healing wounds due to factors such as compromised blood flow, diabetic complications, wounds with high risk of fecal contamination, extremely exudative wounds, and similar situations.

OHAP Prioritized List Changes for HERC Approval
January 2017

1) Interim Prioritized List changes

- a. Add K02 series (Dental caries) to line 349 DENTAL CONDITIONS (EG. SEVERE CARIES, INFECTION) Treatment: ORAL SURGERY (I.E. EXTRACTIONS AND OTHER INTRAORAL SURGICAL PROCEDURES)
- b. Add D7210 (SURGICAL REMOVAL OF ERUPTED TOOTH REQUIRING REMOVAL OF BONE AND/OR SECTIONING OF TOOTH, AND INCLUDING ELEVATION OF MUCOPERIOSTEAL FLAP IF INDICATED) to line 349
- c. Modify GN34 as shown below:

GUIDELINE NOTE 34, ~~ORAL SURGERY~~ EXTRACTION OF IMPACTED WISDOM TEETH

Line 349

~~Treatment only for symptomatic dental pain, infection, bleeding or swelling (D7220, D7230, D7240, D7241, D7250).~~

Extraction of impacted wisdom teeth (D7220, D7230, D7240, D7241, D7250) is only included on this line when there is

- 1) evidence of pathology. Such pathology includes unrestorable caries, non-treatable pulpal and/or periapical pathology, cellulitis, abscess and osteomyelitis, internal/external resorption of the tooth or adjacent teeth, fracture of tooth, disease of follicle including cyst/tumour, tooth/teeth impeding surgery or reconstructive jaw surgery, and when a tooth is involved in or within the field of tumour resection OR
- 2) two or more episodes of pericoronitis OR
- 3) severe pain directly related to the impacted tooth that does not respond to conservative treatment
 - a. extraction for pain or discomfort related to normal tooth eruption or for non-specific symptoms such as “headaches” or “jaw pain” is not considered medically or dentally necessary for treatment.

2) 2018 Biennial review

- a. Add CDT D6100 (IMPLANT REMOVAL, BY REPORT) to line 349 DENTAL CONDITIONS (EG. SEVERE CARIES, INFECTION) Treatment: ORAL SURGERY (I.E. EXTRACTIONS AND OTHER INTRAORAL SURGICAL PROCEDURES)
- b. Add D5221-D5222 (Immediate partial denture – resin base) to line 457 DENTAL CONDITIONS (EG. MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS (E.G. FULL AND PARTIAL DENTURES, RELINES) and removed from line 594 DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH) Treatment: ADVANCED RESTORATIVE-ELECTIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS).

Consent Agenda Issues—January, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
41015 41016 41017 41018	Extraoral incision and drainage of abscess, cyst, or hematoma of floor of mouth; sublingual submental submandibular masticator space	210 SUPERFICIAL ABSCESES AND CELLULITIS	HSD requested that 41017 pair with K12.2 (Cellulitis and abscess of mouth). 41017 is on lines 168, 600. The entire series 41015-41018 is also appropriate to pair.	Add 41015-41018 to line 210
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm	172 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE	HSD requested 14301 to pair with K43.0 (Incisional hernia with obstruction, without gangrene). 14301 is currently on many lines.	Add 14301 to line 172
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk	172 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE	HSD requested 15734 to pair with K43.0 (Incisional hernia with obstruction, without gangrene). 15734 is on lines 204, 212, 234, 259, 280, 292, 319, 384	Add 15734 to line 172
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression)	383 ESOPHAGEAL STRICTURE; ACHALASIA	HSD requested that 44500 pair with K22.2 (Esophageal obstruction). 44500 is on lines 32,46,51,75,92,105,161,319,383.	Add 44500 to line 383
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE	HSD requested that 43270 pair with K31.819 (Angiodysplasia of stomach and duodenum without bleeding). Previously, this procedure was coded with 43258, which is no longer a valid code. 43270 is on lines 319,595,642. Similar codes are on line 60	Add 43270 to line 60
K51.4	Inflammatory polyps of colon without complications	32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE 170 ANAL, RECTAL AND COLONIC POLYPS	HSD requested that K51.4 pair with 45385 (removal of polyp) which is on 5 lines including line 170. K51.4 is more appropriately on line 170.	Remove K51.4 from line 32 Add K51.4 to line 170

Consent Agenda Issues—January, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE	HSD requested that 43270 pair with K26.9 (Duodenal ulcer, unspecified as acute or chronic, without hemorrhage or perforation). 43270 is used for destruction of lesions that are not currently bleeding.	Add 43270 to line 60
44346	Revision of colostomy; with repair of paracolostomy hernia	172 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE	HSD requested that 44346 pair with K43.3 (Parastomal hernia with obstruction, without gangrene). 44346 is currently on lines 92,105,161,428,531.	Add 44346 to line 172
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)	305 CLEFT PALATE AND/OR CLEFT LIP	21210 added to line 305 in error in November, 2016. HSD is requesting that we reverse this decision.	Remove 21210 from line 305
Z15.01 Z15.02	Genetic susceptibility to malignant neoplasm of breast Genetic susceptibility to malignant neoplasm of ovary	195 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	ICD-10 Z15.01 and Z15.02 are currently informational. They are used for genetic testing and various treatment for women who are BRCA+. Line 195 has a GN regarding BRCA positive or other genetically high risk women.	Add Z15.01 and Z15.02 to line 195

Non-Congenital Diaphragmatic Hernia Repair

Question: What procedures should pair with diaphragmatic hernias?

Question source: HSD, Walter Hardin, MD, OHP Medical Director

Issue: Diaphragmatic hernias were reviewed in March, 2016, and moved from the GERD line to the hernia line when obstructed or gangrenous (ICD-10 K44.0 (Diaphragmatic hernia with obstruction, without gangrene) and K44.1 (Diaphragmatic hernia with gangrene)). Uncomplicated diaphragmatic hernias (ICD-10 K44.9) was kept on the uncovered GERD line. Several CPT codes were moved to the complicated hernia line to allow repair; however, it appears that several other CPT codes are required to be moved that were not identified in the previous review in order to allow treatment of this condition.

Current code placement

Code	Description	Line
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	385 ESOPHAGITIS; GERD
43282	with implantation of mesh	385
43283	Laparoscopy, surgical, esophageal lengthening procedure (eg, Collis gastroplasty or wedge gastroplasty) (List separately in addition to code for primary procedure)	68 CONGENITAL ANOMALIES OF UPPER ALIMENTARY TRACT, EXCLUDING TONGUE

HERC staff recommendation:

- 1) Add 43281-43283 to line 172 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE
 - a. Do not add to line 516 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA
 - i. Asymptomatic diaphragmatic hernias do not require repair

Injuries to Blood Vessels of the Extremities, Neck, Thorax and Abdomen

Question: Where should injuries to blood vessels of the extremities, neck, thorax and abdomen be prioritized?

Question source: HERC staff

Issue: Placement of injury of blood vessels of the neck was reviewed in May, 2014 as part of the 2015 Biennial review. At that time, VBBS/HERC moved the diagnoses of neck injuries from line 135 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME to line 82 INJURY TO MAJOR BLOOD VESSELS OF EXTREMITIES, and changed the line title of line 82 to 82 INJURY TO MAJOR BLOOD VESSELS OF EXTREMITIES AND NECK. However, only some of the ICD-10 codes for injuries to major blood vessels were identified and moved.

With the Biennial Review January 1, 2015 Prioritized List, the line title of line 135 changed from 135 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME to 135 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME; INJURIES TO BLOOD VESSEL(S) OF THE NECK. No mention of the addition of INJURIES TO BLOOD VESSEL(S) OF THE NECK to this line was found in the minutes. It is possible that the general surgery ICD-10 review group suggested this change; no documentation of that meeting was found.

It is clear from minutes that the intent of the HSC/HERC is to prioritize injuries of the major blood vessels of the extremities and of the neck on a high line. There is also mention in the minutes of prioritizing minor blood vessel injuries (i.e., of the feet) to a low line (not line 135).

Injuries of blood vessels of the thoracic cavity is on a lower line, 280 INJURY TO BLOOD VESSELS OF THE THORACIC CAVITY. This was reviewed in 2014, and felt to be appropriate due to the lower effectiveness of treatment for these types of injuries.

It was also noted during the review of line 135 that it contained the only entry for ICD-10 codes for many of the injuries to major blood vessels of the chest/thorax/abdomen (i.e. aorta, renal artery, axillary artery, etc.). Most of the CPT repair codes for these types of internal major vessel injuries appear on line 84 INJURY TO INTERNAL ORGANS or 281 INJURY TO BLOOD VESSELS OF THE THORACIC CAVITY. Line 281 contains a much more extensive list of CPT codes for repair of blood vessels in the chest and abdomen compared to line 84. Line 135 only contains a few CPT codes for such repairs.

Injuries to Blood Vessels of the Extremities, Neck, Thorax and Abdomen

HERC staff recommendations:

- 1) Per the previous intent of the HERC, remove head/neck and major extremity blood vessel injury ICD-10 codes from line 135 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME; INJURIES TO BLOOD VESSEL(S) OF THE NECK and consolidate into line 82 INJURY TO MAJOR BLOOD VESSELS OF EXTREMITIES AND NECK
 - a. See the table below
 - b. Injuries to finger/toe blood vessels moved to more appropriate lines if not already present on such lines per past intent of the HSC/HERC
 - c. Change the title of line 135
 - i. 135 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME;
INJURIES TO BLOOD VESSEL(S) OF THE NECK
 - d. Remove blood vessel repair CPT codes from line 135 as shown in the tables below
- 2) Remove the thoracic/abdominal major blood vessel injury ICD-10 codes from line 135 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME; INJURIES TO BLOOD VESSEL(S) OF THE NECK and place on line 281 INJURY TO BLOOD VESSELS OF THE THORACIC CAVITY
 - a. See table below
 - b. Allows pairing with appropriate repair CPT codes
 - c. Change the title of line 281
 - i. 281 INJURY TO BLOOD VESSELS OF THE THORACIC **AND ABDOMINAL** CAVITY**YES**
- 3) Consider reprioritizing line 281 as shown below
 - a. As the scoring for line 281 results in a reprioritization at approximately line 107, consider merging lines 82 and 107 into "INJURIES TO MAJOR BLOOD VESSEL(S)"
 - i. Include all current CPT codes on both lines
 - ii. Prioritize at line 82

Line scoring:

Line 281 INJURY TO BLOOD VESSELS OF THE THORACIC **AND ABDOMINAL** CAVITY**YES** (current scores in parentheses)

Category 6 (6)

Impact on healthy life: 8 (8)

Pain/Suffering: 2 (2) [line 84 score=3; line 82=2]

Population effects: 0 (0)

Vulnerable population: 0 (0)

Tertiary Prevention: 4 (0) [line 84 score=4]

Effectiveness: 4 (3) [line 84 score=4; line 82=5]

Need for services: 1 (1)

Cost: 3 (3)

Score: 2240 (1200)

Line 107 (281)

Line 82 INJURY TO MAJOR BLOOD VESSELS OF EXTREMITIES AND NECK

Line 84 INJURY TO INTERNAL ORGANS

Injuries to Blood Vessels of the Extremities, Neck, Thorax and Abdomen

ICD-10 Codes for blood vessel injury appearing on lines 82 and/or 135

ICD-10 Code	Code description	Recommended Placement
S09.OXX	Injury of blood vessels of head, not elsewhere classified	~~82~~ ~~135~~
S45.0	Injury of axillary artery	82 ~~135~~
S45.1	Injury of brachial artery	82 ~~135~~
S45.2	Injury of axillary or brachial vein	82 ~~135~~
S45.3	injury of superficial vein at shoulder and upper arm level	82 ~~135~~
S45.8	injury of other specified blood vessels at shoulder and upper arm level	82 ~~135~~
S45.9	injury of unspecified blood vessel at shoulder and upper arm level	82 ~~135~~
S55.0	injury of ulnar artery	82 ~~135~~
S55.1	injury of radial artery	82 ~~135~~
S55.2	injury of vein at forearm level	82 ~~135~~
S55.8	injury of other blood vessels at forearm level	82 ~~135~~
S55.9	injury of unspecified blood vessel at forearm level	82 ~~135~~
S65.0	injury of ulnar artery at wrist and hand level	82 ~~135~~
S65.1	injury of radial artery at wrist and hand level	82 ~~135~~
S65.2	injury of superficial palmar arch	82 ~~135~~
S65.3	injury of deep palmar arch	82 ~~135~~
S65.4	injury of blood vessel of thumb	~~82~~ 294
S65.5	injury of blood vessel of finger	~~82~~ 294
S65.8	injury of other blood vessels at wrist and hand level	82 ~~135~~
S65.9	injury of unspecified blood vessel at wrist and hand level	82 ~~135~~
S75.0	injury of femoral artery	82 ~~135~~
S75.1	injury of femoral vein at hip and thigh level	82 ~~135~~
S75.2	injury of greater saphenous vein at hip and thigh level	82 ~~135~~
S75.8	injury of other blood vessels at hip and thigh level	82 ~~135~~
S75.9	injury of unspecified blood vessel at hip and thigh level	82 ~~135~~
S85.0	injury of popliteal artery	82 ~~135~~
S85.1	injury of tibial artery	82 ~~135~~
S85.2	injury of peroneal artery	82 ~~135~~
S85.3	injury of greater saphenous vein at lower leg level	82 ~~135~~
S85.4	injury of lesser saphenous vein at lower leg level	82 ~~135~~
S85.5	injury of popliteal vein	82 ~~135~~
S85.8	injury of other blood vessels at lower leg level	82 ~~135~~
S85.9	injury of unspecified blood vessel at lower leg level	82 ~~135~~
S95.0	injury of dorsal artery	~~135~~ 212
S95.1	injury of plantar artery	~~135~~ 212
S95.2	injury of dorsal vein	~~135~~ 212
S95.8	injury of other blood vessels at ankle and foot level	~~135~~ 212
S95.9	injury of unspecified blood vessel at ankle and foot level	~~135~~ 212

212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT

294 CRUSH AND OTHER INJURIES OF DIGITS

Injuries to Blood Vessels of the Extremities, Neck, Thorax and Abdomen

Relevant CPT codes appearing on line 82 and/or line 135

CPT	Code Description	Comments
35206	Repair blood vessel, direct; upper extremity	82, ~~135~~ , 285
35207	Repair blood vessel, direct; hand, finger	82, ~~135~~ , 285, 294
35236	Repair blood vessel with vein graft; upper extremity	82, ~~135~~ , 285
35266	Repair blood vessel with graft other than vein; upper extremity	82, ~~135~~ , 285
35521	Bypass graft, with vein; axillary-femoral	~~135~~ , 240, 290, 354
37618	Ligation, major artery (eg, post-traumatic, rupture); extremity	82, ~~135~~ , 330

285 BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS

330 NON-DISSECTING ANEURYSM WITHOUT RUPTURE

Major internal blood vessel ICD-10 codes on line 135

ICD-10 code	Code description	Recommended Placement
S27.9XX	Injury of unspecified intrathoracic organ	~~135~~ 281
S35.0	injury of abdominal aorta	~~135~~ 281
S35.1	injury of inferior vena cava	~~135~~ 281
S35.2	injury of celiac/inferior mesenteric/superior mesenteric artery	~~135~~ 281
S35.3	injury of portal/splenic/superior mesenteric/inferior mesenteric vein	~~135~~ 281
S35.4	injury of renal artery/vein	~~135~~ 281
S35.5	Injury of iliac artery/vein, uterine artery/vein, other vessels of lower abdomen or pelvis	~~135~~ 281

**2018 Biennial Review
Secondary and Ill-Defined Malignancies**

Question: Should the secondary and ill-defined malignancies line be reprioritized, or should some diagnoses on this line be moved to other, covered lines?

Question source: OHP medical directors, HERC staff

Issue: Line 595 SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS contains approximately 50 cancer diagnoses; none of which are currently eligible for any treatment due to the low priority position of this line. Most of these diagnoses have a very poor prognosis even with treatment. Other diagnoses are very vague or unspecified.

Historically, these cancers were put below the funding line based on poor prognosis; they were expected to have less than a 5% 5-year survival, and then kept there because they were not expected to respond to treatments to meet the extended life expectancy requirements of the original language in GN12 TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT. GN12 was revised a few years ago to specify that palliative care is always covered for cancers, but that treatment with intent to prolong survival is not covered only for patients with severe co-morbidities or very poor performance status (i.e. unlikely to survive treatment).

HERC staff have received multiple questions about why certain cancers appear on line 595. All other cancers, even those with poor prognosis such as pancreatic cancer, are in the funded area of the Prioritized List. Many secondary cancer or ill-defined cancer diagnosis codes are actually currently on other cancer lines. It is the custom with the List that very vague diagnoses, such as unspecified diagnoses, be placed on low priority lines to encourage more specific coding.

STATEMENT OF INTENT 1: PALLIATIVE CARE and GN12 TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT are shown below. The diagnoses included in line 595 are also shown below in the table.

**2018 Biennial Review
Secondary and Ill-Defined Malignancies**

HERC staff recommendations:

- 1) **Option 1:** move the majority of diagnoses on line 595 SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS onto other, covered cancer lines with similar organ type. Leave only completely unspecified diagnoses on line 595.
 - a. See the table below for recommended code movements
 - i. ICD-10 C26.1 (Malignant neoplasm of spleen) needs discussion as extremely poor prognosis even with treatment
 - ii. Blank box indicates recommendation is to leave on line 595
 - b. Rename line 595 ~~SECONDARY AND~~ ILL-DEFINED MALIGNANT NEOPLASMS
 - i. Most secondary neoplasms will move to other lines
 - c. Do not reprioritize as the extremely vague diagnoses remaining on this line are appropriately low priority
- 2) **Option 2:** reprioritize line 595.
 - a. Suggested line scoring shown below
 - b. Palliative care would still be covered as in SOI1
- 3) **Option 3:** make no changes

Line scoring:

Line 595 SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS (current scores in parentheses)

Category 9 (9)

Impact on healthy life: 8 (7)

Pain/Suffering: 5 (5)

Population effects: 0 (0)

Vulnerable population: 0 (0)

Tertiary Prevention:

Effectiveness: 1 (1)

Need for services: 1 (1)

Cost: 1 (1)

Score: 40 (12)

Line 566 (595)

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ICD-10 Code	Code Description	Suggested Alternate Placement	Comments
C26.0	Malignant neoplasm of intestinal tract, part unspecified	161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS	
C26.1	Malignant neoplasm of spleen	198 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN Alternative: leave on line 595	Very rare, extremely poor prognosis. Only treatment is splenectomy, not responsive to chemotherapy. Prognoses extremely poor (3-6 months) even with surgery. Line 198 contains radical splenectomy CPT codes
C26.9	Malignant neoplasm of ill-defined sites within the digestive system		Too vague. Would need to be on stomach cancer and intestinal cancer lines.
C45.7	Mesothelioma of other sites		Mesothelioma of pleura, pericardium, and peritoneum on three separate covered lines
C45.9	Mesothelioma, unspecified		Too vague
C7A.1	Malignant poorly differentiated neuroendocrine tumors	264 CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME	C7A.00 (Malignant carcinoid tumor of unspecified site) is on line 264. Other malignant carcinoid tumors are on various GI cancer lines
C7A.8	Other malignant neuroendocrine tumors	264	See above
C7B.00	Secondary carcinoid tumors, unspecified site	264	
C7B.01	Secondary carcinoid tumors of distant lymph nodes	264	
C7B.02	Secondary carcinoid tumors of liver	320 CANCER OF LIVER	C78.7 (Secondary malignant neoplasm of liver and intrahepatic bile duct) is on line 320
C7B.03	Secondary carcinoid tumors of bone	205 CANCER OF BONES	C79.51 (Secondary malignant neoplasm of bone) is on line 205

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C7B.04	Secondary carcinoid tumors of peritoneum	266 CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY	
C7B.09	Secondary carcinoid tumors of other sites	264	
C7B.1	Secondary Merkel cell carcinoma	280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA	All other Merkel cell carcinoma ICD-10 codes on line 280
C7B.8	Other secondary neuroendocrine tumors	264	
C76.1	Malignant neoplasm of thorax		Too vague
C76.2	Malignant neoplasm of abdomen		Too vague
C76.3	Malignant neoplasm of pelvis		Too vague
C76.40	Malignant neoplasm of unspecified upper limb		Too vague
C76.41	Malignant neoplasm of right upper limb		Too vague
C76.42	Malignant neoplasm of left upper limb		Too vague
C76.50	Malignant neoplasm of unspecified lower limb		Too vague
C76.51	Malignant neoplasm of right lower limb		Too vague
C76.52	Malignant neoplasm of left lower limb		Too vague
C76.8	Malignant neoplasm of other specified ill-defined sites		Too vague
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck		Too vague – could relate to any type of cancer that has metastasized Alternative: C96.Z (Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue) is on lines 162,167 Non-Hodgkins Lymphoma
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes		Too vague

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C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes		Too vague
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes		Too vague
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes		Too vague
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes		Too vague
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions		Too vague
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified		Too vague
C78.00	Secondary malignant neoplasm of unspecified lung	267 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS	
C78.01	Secondary malignant neoplasm of right lung	267	
C78.02	Secondary malignant neoplasm of left lung	267	
C78.1	Secondary malignant neoplasm of mediastinum	267	
C78.2	Secondary malignant neoplasm of pleura	267	
C78.30	Secondary malignant neoplasm of unspecified respiratory organ	267	
C78.39	Secondary malignant neoplasm of other respiratory organs	267	
C78.4	Secondary malignant neoplasm of small intestine	161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS	

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C78.5	Secondary malignant neoplasm of large intestine and rectum	161	
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum	266 CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY	
C78.80	Secondary malignant neoplasm of unspecified digestive organ		Too vague
C78.89	Secondary malignant neoplasm of other digestive organs		Too vague
C79.81	Secondary malignant neoplasm of breast	195 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	
C79.82	Secondary malignant neoplasm of genital organs	291 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS 263 CANCER OF PENIS AND OTHER MALE GENITAL ORGANS	
C79.89	Secondary malignant neoplasm of other specified sites		Too vague. Used for many, many types of cancers
C79.9	Secondary malignant neoplasm of unspecified site		Too vague
C80.0	Disseminated malignant neoplasm, unspecified		Too vague
C80.1	Malignant (primary) neoplasm, unspecified		Too vague
D44.9	Neoplasm of uncertain behavior of unspecified endocrine gland		Too vague
Z85.020	Personal history of malignant carcinoid tumor of stomach	220 CANCER OF STOMACH	

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Z85.030	Personal history of malignant carcinoid tumor of large intestine	161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS	
Z85.040	Personal history of malignant carcinoid tumor of rectum	161	
Z85.060	Personal history of malignant carcinoid tumor of small intestine	161	
Z85.110	Personal history of malignant carcinoid tumor of bronchus and lung	267 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS	
Z85.230	Personal history of malignant carcinoid tumor of thymus	Informational Diagnosis File	Other history of thymus cancers is Informational
Z85.520	Personal history of malignant carcinoid tumor of kidney	219 CANCER OF KIDNEY AND OTHER URINARY ORGANS	
Z85.821	Personal history of Merkel cell carcinoma	292 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX	
Z85.858	Personal history of malignant neoplasm of other endocrine glands	Informational Diagnosis File	Too vague

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STATEMENT OF INTENT 1: PALLIATIVE CARE

It is the intent of the Commission that palliative care services be covered for patients with a life-threatening illness or severe advanced illness expected to progress toward dying, regardless of the goals for medical treatment and with services available according to the patient's expected length of life (see examples below).

Palliative care is comprehensive, specialized care ideally provided by an interdisciplinary team (which may include but is not limited to physicians, nurses, social workers, etc.) where care is particularly focused on alleviating suffering and promoting quality of life. Such interdisciplinary care should include assessment, care planning, and care coordination, emotional and psychosocial counseling for patients and families, assistance accessing services from other needed community resources, and should reflect the patient and family's values and goals.

Some examples of palliative care services that should be available to patients with a life-threatening/limiting illness,

- A) without regard to a patient's expected length of life:
 - Inpatient palliative care consultation; and,
 - Outpatient palliative care consultation, office visits.
- B) with an expected median survival of less than one year, as supported by the best available published evidence:
 - Home-based palliative care services (to be defined by DMAP), with the expectation that the patient will move to home hospice care.
- C) with an expected median survival of six months or less, as supported by peer-reviewed literature:
 - Home hospice care, where the primary goal of care is quality of life (hospice services to be defined by DMAP).

It is the intent of the Commission that certain palliative care treatments be covered when these treatments carry the primary goal to alleviate symptoms and improve quality of life, without intending to alter the trajectory of the underlying disease.

Some examples of covered palliative care treatments include:

- A) Radiation therapy for painful bone metastases with the intent to relieve pain and improve quality of life.
- B) Surgical decompression for malignant bowel obstruction.
- C) Medication therapy such as chemotherapy with low toxicity/low side effect agents with the goal to decrease pain from bulky disease or other identified complications. Cost of chemotherapy and alternative medication(s) should also be considered.
- D) Medical equipment and supplies (such as non-motorized wheelchairs, walkers, bandages, and catheters) determined to be medically appropriate for completion of basic activities of daily living, for management of symptomatic complications or as required for symptom control.
- E) Acupuncture with intent to relieve nausea.

Cancer treatment with intent to palliate is not a covered service when the same palliation can be achieved with pain medications or other non-chemotherapy agents.

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It is NOT the intent of the Commission that coverage for palliative care encompasses those treatments that seek to prolong life despite substantial burdens of treatment and limited chance of benefit. See Guideline Note 12 TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT.

GUIDELINE NOTE 12, TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT

Lines 97,116-120,129,133,137,139,161,162,167,183,195,204,205,213,215,219,220,222,234,239,242, 243,263-267,275,280,291,292,299,319-321,334,377,402,403,424,439,595,606

Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall health, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see Statement of Intent 1, Palliative Care).

Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with

- A) severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy; OR
- B) a continued decline in spite of best available therapy with a non reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.

Treatment with intent to relieve symptoms or improve quality of life is a covered service as outlined in Statement of Intent 1, Palliative Care.

To qualify for treatment coverage, the cancer patient must have a documented discussion about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. This discussion may take place with the patient's oncologist, primary care provider, or other health care provider, but preferably in a collaborative interdisciplinary care coordination discussion. Treatment must be provided via evidence-driven pathways (such as NCCN, ASCO, ASH, ASBMT, or NIH Guidelines) when available.

Fecal Microbiota Transplant

Question: Should fecal transplant be added to the Prioritized List as a treatment for recurrent *C. difficile* infection?

Question source: coverage guidance process

Issue: Fecal microbiota transplant (FMT) is a rapidly evolving area for treatment of *C. difficile* colitis (*C. difficile* infection or CDI). This procedure involves transplanting donor feces into the intestinal tract of a patient with CDI, either via a nasogastric tube, endoscope, enema or colonoscope. There is also ongoing research into using a capsule form of administration. Generally, this procedure is reserved for patients who have been treated with several courses of antibiotics with high activity against CDI and who still have significant symptoms. FMT is rapidly becoming a standard therapy for treatment of recurrent CDI.

C. Difficile colitis can cause severe diarrhea, fever and abdominal pain. It can lead to pseudomembranous colitis, toxic megacolon, perforation of the colon, sepsis, and death. This infection generally occurs after a patient has been treated for an infection with antibiotics or has been hospitalized.

FMT is also being investigated as a treatment for inflammatory bowel disease (IBD). At this time, the FDA requires an investigational license for this use of fecal transplant.

Fecal transplant was reviewed as a new CPT code in 2012 and found to be experimental at that time. Since that review, several new studies have been published. Recently, Washington HTA conducted a systematic review of the topic.

Current code placements:

ICD-10 A04.7 (Enterocolitis due to *Clostridium difficile*) is on line 150 ENTERIC INFECTIONS AND OTHER BACTERIAL FOOD POISONING

CPT 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen) is currently SNRC

HCPCS G0455 (Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen) is currently SNRC

Evidence

1) Washington HTA 2016 (document not included due to length, please view online:

<http://www.hca.wa.gov/assets/program/fmt-final-report-20161005.pdf>

- a. N=27 (7 randomized trials, 5 cohort studies, and 15 case series)
- b. After a single treatment, significantly more FMT patients (previously treated 1-3 times with antibiotics) achieved cure through 2.5 months than those in the vancomycin group (pooled RD 45% (95% CI 25%, 64%))
- c. Pooled results suggest no difference in mortality attributed to CDI within 2.5 months of treatment (pooled RD 0% (95% CI -9%, 8%)) in FMT vs vancomycin groups
- d. The pooled effect estimate suggests no difference between FMT and vancomycin groups in all-cause mortality through 2.5 months (RD -4% (95% CI -14%, 7%))
- e. Adverse events: No serious adverse events were attributed to the FMT or colonoscopy procedures. *Non-serious adverse events*: A number of procedure-related adverse events were collected through one week of the procedure; other than chills, which occurred in slightly fewer donor FMT than autologous FMT patients (data NR, p=0.053), there was no difference between groups
- f. Cost utility analysis: FMT via colonoscopy was found to be dominant¹²⁴ or more cost effective compared to vancomycin in all four studies of patients with recurrent CDI. Conclusions were similar when comparing FMT to metronidazole or fidaxomicin. For the initial CDI occurrence, one study found that FMT via colonoscopy was dominant over vancomycin alone. In general, sensitivity analyses supported the conclusion that FMT was more cost-effective than antibiotic treatment for first or recurrent CDI.
- g. Summary of results:
 - i. For patients with recurrent CDI and randomized to FMT or vancomycin, there was low quality evidence for the following outcomes as evaluated through 2.5 months. Cure was achieved by 45% (95% CI 25% to 64%) more patients following a single FMT (+ bowel lavage) procedure compared with vancomycin ($\pm$ bowel lavage) therapy. To that end, the need for additional FMT procedure(s) for treatment of recurrent CDI (after the initial allocated treatment) was greater in the FMT group than in the vancomycin group. The incidence of CDI-related as well as all-cause mortality were similar across both groups. One trial additionally provided low quality evidence of no difference between groups in all-cause mortality through eight months.
 - ii. For patients with recurrent CDI and randomized to FMT (donor feces) or placebo (autologous feces), moderate quality evidence from one small trial supports the following conclusions. Through two months, cure was 28% more likely following FMT than placebo (95% CI 6%, 51%); similarly, 33% fewer FMT patients underwent an additional FMT procedure due to recurrent CDI (after the initial allocated treatment) compared with the placebo group. Finally, no patients died in either group from any cause through six months.
 - iii. For IBD: For patients with UC, moderate quality evidence suggests that clinical remission with an endoscopic response was slightly more common with FMT versus placebo through 1.75 months, however, both trials were terminated early due to lower remission rates than anticipated. No difference was found between groups in the percentage of patients who achieved clinical response through 1.75 months (low quality evidence) or in clinical remission through three months (moderate quality evidence); the need for additional procedures was also similar between groups through three months (low quality evidence).

- iv. Based on results from the five included cost utility analyses, there was a suggestion that FMT was more cost-effective than antibiotic treatment for first or recurrent CDI.
- 2) **AHRQ 2016 (document not included due to length, please view online:**
<https://effectivehealthcare.ahrq.gov/ehc/products/604/2208/c-difficile-update-report-160502.pdf>
 - a. N=26 studies (3 RCTs, 23 observational studies)
 - b. Based on a qualitative analysis of the unpooled data, low-strength evidence showed that FMT resolves diarrhea and prevents relapse in people with recurrent CDI.
 - c. Data insufficient for patients with refractory CDI
- 3) **NICE 2014 (document not included due to length, please view online:**
<https://www.nice.org.uk/guidance/ipg485/resources/faecal-microbiota-transplant-for-recurrent-clostridium-difficile-infection-1899869993554885>)
 - a. Current evidence on the efficacy and safety of fecal microbiota transplant for recurrent *Clostridium difficile* infection is adequate to support the use of this procedure
 - b. This procedure should only be considered for patients with recurrent *C. difficile* infections that have failed to respond to antibiotics and other treatments.

Expert guidelines

- 1) **American College of Gastroenterology 2013**
 - a. If there is a third recurrence after a pulsed vancomycin regimen, fecal microbiota transplant (FMT) should be considered. (Conditional recommendation, moderate-quality evidence)
- 2) **European Society of Clinical Microbiology and Infectious Diseases, 2014**
 - a. FMT in combination with oral antibiotic treatment is strongly recommended for multiple, recurrent *C. difficile* infections unresponsive to antibiotic treatment.

Other policies:

All major insurers cover FMT for treatment of recurring or refractory CDI after two or more courses of appropriate antibiotics.

HERC staff summary:

Trusted sources (AHRQ, Washington HTA, NICE) have all found that FMT is more effective than antibiotic therapy for resolution of recurrent CDI based on low quality evidence. FMT is cost effective compared to antibiotic therapy. There are few adverse events related to this therapy. Expert groups recommend its use for treatment of recurrent CDI.

There is minimal evidence to support the use of FMT for treatment of IBD.

Fecal Microbiota Transplant

HERC staff recommendations:

- 1) Add coverage for fecal microbiota transplant for treatment of recurrent C Difficile infection
 - a. Add CPT 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen) to line 150 ENTERIC INFECTIONS AND OTHER BACTERIAL FOOD POISONING and remove from the Services Recommended for Non-Coverage Table
 - b. Add HCPCS G0455 (Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen) to line 150 ENTERIC INFECTIONS AND OTHER BACTERIAL FOOD POISONING and remove from the Services Recommended for Non-Coverage Table
 - c. Would not be available to treat IBD as these diagnoses are not included on line 150
- 2) Consider adding the following new guideline note to line 150
 - a. FMT may become first line therapy for CDI and therefore a guideline may need to be addressed in the future.

GUIDELINE XXX FECAL MICROBIOTA TRANSPLANT

Line 150

Fecal microbiota transplant (FMT; CPT 44705, HCPCS G0455) is included on this line for treatment of recurrent C difficile infection only.

Pharmacogenetic Testing for Antidepressant Therapy

Question: Should pharmacogenetics testing be covered to help guide medication decisions for patients with depression or similar mood disorders; if so, for which patient groups and with what restrictions?

Question source: EGBS

Issue: Pharmacogenetics testing for depression was raised as a topic for EGBS to examine through the coverage guidance process. However, it was determined that Washington HTA was undergoing a major review of this topic and therefore a coverage guidance review would be redundant. EGBS referred this topic to VBBS to consider, with review of the WaHTA report.

Pharmacogenetics testing is the process of testing selected genes believed to be associated with drug response or potential adverse reactions. Available panels have some overlap in the genes included in each panel, but not all panels test the same genes. Potential uses for the information gleaned from both types of tests include drug and dose selection for initiating or changing medications with the intent to improve patient outcomes and experiences with treatment.

The Genetics Advisory Panel at their September 2016 meeting discussed this topic. The advisory panel felt that it was probably premature to cover such testing, and it was unclear how the information obtained from such testing was best utilized.

Current Prioritized List status

CPT 81479 (Unlisted molecular pathology procedure) is on the Suspend for Review File
81225-81227 (CYP2C19 (cytochrome P450...) (eg, drug metabolism), gene analysis) are all on the Services Recommended for Non-Coverage table

Evidence

- 1) **WaHTA 2016**, Pharmacogenomic testing (PGx) for selected conditions (**Report here:** <http://www.hca.wa.gov/assets/program/pharmacogenomics-final-rpt-20161209.pdf>)
 - a. N=14 studies
 - i. Examined use in major depression, schizophrenia, anxiety, ADHD, bipolar disorder and substance use disorder
 - ii. Looked at genetic panels as well as single gene testing
 - b. Impact of PGx on clinical decision making
 - i. N=4 studies
 - ii. Overall quality of evidence rated low
 - iii. Pharmacogenomic test results consistently led medication treatment prescribers to change their treatment decisions compared with treatment as usual but the overall quality of evidence was low. While management change is a necessary step toward improving patient outcomes, it is not sufficient to support a conclusion of clinical benefit
 - c. Impact on clinical outcomes
 - i. Remission
 1. N=4 studies (3 fair quality, 1 poor quality)

Pharmacogenetic Testing for Antidepressant Therapy

2. In summary, despite consistency of results favoring improved remission rates as a result of genotyping, the quality of the evidence is low and our confidence that the results represent a true effect is therefore also low. Evidence based summary statement
 - 3.
- ii. Response to treatment
 1. N=4 studies (3 fair quality, 1 poor quality)
 2. Overall, the results for response to treatment, comparing pharmacogenomic testing–informed prescribing with treatment as usual, lack consistency, are limited in some cases by lack of acceptable measures of response, or were underpowered. The overall quality of the evidence is low.
 3. Best results are reported by a fair-quality prospective controlled trial that used 3 such measures of response and showed that patients whose prescribing physicians had access to results from a U.S.-based pharmacogenomic genotyping panel were statistically significantly more likely to respond than control patients who were prescribed treatment as usual for 8 weeks.
 - iii. Adherence, Tolerance, Adverse Events; Hospital Stay
 1. 1 fair quality RCT reported on tolerance of medications, finding that non-genotyped control patients were less tolerant of medications, statistically significantly more often requiring dose reduction or cessation. In addition, genotyped patients took sick leave less often, and took leave times of shorter duration when needed, compared with non-genotyped patients.
 2. In a poor-quality retrospective comparative study, patients who were prescribed dose increases for genotype-appropriate antidepressants had statistically significantly shorter hospital stays, which were reduced by an average of 4.7 weeks if the antidepressant dose was increased by more than 1.5-fold.
 - iv. Use for treatment of alcohol use disorder
 1. very-low-quality evidence from 1 fair-quality study is insufficient evidence to draw conclusions.
 - v. Overall summary of clinical effectiveness:
 1. The evidence supporting the use pharmacogenomic test results for patient management and their impact on patient outcomes is extremely limited and compromised and is considered to be of low to very low quality, depending on the outcome measured. As such, the evidence is insufficient for conclusions regarding clinical use.
 - d. Economic study results in some cases suggested cost-effectiveness but lacked consistency overall.
 - e. Other guidelines/payer policies:
 - i. Of the practice guidelines that mention pharmacogenomic testing at all, most make no formal recommendations for use, but rather indicate a need for future research. Some guidelines suggest that

Pharmacogenetic Testing for Antidepressant Therapy

pharmacogenomic testing in combination with therapeutic drug monitoring may be beneficial in certain circumstances.

- ii. Few payer policies provide general coverage for pharmacogenomic testing; specific gene tests may be covered in certain cases.
- f. Found a significant gap in the evidence about which genes/variants or combinations thereof best address specific clinical indications and outcomes of interest

Submitted evidence disposition

- 1) Herbild 2013: included in WaHTA report
- 2) Liu 2011: studies a single gene variant
- 3) Ramsey 2011: studies a single gene variant

Other policies

- 1) Aetna and most BCBS plans consider pharmacogenetics testing for antidepressant management to be experimental
- 2) Cigna has limited coverage of single gene tests when the outcome is expected to affect clinical management

HERC staff summary:

The major evidence based review of pharmacogenetic testing for psychiatric medication management did not find sufficient evidence to support its use for panel testing or single gene testing.

HERC staff recommendations:

- 1) Do not add coverage for pharmacogenetics testing for antidepressant therapy management for depression
- 2) Do not add coverage for pharmacogenetics testing for any other mental health condition (i.e. schizophrenia, alcohol abuse)
- 3) Adopt the following diagnostic guideline

DIAGNOSTIC GUIDELINE DXX PHARMACOGENETICS TESTING FOR PSYCHIATRIC MEDICATION MANAGEMENT

Pharmacogenetics testing for management of psychiatric medications is not a covered service.

Gallstones and Cholecystitis

Questions:

- 1) What conditions should be included on the upper gallstone line for treatment with cholecystectomy?
- 2) Should a guideline be added to clarify when cholecystitis is present?

Question source: OHP medical directors; HERC staff; Dr. Jack Hartley, community surgeon

Issue: Gallstones (cholelithiasis) are present in 7% of the population, and more common in women and with increasing age. Gallstones can be asymptomatic, or can cause acute abdominal pain, called biliary colic. Cholecystitis occurs when the gallbladder becomes inflamed, and results in more prolonged pain and generally fever. The gallbladder is tender to palpation. Other signs of gallbladder inflammation included a thickened gallbladder wall on ultrasound, positive HIDA scan, etc. Approximately 20% of patients with gallstones will become symptomatic within 15 years of follow-up, 1-2% will develop other complications and the majority of these complications will occur in patients with biliary colic. Acalculous cholecystitis is clinically identical to acute cholecystitis but is not associated with gallstones and usually occurs in critically ill patients. It accounts for approximately 10% of cases of acute cholecystitis and is associated with high morbidity and mortality rates.

Gallstones are on both a covered and an uncovered line on the Prioritized List, with placement determined by the presence or absence of cholecystitis or obstruction. If cholecystitis is present, the diagnosis is included on line 59 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS; if not, the diagnosis is included on line 645 GALLSTONES WITHOUT CHOLECYSTITIS. There is no guideline to define when cholecystitis is present. Significantly, general surgeons feel that symptomatic gallstones (i.e. with biliary colic but without cholecystitis) should be included on the covered line. Whether to include symptomatic gallstones without cholecystitis on the upper line has been discussed twice in the past 10 years, in 2009 and 2012. There continues to be tension between community surgeons and the CCOs regarding whether painful gallstones/biliary colic should be an indication for cholecystectomy.

The decision to date by the HSC/HERC has been to only cover gallstones in the presence of cholecystitis or other complication. Given the overlap of symptoms between biliary colic and cholecystitis, the medical directors feel that there is a need for a definition of when cholecystitis is present. In 2004, Alison Little proposed a guideline to define cholecystitis; the decision was made to not adopt this guideline unless there was additional input from medical directors or surgeons that a guideline was needed:

CHOLECYSTECTOMY GUIDELINE

Presence of RUQ abdominal pain

AND

Presence of gallstones or evidence of gall bladder wall thickening on ultrasound

OR

Non-visualization of the gall bladder on oral cholecystogram or HIDA scan

OR

Gallbladder ejection fraction of < 35%

Currently cholecystectomy is covered for gallstones in the presence of acute or chronic cholecystitis, gallbladder or liver cancer, congenital anomalies of the GI system and of the gallbladder, paralytic ileus of the intestine, and for other "specified diseases of the gallbladder."

Other issues related to the gallbladder

ICD-10 K82.8 (Other specified diseases of gallbladder) is present on both gallbladder lines without any guideline indicating when this condition is intended to be included for treatment on the upper line. K82.8 includes several subdiagnoses: adhesions/atrophy/cyst/hypertrophy/ulcer of cystic duct or gallbladder, biliary dyskinesia, gallbladder mass, intramural calcification of the gallbladder and porcelain gallbladder.

Porcelain gallbladder is an uncommon manifestation of chronic cholecystitis, characterized by intramural calcification of the gallbladder wall. Patients with a porcelain gallbladder are often asymptomatic, but are at increased risk for the development of gallbladder carcinoma, which has a poor prognosis. Intramural calcification can be present to a lesser degree as well, and simply diagnosed as calcification of the gallbladder.

Biliary dyskinesia is a symptomatic functional disorder of the gallbladder whose precise etiology is unknown. In order to diagnose biliary dyskinesia, the patient should have right upper quadrant pains similar to biliary colic but have a normal ultrasound examination of the gallbladder. Biliary dyskinesia is diagnosed by HIDA scan, with an abnormal scan showing <35% ejection fraction. Cholecystectomy is the only known effective treatment for the diagnosis of biliary dyskinesia. The likelihood of symptom relief at one year after cholecystectomy is variable and highly dependent on patient selection but ranges from 50-70%.

Gallstones and Cholecystitis

Current Prioritized List status:

47544 (Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy), and all associated radiological supervision and interpretation) is on lines 59,105,298

47562 (Laparoscopy, surgical; cholecystectomy) is on lines 59,198,311,320,439

47563 (Laparoscopy, surgical; cholecystectomy with cholangiography) is on lines 59,198,439

47564 (Laparoscopy, surgical; cholecystectomy with exploration of common duct) is on lines 59,298,439,645

47600-47620 (Cholecystectomy) are on lines 59,105,298,320,439,645

59 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS

105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS;
CHRONIC INTESTINAL PSEUDO-OBSTRUCTION

198 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN

298 ANOMALIES OF GALLBLADDER, BILE DUCTS, AND LIVER

311 PARALYTIC ILEUS

320 CANCER OF LIVER

439 CANCER OF GALLBLADDER AND OTHER BILIARY

645 GALLSTONES WITHOUT CHOLECYSTITIS

ICD-10 K85.1 (Biliary acute pancreatitis) is on line 199 ACUTE PANCREATITIS. This ICD-10 code represents gallstone pancreatitis.

HSC/HERC history

- 1) Coverage of painful gallstones without cholecystitis was discussed in August of 2009

From VBBS minutes:

Cholelithiasis with cholecystitis

Smits reviewed a document outlining problems the health plans are having with list placement and line names for lines dealing with cholelithiasis. The HSC has always intended that asymptomatic gallstones should be placed on an uncovered line. The discussion first centered around whether symptomatic gallstones should be covered. Saha wondered if there could be an obstructing stone without some type of cholecystitis. Gubler stated that pain without other signs of cholecystitis is relatively rare. Pathology usually comes back chronic inflammation. Surgeons generally do not remove gallstones which are only found incidentally based on Interqual guidelines. Kirk responded that Interqual guidelines used to be "biliary colic and evidence of inflammation," but the new version is "more than one incidence of biliary colic." He did not feel that renaming the upper line "Clinically significant" would work. Saha stated that the HSC needs to make clear that we won't pay for this unless there is active infection or active pain due to their gallstones. The discussion then centered around whether pain should be an indication. Kirk asked about the statistics for complications in people with colic. Gubler stated that the majority will develop cholecystitis without treatment. If there is no colic, only 10% will develop complications. Saha proposed attaching a guideline or SOI to the cholecystitis lines. Such a guideline would state "Asymptomatic cholelithiasis with or without pathologic diagnosis of cholelithiasis is not covered." However, Gubler argued that surgeons don't want to watch diabetics with stones, even if they don't have pain or complications, due to higher complication rates when untreated. Dodson felt that the HSC should just leave it the way it is, that the HSC can't mandate that a provider take a good history. The decision was to make no changes to the current lines other than the simple code changes proposed in the summary document.

- 2) Coverage of cholecystectomy was reviewed in the 2012 ICD-10 General surgery review. From the August, 2012 VBBS minutes:

The data on symptomatic and asymptomatic gallstones was reviewed. There was a discussion about the evidence and expected recurrence, as well as the significant risk of performing surgeries in patients with incidentally found gallstones who present with abdominal pain. Given the data demonstrating safety associated with conservative (non-surgical) management, and the large proportion of individuals who will not go on to develop further episodes, the decision was made to continue the current line structure.

Evidence—delayed cholecystectomy for uncomplicated biliary colic

- 1) **Gurusamy 2013**, (Article not included in packet due to length; please view online: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007196.pub3/epdf>) Cochrane review of early vs delayed cholecystectomy for uncomplicated biliary colic
 - a. N=1 trial (75 participants—35 early laparoscopic cholecystectomy, 40 delayed cholecystectomy)
 - i. Mean waiting period for delayed group 4.2 months
 - ii. Trial deemed at high risk of bias
 - b. Mortality: 0/35 (early) vs 1/40 (delayed, 2.5%) ($P > 0.9999$).
 - c. There were no serious adverse events related to the surgery in either group.
 - d. Complications in delayed group: pancreatitis ($n = 1$), empyema of the gallbladder ($n = 1$), gallbladder perforation ($n = 1$), acute cholecystitis ($n = 2$), cholangitis ($n = 2$), obstructive jaundice ($n = 2$), and recurrent biliary colic (requiring hospital visits) ($n = 5$). In total, 14 participants required hospital admissions for the above symptoms. The proportion of people who developed serious adverse events was 0/28 (0%) in the early group, which was significantly lower than in the delayed laparoscopic cholecystectomy group 9/40 (22.5%) ($P = 0.0082$). This trial did not report quality of life or return to work.
 - e. There was no significant difference in the proportion of people who required conversion to open cholecystectomy in the early group 0/28 (0%) compared with the delayed group (6/35 or 17.1%) ($P = 0.0743$). There was a statistically significant shorter hospital stay in the early group than in the delayed group (MD -1.25 days, 95% CI -2.05 to -0.45). There was a statistically significant shorter operating time in the early group than the delayed group (MD -14.80 minutes, 95% CI -18.02 to -11.58).
 - f. **Authors' conclusions:** Based on evidence from only one high-bias risk trial, it appears that early laparoscopic cholecystectomy (less than 24 hours after diagnosis of biliary colic) decreases the morbidity during the waiting period for elective laparoscopic cholecystectomy (mean waiting time 4.2 months), the hospital stay, and operating time. Further randomised clinical trials are necessary to confirm or refute these findings
- 2) **Palmar 2015**, prognostic nomogram for management of symptomatic cholelithiasis in older patients
 - a. Medicare claims data study of outcomes for patients aged 65 and older who did not receive cholecystectomy within 2.5 months of first episode of biliary colic. Evaluated risk for cholecystectomy or hospitalization at 2 yrs
 - b. N=92,436 patients with biliary colic/dyskinesia (65.3%), acute cholecystitis (26.6%), choledocholithiasis (5.7%), or gallstone pancreatitis (2.4%).
 - c. The 2-year emergent gallstone-related hospitalization rate was 11.1%, with associated in-hospital morbidity and mortality rates of 56.5% and 6.5%. Factors associated with gallstone-related acute hospitalization included male sex, increased age, fewer comorbid conditions, complicated biliary disease on initial presentation, and initial presentation to the emergency department.
 - d. Biliary colic was the lowest risk of the diagnoses evaluated
 - e. **Conclusions:** Surgeons can use this prognostic nomogram to accurately provide patients with their 2-year risk of developing gallstone-related complications, allowing patients and physicians to make informed decisions in the context of their symptom severity and its impact on their quality of life.

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Expert guidelines

- 1) **Society of American Gastrointestinal and Endoscopic Surgeons 2010**, guidelines for laparoscopic cholecystectomy (document is here: <https://www.sages.org/publications/guidelines/guidelines-for-the-clinical-application-of-laparoscopic-biliary-tract-surgery/#>)
 - a. Asymptomatic gallstones are generally not an indication for laparoscopic cholecystectomy.
 - b. Indications for laparoscopic cholecystectomy include but are not limited to symptomatic cholelithiasis, biliary dyskinesia, acute cholecystitis, and complications related to common bile duct stones including pancreatitis with few relative or absolute contraindications (Level II, Grade A).
 - c. Patients with symptoms of biliary obstruction without evidence of gallstones, but with abnormal gallbladder emptying [biliary dyskinesia] may benefit from laparoscopic cholecystectomy. (Level II, Grade B).
 - d. Patients with suspected gallbladder calcifications should be carefully studied, with open cholecystectomy recommended for those with selective mucosal calcifications. (Level III, Grade B).
 - e. Laparoscopic cholecystectomy should be considered for larger, especially single, [gallbladder] polyps or those with associated symptoms, with watchful waiting for small (< 5mm) asymptomatic polyps. (Level II, Grade B).
 - f. Laparoscopic cholecystectomy is considered curative for cancers confined to the gallbladder mucosa (T1a). (Level II, Grade B).
 - g. Cancers which are more locally advanced or those with nodal involvement should be referred to specialty centers for consideration of more extensive resection or re-resection. (Level II, Grade B).
- 2) **Yokoe 2013**, updated Tokyo guidelines for diagnosis of cholecystitis (document found here: http://download.springer.com/static/pdf/155/art%253A10.1007%252Fs00534-012-0568-9.pdf?originUrl=http%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs00534-012-0568-9&token2=exp=1483488131~acl=%2Fstatic%2Fpdf%2F155%2Fart%25253A10.1007%25252Fs00534-012-0568-9.pdf%3ForiginUrl%3Dhttp%253A%252F%252Flink.springer.com%252Farticle%252F10.1007%252Fs00534-012-0568-9*~hmac=1ff4bb2466d6dd834a6bab214aba8f398e5384223d6062550833914f49d52bd1)
 - a. TG13 diagnostic criteria for acute cholecystitis
 - A. Local signs of inflammation etc.
 - (1) Murphy's sign, (2) RUQ mass/pain/tenderness
 - B. Systemic signs of inflammation etc.
 - (1) Fever, (2) elevated CRP, (3) elevated WBC count
 - C. Imaging findings
 - Imaging findings characteristic of acute cholecystitis
 - Suspected diagnosis: One item in A + one item in B
 - Definite diagnosis: One item in A + one item in B + C

Other policies:

All other major insurers and CMS cover cholecystectomy for biliary colic, as well as cholecystitis or other complications.

Expert input

Dr. Jack Hartley

The requirement for fever or abnormal laboratory values excludes a significant number of patients with cholecystitis. 20% of patients with cholecystitis will have the disease confirmed by HIDA scanning. (Ann. Emerg. Med. 1996 Sept 28(3):267-72). The presence of normal laboratory values does not exclude cholecystitis.

The indications for surgery should include the diagnosis of biliary colic or symptomatic cholelithiasis. Biliary colic is the indication for a significant number of cholecystectomies. Biliary colic is defined as the presence of typical right upper quadrant pain and the presence of gall stones on imaging without signs of inflammation as indicated by abnormal lab values and imaging.

2010 SAGES guidelines recommend surgery for symptomatic cholelithiasis.

I would agree with your suggested compromise of covering recurrent biliary colic. In one report, over half of patients with complicated biliary tract disease (acute cholecystitis, pancreatitis, CBD stones) had biliary colic by history. Operating in the presence of more advanced disease is more prone to complications or the need to convert to an open procedure. At this time, laparoscopic cholecystectomy is widely practiced and the individual surgeons should have enough experience with the technique to avoid a significant incidence of complications.

Dr. Hartley provided several references to support his argument that cholecystectomy should be covered for biliary colic:

- 1) Duncan 2012: evidence based review of gallstone disease (document here: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3496004/pdf/nihms408614.pdf>)
 - a. Biliary colic and acute cholecystitis are best treated with early laparoscopic cholecystectomy.
 - i. Based on evidence of increased complication rate, increased ER visits, and reduced rates of conversion to open cholecystectomy.
 - ii. Major evidence source cited is the Cochrane review included above
- 2) Besselink 2009: retrospective cohort study of incidence of biliary colic prior to complicated gallstone disease
 - a. N=175 patients with complicated gallstone disease [pancreatitis (n=53), symptomatic common bile duct (CBD) stones (n=64), and acute cholecystitis (n=58)] and 175 patients with symptomatic uncomplicated gallstones were interviewed at admission.
 - b. 57% (100 of 175) of patients with complicated disease (95% confidence interval=50–65%) experienced “warning” episodes of biliary colic (pancreatitis 58%, CBD stones 67%, cholecystitis 45%) vs 96% (164 of 175) in uncomplicated disease.
 - c. Conclusions: Half of patients with biliary pancreatitis experience “warning” episodes of biliary colic, similar to other gallstone complications. In symptomatic patients, complications are often not prevented because of significant delays in diagnosis and treatment.

Gallstones and Cholecystitis

OHP CCO input:

Tracy Muday, MD, medical director Western Oregon Advanced Health

Utilization: 98 requests for cholecystectomy in the past year, with 18 of these denied.

In general, I think I am in favor of adding biliary colic to the covered line and calling it something like “symptomatic gallbladder diseases.” I think the absolute number of surgeries would be small. Our plan is around 20,000 members, so this would be 5 extra surgeries per year per 10,000 members. At 1 million on the plan, does that come out to about 500 extra gallbladders a year statewide? Fewer if some plans are more permissive than we are.

Jim Calvert, MD, medical director Cascade Comprehensive

I think if a person has persistent pain from their gallbladder, or consistently recurrent pain, then it is medically appropriate to have a cholecystectomy. Usually this is associated with obvious stones and often an abnormal nuclear med gallbladder function test (HIDA) but not always – sometimes it is just a clinically apparent issue but the tests are equivocal or negative. So in those situations I would favor surgery. It would have to be recurrent- I would not get surgery with just one or two gallbladder attacks but not cholecystitis.

I don't really know if 2 of 3 signs is ok- I still think clinical judgment would play a role- so probably if 2 of 3 are present and the surgeon feels surgery is appropriate that is good enough.

Mark Maddox, MD, MVIPA

The decision that needs to be made is about coverage for symptomatic disease; is there a desire to cover biliary colic or not. The objective portion of the examination would be key and UM would be difficult given the subjective nature. I would not base indication on a specific number of “events”, in other words, either cover it or don't cover it. I don't know of any risks of biliary colic.

For cholecystitis, either 2/3 or 3/3 is reasonable.

HERC staff summary:

There has been a longstanding debate at the HSC/HERC regarding coverage of cholelithiasis with biliary colic or other pain related to gallstones. The evidence and expert guidelines all agree that complications from gallstones, including cholecystitis, pancreatitis, gallbladder obstruction, etc. should be treated with cholecystectomy; all also agree that asymptomatic gallstones should not be treated surgically. The major area of disagreement is biliary colic. Expert guidelines recommend cholecystectomy for biliary colic. Poor quality studies show a significant complication rate for painful but otherwise uncomplicated cholelithiasis that is not treated by cholecystectomy, with approximately 20% of patients developing significant complications including death within 2 years. Evidence shows that many patients with complications of gallstones initially had biliary colic; however, it is unclear how many patients with biliary colic will go on to have complications. Previous discussions of coverage of cholecystectomy for biliary colic determined that the risks of surgery outweighed the risks of complications with conservative (non-operative) treatment, particularly for first time presentations.

In a similar situation, the HSC/HERC has consistently determined that painful but otherwise uncomplicated inguinal hernias should not have surgical treatment covered. Painful but otherwise uncomplicated inguinal hernias are recommended for surgical treatment by expert guidelines, and have a reported complication rate (obstruction, gangrene) of 1-2% per year.

Additionally, there is confusion regarding when cholecystitis is present, with expert guidelines including criteria for “definite” and “probable” cholecystitis. Using the expert criteria for definite cholecystitis would exclude some patients with disease. Using probable criteria would allow treatment of painful gallstones depending on how imaging is interpreted. HERC staff recommend adoption of a new guideline clearly indicating the intent of the HERC for defining when cholecystitis is present.

HERC staff recommendations:

- 1) Housekeeping
 - a. Add cholecystectomy to line 199 ACUTE PANCREATITIS for pairing with gallstone pancreatitis (ICD10 K85.1)
 - i. 47562 (Laparoscopy, surgical; cholecystectomy)
 - ii. 47563 (Laparoscopy, surgical; cholecystectomy with cholangiography)
 - iii. 47564 (Laparoscopy, surgical; cholecystectomy with exploration of common duct)
 - iv. 47600-47620 (Cholecystectomy)
 - b. Remove 47562 (Laparoscopy, surgical; cholecystectomy) from line 311 PARALYTIC ILEUS
 - i. No appropriate diagnosis for pairing on this line
- 2) Do not include first episode of biliary colic as a condition present on the upper gallstone line
 - a. Consider including recurrent biliary colic on the upper line (see below)
- 3) Adopt the guideline shown below for lines 59 and 645
 - a. In #2, “or” correlates with suspected diagnosis (yellow highlight)
 - i. Alternative: “and” instead of “or” would correlate with a definite diagnosis of cholecystitis in the Tokyo 2013 guidelines
 - b. The wording in blue highlight would allow recurrent biliary colic to be included on the upper gallstone line
 - i. Alternative: specify that biliary colic (initial or recurrent) without other complications is included on line 645

GUIDELINE NOTE XXX, CHOLECYSTITIS

Lines 59, 645

Cholecystitis is defined as

- 1) The presence of right upper quadrant abdominal pain, mass, tenderness or a positive Murphy’s sign, AND
- 2) Evidence of inflammation (e.g. fever, elevated white blood cell count, elevated C reactive protein), OR
- 3) Ultrasound findings characteristic of acute cholecystitis or non-visualization of the gall bladder on oral cholecystogram or HIDA scan, or gallbladder ejection fraction of < 35%

Recurrent biliary colic (i.e. more than one episode of abdominal pain with gallstones seen on imaging) without evidence of cholecystitis or other complications is included on line 59.

ICD-10 K82.8 (Other specified diseases of gallbladder) is included on line 59 when the patient has

- 1) Porcelain gallbladder, or
- 2) Gallbladder dyskinesia with a gallbladder ejection fraction <35%.

Otherwise, K82.8 is included on line 645.

GN98 Clarification Regarding Meniscal Injuries

Question: Should GN98 SIGNIFICANT INJURIES TO LIGAMENTS AND TENDONS be modified to include injuries to the meniscus?

Question source: HERC staff; provider

Issue: Multiple joint injury ICD-10 codes are included on both or one of two covered lines (line 381 DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT or line 436 INTERNAL DERANGEMENT OF KNEE AND LIGAMENOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT) and on an uncovered line (line 611 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR); code placement is determined by GN98 SIGNIFICANT INJURIES TO LIGAMENTS AND TENDONS. Only significant injuries are intended for inclusion on line 381/436. Currently, GN98 only includes reference to injuries to tendons and ligaments. However, the ICD-10 codes for meniscal injury and derangement are also included on both covered and uncovered lines.

The current GN98 replaces the previous delineation of these lines, which was based on line titles limiting inclusion on the upper line to “grade 2 and 3” injuries. The Sports Medicine experts, as well as the orthopedic experts, felt that this grading system applied to only one type of injury on these lines (acromioclavicular joint sprain). They recommended a name change for these lines to better represent the HERC intent to have more severe injuries only included on the upper, covered, lines. They also recommended a new guideline to also clarify intent. The intent of the guideline note as written by the ICD-10 Sports Medicine/Orthopedic reviewers was to allow significant injuries to be covered on the upper line while non-significant injuries were not covered and included only on the lower line. Meniscal injuries were not considered in these discussions.

Injuries to menisci can occur with trauma, or with degenerative changes. Typical symptoms of torn or deranged menisci include knee pain, joint swelling, joint locking (the inability to extend the knee fully), or a sensation that the knee is going to give way. Conservative treatment of meniscal injuries include physical therapy, anti-inflammatories, and corticosteroid injections.

Evidence supports only conservative therapy for degenerative meniscal injuries. Traumatic meniscal injuries which also involve ligament injury are candidates for surgical repair.

Currently, GN98 limits all treatment of non-significant injuries to ligaments and tendons to the uncovered line 611. Some of these injuries might also benefit from PT, or other conservative therapy.

GN98 Clarification Regarding Meniscal Injuries

HERC staff recommendation:

- 1) Modify GN98 as shown below
 - a. Include meniscal injury (blue wording)
 - b. Meniscal injuries that result in interference with motion or which accompany significant ligament instability should have surgical correction
 - c. Consider whether non-significant injuries should have coverage of conservative therapy such as PT. Is yes, then the guideline will need to be further revised.

GUIDELINE NOTE 98, SIGNIFICANT INJURIES TO LIGAMENTS AND TENDONS AND MENISCI

Lines 381,436,611

Significant injuries to ligaments and/or tendons and/or menisci are those that result in clinically demonstrable joint instability or mechanical interference with motion. Significant injuries are covered on Line 381 or Line 436; non-significant injuries are included on Line 611.

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Tympanostomy Tubes and Adenoidectomy for Chronic Otitis Media with Hearing Loss

Questions:

- 1) Should adenoidectomy CPT codes be added to the hearing loss lines?
- 2) Should the chronic otitis media with effusion (COME) that results in hearing loss be paired with tympanostomy tube placement and adenoidectomy for children over age 5 with other special risk factors such as craniofacial anomalies or speech/language delay?
 - a. Should COME with hearing loss in normal children be prioritized to a higher line?
- 3) Should adenoidectomy be covered with the first tube placement procedure?

Question source: HERC staff, HSD staff, ENT providers

Issues:

- 1) Guideline Note 51 regarding coverage of treatments for chronic otitis media mentions adenoidectomy with second placement of tympanostomy tubes; however, the CPT codes for adenoidectomy do not appear on line 316 HEARING LOSS - AGE 5 OR UNDER which is one of the lines mentioned in the guideline. The appropriate codes do appear on line 479 CHRONIC OTITIS MEDIA; OPEN WOUND OF EAR DRUM, which is below the current funding line.
- 2) Providers and CCO medical directors are requesting clarification of HERC intent regarding coverage for PE tubes for children over age 5 with hearing loss and COM and other special risk factors. GN51 discusses coverage for tympanostomy tubes for hearing loss without specifying the age of the child. Line 316 HEARING LOSS - AGE 5 OR UNDER is mentioned in the GN, but line 450 HEARING LOSS - OVER AGE OF FIVE is not. Additionally, Line 450 does not have CPT codes for tympanostomy tube placement or for adenoidectomy. Review of the 2012-2013 discussion regarding this guideline and accompanying code/line changes does not find any discussion of limiting the benefit by age. The current guideline and lines appears to imply that the HERC intended that children older than age 5 with chronic otitis media and hearing loss with other risk factors should not be covered for tympanostomy tube placement and/or adenoidectomy.
 - a. ENT providers are requesting that children with COME and prolonged hearing loss without other special risk factors be considered for coverage for tympanostomy tubes and adenoidectomy. The HERC has previously addressed this question on several occasions, and concluded that only children with language delay and hearing loss, craniofacial anomalies, or other high risk factors with COME were intended for inclusion on the covered line (316). Children without high risk factors were included on line 479, which is unfunded. The lower placement was due to the fact that tympanostomy tubes provide only a short-term benefit, and have no proven long term effect on language or speech. The lack of funding for line 479 is due to the movement of the funding line by the Legislature a few years ago; previously this line was among the last funded lines on the Prioritized List.
- 3) On staff review of this issue, new literature was identified that provided evidence of benefit of adenoidectomy with the first PE tube placement. Currently, adenoidectomy is an option with the second PE tube placement procedure.

HERC history

Chronic otitis media in children was reviewed in a 2012 coverage guidance which was reaffirmed in 2014. A rescan was recently completed for this coverage guidance, which found:

In general, the literature supports the 2014 findings that interventions for chronic otitis media result in short-term improvements in hearing and resolution of the effusion, but that long-term differences are negligible or non-existent. Since 2014, there is new evidence that adenoidectomy, with or without other interventions, may also improve short-term outcomes particularly in children over the age of 4 years (Boonacker et al., 2014; Mikals & Brigger, 2014; Rosenfeld et al., 2016; Wallace et al., 2014). There is also a recent Cochrane review that found that antibiotics were effective for resolution of effusion at 2-3 months, but with higher rates of diarrhea, vomiting, and skin rash (Venekamp et al., 2016).

Based on this rescan, EGBS did not feel that a review of the 2014 coverage guidance was required.

BAHA hearing aids are included on line 450 HEARING LOSS OVER THE AGE OF 5 for children with severe to profound hearing loss in one ear. The vast majority of children with COME would not have severe or profound hearing loss (i.e. deaf) in one ear with normal hearing in the other. Therefore, BAHA would not be a normal treatment for COME.

From Dr. Kristi Seidel, Family Practice physician in Eugene and Medical Director at Trillium Community Health Plan

The issue of concern is the lack of coverage for PE tubes and adenoidectomy for children over the age of 5 with conductive hearing loss due to chronic otitis media with effusion. The ENT providers state that current standard of care is to follow the child with watchful waiting for 6 months and if there is no improvement or if the hearing loss worsens, PE tubes should be placed. If the tubes become extruded (common with growth) and the condition has not resolved, PE tubes are typically placed a second time and at that time it is standard of care, in patients who are at least 3 years of age, to remove the adenoids when placing the second set of PE tubes.

Conductive hearing loss in a child > 5 years old is found on line 450, funded, however, it does not include PE tubes or adenoidectomy in the covered procedures for this line. It does include implantation of a BAHA device (69717, 69718) if the condition is unilateral.

Several ENTs have voiced concern that they can only treat unilateral conductive hearing loss (it is often bilateral in these children) and the covered treatment is limited to the very invasive, expensive treatment of a BAHA (Bone Anchored Hearing Aid) device. They feel implantation of a BAHA is too aggressive for this diagnosis, but they feel this is the only option OHP will allow for these kids. If the member has chronic OM with effusion and their hearing is normal or minimally affected, they are very comfortable continuing to follow conservatively. But when the hearing loss is >25-30dB in both ears, for over 6-12 months they really would like to provide the PE tubes for the members. (Our claims review shows we spend approximately \$1100 for a set of tubes, and about \$11,700 for a BAHA.)

Current List guidelines

GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

Lines 316,479

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) are not indicated for children with chronic otitis media with effusion (OME) (without another appropriate diagnosis).

Patients with specific higher risk conditions (including craniofacial anomalies, Down's syndrome, and cleft palate, or documented speech and language delay) along with hearing loss and chronic otitis media with effusion are intended to be included on Line 316. Otherwise hearing loss associated with chronic otitis media with effusion (without those specific higher risk conditions) is only included on Line 479.

For coverage to be considered on either Line 316 or Line 479, there should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented hearing loss is greater than or equal to 25dB in the better hearing ear, tympanostomy surgery may be indicated, given short-but not long-term improvement in hearing. Formal audiometry is indicated for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing upon diagnosis. Children with chronic OME who are not at risk for language delay (such as those with hearing loss <25dB in the better hearing ear) or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy is not indicated at the time of first pressure equalization tube insertion. It may be indicated in children over 3 years who are having their second set of tubes.

Removal of retained tympanostomy tubes requiring anesthesia (CPT code 69424) or as an office visit, is included on Line 428 as a complication, pairing with ICD-10-CM H74.8.

The development of this guideline note was informed by a HERC coverage guidance. See <http://www.oregon.gov/oha/herc/Pages/blog-management-chronic-otitis.aspx>

GUIDELINE NOTE 103, BONE ANCHORED HEARING AIDS

Lines 316,450

Bone anchored hearing aids (BAHA, CPT 69714, 69715) are included on these lines when the following criteria are met:

- A) The patient is aged 5-20 years for implanted bone anchored hearing aids; headband mounted BAHA devices may be used for children under age 5
- B) Treatment is for unilateral severe to profound hearing loss when the contralateral ear has normal hearing with or without a hearing aid
- C) Traditional air amplification hearing aids and contralateral routing of signal (CROS) hearing aid systems are not indicated or have been tried and are found to be not effective
- D) Implantation is unilateral.

Use of BAHA for treatment of tinnitus is not covered

Evidence

- 1) **Washington HTA 2015**, [systematic review of tympanostomy tubes](#) Study not included in packet due to length.
 - a. Studies on improvement in hearing included children up through age 7
 - b. Studies on speech and language development included children up to age 4.7 yrs
 - c. Short term improvement in hearing; no long term difference with watchful waiting. No difference in behavioral scores or educational outcomes/scores with tympanostomy tubes vs watchful waiting.
- 2) **Boonacker 2014**, (Report not included in packet due to length, see online version: https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0083658/pdf/PubMedHealth_PMH0083658.pdf) systematic review of adenoidectomy with or without tympanostomy tubes (“grommets”) for COME
 - a. N= 10 studies, including 1761 children
 - i. 8 at low risk of bias, 2 at moderate risk
 - b. Indication for surgery included recurrent acute otitis media or COME
 - c. “Failure” of treatment defined as one or more of the following:
 - i. four or more AOM episodes (including episodes of otorrhea) per year
 - ii. presence of effusion for $\geq 50\%$ of the time (i.e. effusion for > 6 months)
 - iii. need for additional surgery
 - iv. hearing improved by < 10 dB.
 - d. Children (N=343) randomized to non-surgical treatment: 193 (56%) had failure to improve at 12 months
 - i. The absolute risk of failing to improve for children with an indication of persistent OME was 89%
 - e. The proportion of children who failed at 12 months in the adenoidectomy group (adenoidectomy with or without grommets) was 32% whereas the proportion of children who failed at 12 months in the no adenoidectomy (non-surgical or grommets alone) group was 45%. The unadjusted for failure at 12 months was -13% [95% confidence interval (CI) -17% to -8%], resulting in a number needed to treat (NNT) of eight children to prevent one failure. The adjusted RR was 0.76 (95% CI 0.69 to 0.85), which was similar to the unadjusted RR (0.72, 95% CI 0.63 to 0.81). For all secondary outcomes, with the exception of presence of effusion for $\geq 50\%$ of the time in the first 12 months, results for children in the adenoidectomy group were also statistically significantly better than results for those in the no adenoidectomy group.
 - f. The effects in the secondary comparisons also showed that children who have had their adenoid removed have a greater chance of clinical improvement. The size of that effect is, in general, small but persists for at least 2 years after surgery. Two subgroups of children are most likely to benefit from adenoidectomy. These are (1) children with recurrent AOM aged < 2 years and (2) children aged ≥ 4 years with persistent OME. The proportion of children aged < 2 years with recurrent AOM who failed at 12 months was 16% (44/281) in the adenoidectomy group and 27% (120/438) in the group who did not have adenoidectomy (RD 12%, 95% CI 6% to 18%; NNT = 8; adjusted RR 0.63, 95% CI 0.47 to 0.85). In contrast, in children aged ≥ 2 years with recurrent AOM, no benefit of adenoidectomy was seen; 18% (8/44) of the children in the adenoidectomy group failed at 12 months and 3% (1/40) of the group who did not have adenoidectomy failed (RD 16%, 95% CI 3% to 28%, in favour of no adenoidectomy; adjusted RR 4.96, 95% CI 0.69 to 35.5). The proportion of children aged ≥ 4 years with persistent OME who failed at 12

months was 51% (163/322) in the adenoidectomy group and 70% (289/415) in the group who did not have adenoidectomy (RD 19%, 95% CI 12% to 26%; NNT = 6; adjusted RR 0.77, 95% CI 0.68 to 0.86). In contrast, in children aged < 4 years with persistent OME, no significant benefit of adenoidectomy was seen; 23% (30/128) of the children in the adenoidectomy group failed at 12 months and 30% (33/111) of the group who did not have adenoidectomy failed (RD 7%, 95% CI -5% to 18%; adjusted RR 0.98, 95% CI 0.69 to 1.38).

- g. Conclusion: Children with OM who have their adenoid removed have a greater chance of clinical improvement: eight children need to receive adenoidectomy to prevent one failure. Adenoidectomy is most beneficial in children aged ≥ 4 years with persistent OME (six children needing adenoidectomy to prevent one failure). A smaller beneficial effect was found in children with recurrent AOM aged < 2 years (nine children needing adenoidectomy to prevent one failure). No beneficial effect was seen in children aged < 4 years with persistent OME or in those aged ≥ 2 years with recurrent AOM.
- 3) **Merkels 2014 (Document not included in packet due to length; see online version: <http://jamanetwork.com/journals/jamaotolaryngology/fullarticle/1782135>)**, systematic review and meta-analysis of adenoidectomy as adjuvant treatment with tympanostomy tubes (TT)
- a. N=15 studies examining the risk of repeat TT tube placement (r-TT)
 - b. Ten studies (n = 71 353) reported that primary adenoidectomy + TT decreased the risk of r-TT or risk of recurrent acute otitis media (RAOM), OME, or otorrhea compared with TT alone.
 - c. Four studies (n = 538) reported no difference between Ad + TT groups compared with TT-only groups in the prevention of r-TT or of RAOM, OME, or otorrhea.
 - d. limited meta-analysis and pooling of data revealed that the estimated rate of r-TT for children undergoing primary adenoidectomy was 17.2%(95%CI, 12.2%-22.2%) vs 31.8%(95%CI, 23.9%-39.8%) for children undergoing primary TT only. When stratified by age younger than 4 years, the protective effects of adenoidectomy were diminished.
 - e. **CONCLUSIONS** The current evidence suggests that primary adenoidectomy + TT may be superior to TT only in decreasing the risk of r-TT and the risk of RAOM, OME, or otorrhea.
- 4) **Wallace 2014 (Document not included in packet due to length; see online version: <http://pediatrics.aappublications.org/content/pediatrics/early/2014/01/01/peds.2013-3228.full.pdf>)**, systematic review of surgical treatments for OME
- a. N=41 studies
 - b. In comparison with watchful waiting or myringotomy (or both), tubes decreased time with OME and improved hearing; no specific tube type was superior.
 - c. Adenoidectomy alone, as an adjunct to myringotomy, or combined with tubes, reduced OME and improved hearing in comparison with either myringotomy or watchful waiting.
 - i. No comparison was done of tubes with adenoidectomy vs tubes alone
 - d. Tubes and watchful waiting did not differ in language, cognitive, or academic outcomes.
 - e. Otorrhea and tympanosclerosis were more common in ears with tubes. Adenoidectomy increased the risk of postsurgical hemorrhage.
 - f. **CONCLUSIONS:** Tubes and adenoidectomy reduce time with OME and improve hearing in the short-term. Both treatments have associated harms.

Expert guidelines

- 1) **Rosenfeld 2016, (Document not included in packet due to length; see online version: <http://journals.sagepub.com/doi/pdf/10.1177/0194599815624407>)** AAOM practice guideline for OME
 - a) Strong recommendation against antibiotics for OME
 - b) New recommendation: Clinicians should recommend tympanostomy tubes when surgery is performed for OME in a *child less than 4 years old*; adenoidectomy should not be performed unless a distinct indication (eg, nasal obstruction, chronic adenoiditis) exists other than OME. (Grade B, moderate strength of evidence)
 - c) Recommendation: Clinicians should recommend tympanostomy tubes, adenoidectomy, or both when surgery is performed for OME in a *child 4 years old or older*. This should be shared decision making.
 - d) Adenoidectomy may be contraindicated in children with cleft palate or syndromes associated with a risk of velopharyngeal insufficiency

HERC staff summary:

The benefit of tympanostomy tubes +/- adenoidectomy for COME remains limited, with short-term benefits for hearing but no long-term benefits for hearing, speech or language development, or school/behavioral outcomes. There is a growing body of evidence that indicates that adenoidectomy may be beneficial with the first set of PE tube placement; however, expert guidelines do not recommend adenoidectomy at all for children under age 4, and shared decision making for children aged 4 and older.

HERC staff recommendations:

- 1) Do not expand coverage to children of any age with COME with hearing loss without other high risk conditions
 - a. Limited evidence of any long-term benefit
 - b. Significant fiscal impact
- 2) Add adenoidectomy CPT codes to lines 316 HEARING LOSS - AGE 5 OR UNDER
 - a. CPT 42830 Adenoidectomy, primary; younger than age 12
 - b. CPT 42835 Adenoidectomy, secondary; younger than age 12
 - c. Utilization is covered by GN51 and would be limited to children with special risk factors aged 4 and older for second set of PE tubes only
 - d. The CPT codes for adenoidectomy for children age 12 and older are not appropriate as the line is specific for children aged 5 and under
- 3) Add treatment for chronic otitis media resulting in hearing loss for children with high risk conditions older than age 5
 - a. Add tympanostomy tube placement codes to line 450
 - i. CPT 69433 Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia
 - ii. CPT 69436 Tympanostomy (requiring insertion of ventilating tube), general anesthesia
 - b. Add adenoidectomy codes to line 450 for young children
 - i. CPT 42830 Adenoidectomy, primary; younger than age 12
 - ii. CPT 42835 Adenoidectomy, secondary; younger than age 12
 - c. Consider adding adenoidectomy codes for older children
 - i. CPT 42831 Adenoidectomy, primary; age 12 or over
 - ii. CPT 42836 Adenoidectomy, secondary; age 12 or over
 - iii. Children aged 12 and over should no longer be at risk for speech/language delay
 - d. Add line 450 HEARING LOSS - OVER AGE OF FIVE to GN51 CHRONIC OTITIS MEDIA WITH EFFUSION
 - i. See edits below

GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

Lines 316, [450](#), 479

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) are not indicated for children with chronic otitis media with effusion (OME) (without another appropriate diagnosis).

Patients with specific higher risk conditions (including craniofacial anomalies, Down's syndrome, and cleft palate, or documented speech and language delay) along with hearing loss and chronic otitis media with effusion are intended to be included on Line 316 [or line 450](#). Otherwise hearing loss associated with chronic otitis media with effusion (without those specific higher risk conditions) is only included on Line 479.

For coverage to be considered on either Line 316, [Line 450](#) or Line 479, there should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented hearing loss is greater than or equal to 25dB in the better hearing ear, tympanostomy surgery may be indicated, given short- but not long- term improvement in hearing. Formal audiometry is indicated for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing upon diagnosis. Children with chronic OME who are

not at risk for language delay (such as those with hearing loss <25dB in the better hearing ear) or developmental delay (should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected).

Adenoidectomy is not indicated at the time of first pressure equalization tube insertion. It may be indicated in children over 3 years who are having their second set of tubes.

VbBS Issues Summary Docs 1-12-17

Preventive services USPSTF edits

Question: Should Guideline Note 106 for preventive services be modified for clarity?

Question source: HERC Staff

Issue: In October 2016 the guideline note on preventive services was edited to include language about federal law. It is possible that federal laws may change about what is required by insurers (i.e. through repeal of the ACA). For clarity, this guideline can be changed to avoid confusion about HERC intent about coverage of preventive services, should federal law change. This guideline will need to be updated in conjunction with each January 1st list to include the additional years' worth of recommendation that will be going into effect (those recommendations approved during the calendar year two years prior).

Also, the USPSTF "D" recommendations now fall on an unfunded line. However, even if there were funding to expand coverage to this area of the Prioritized List, these are still not recommended services. Therefore the staff recommendation is to remove them from the List altogether (including an unfunded line) to signify the intent for noncoverage of services that are not recommended.

Recommendations:

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Line 3

Included on this line are the following preventive services: ~~as required by federal law:~~

1. US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2016:
<http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/>
 - a. USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List
2. American Academy of Pediatrics (AAP) Bright Futures Guidelines:
<http://brightfutures.aap.org>. Periodicity schedule available at
http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity%20Schedule_FINAL.pdf.
3. Health Resources and Services Administration (HRSA) Women's Preventive Services - Required Health Plan Coverage Guidelines:
As retrieved from <http://www.hrsa.gov/womensguidelines/> on 1/1/2017.
4. Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP):
<http://www.cdc.gov/vaccines/schedules/hcp/index.html>

~~USPSTF "D" recommendations are included on line 625, PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS.~~

Question: Should current marijuana use be a contraindication for bariatric surgery?

Question source: VBBS

Issue: The bariatric surgery guideline was recently updated at the October, 2016 VBBS/HERC meetings. The major topic of that discussion was regarding tobacco cessation. Marijuana use had previously been an exclusion to surgery—patients must be “abstinent from illicit drugs.” However, marijuana is now legal in Oregon for both medical and recreational use. The Obesity Task Force had specifically examined the question about use of marijuana prior to bariatric procedures.

The summary of the VBBS discussion is below:

Livingston discussed one of the recommendations by the Obesity Task Force with regard to a 6-month absence of abuse or dependence of marijuana needed prior to the procedure. Members raised that despite the legality of marijuana, there are clear clinical implications of increasing appetite. Marijuana was confirmed to be used to treat cachexia (wasting syndrome). Dr. Bruce Wolfe, the appointed expert on this topic, introduced himself. Wolfe stated the evidence is unknown whether the weight loss goals of bariatric surgery may be compromised by the use of marijuana. He said surgeons do not want to perform surgery on people who have an active addiction. Twenty percent of bariatric surgery candidates are active smokers and may quit for surgery, but by 2-3 years later many are smoking again. Smoking marijuana may affect postoperative complications.

Based on the discussion above, a clause was added to make abuse or dependence of marijuana in the 6 month pre-operative period a contraindication to surgery. However, there was no mention about casual marijuana use. The relevant changes to the guideline is excerpted below.

- D) 1) 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 surgery to confirm abstinence from illicit drugs. Tobacco abstinence to be confirmed in active smokers by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.

VBBS staff was asked to review the evidence of the impact of marijuana use on bariatric surgery outcomes, including post-operative complications and lack of effectiveness for weight loss. The major concern of VBBS was that marijuana was useful for weight gain for certain conditions (i.e. AIDS, cachexia). Staff undertook a review of the evidence for the effectiveness of marijuana on weight gain for medication conditions such as cachexia, as well as evidence of harms of marijuana use related to bariatric surgery.

Evidence for marijuana use for treatment of cachexia

- 1) **Lutge 2013**, cannabis in HIV/AIDS (document found here: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005175.pub3/epdf>)
 - a. N=7 studies, all RCTs
 - i. Considerable issue with blinding given the psychoactive effects
 - b. The evidence for substantial effects on morbidity and mortality is currently limited. Data from only one relatively small study (n=139, of which only 88 were evaluable), conducted in the period before access to highly-active antiretroviral therapy (HAART), showed that patients administered dronabinol were twice as likely to gain 2kg or more in body weight (RR 2.09), but the confidence interval for this measure (95% CI 0.72 - 6.06) included unity. The mean weight gain in the dronabinol group was only 0.1kg, compared with a loss of 0.4kg in the placebo group.
 - c. **Authors' conclusions:** Despite dronabinol being registered by at least some medicines regulatory authorities for the treatment of AIDS-associated anorexia, and some jurisdictions making allowances for the "medical" use of marijuana by patients with HIV/AIDS, evidence for the efficacy and safety of cannabis and cannabinoids in this setting is lacking. The studies to date have been of short duration, in small numbers of patients, and have focused on short-term measures of efficacy. Long-term data, showing a sustained effect on AIDS related morbidity and mortality and safety in patients on effective antiretroviral therapy, has yet to be presented.
- 2) **Belendiuk 2015 (Not included in packet due to length; [view online](#))**: , review of effects of marijuana on commonly approved medical indications
 - a. Marijuana use for cachexia from HIV/AIDS or cancer:
 - i. ...studies demonstrate that marijuana has positive effects on cachexia resulting from a medical condition, but are largely limited by small sample sizes. Additionally, studies comparing THC to FDA-approved medication (i.e., megestrol) indicate that THC is less effective in promoting appetite and weight gain.
 - ii. In sum, there is moderate support for the use of cannabinoids for cachexia/wasting. Additional studies with larger sample sizes that examine the efficacy of marijuana compared to nutritional support/calorie augmentation in the treatment of cachexia are indicated.
- 3) **Strasser 2006, (Not included in packet due to length; [view online](#))** RCT for cannabis vs placebo for cancer related anorexia-cachexia
 - a. N=243 (95 cannabis extract, 100 THC, 48 control)
 - b. Intent-to-treat analysis showed no significant differences between the three arms for appetite, QOL, or cannabinoid-related toxicity. Increased appetite was reported by 73%, 58%, and 69% of patients receiving CE, THC, or PL, respectively. An independent data review board recommended termination of recruitment because of insufficient differences between study arms.
 - c. Conclusion: No differences in patients' appetite or QOL were found either between CE, THC, and PL or between CE and THC at the dosages investigated.

Evidence for marijuana on bariatric surgery:

- 1) **Rummel 2014**, review of marijuana use and bariatric surgery
 - a. Reviewed the known risk of complications from alcohol and tobacco use perioperatively
 - b. No empirical research to date has examined the effects of cannabis use after weight loss surgery.

- c. Effects of cannabis on surgical complications:
 - i. There is no isolated data regarding surgical outcomes for historical cannabis abusers.
 - ii. In a few studies, patients who successfully completed substance abuse treatment actually had higher post-operative weight loss than patients with no substance abuse diagnoses.
 - iii. There may be a hypothesized potential for cannabis use to exacerbate post-surgical complications; however, this remains undocumented in the medical literature.
 - d. Overall impact on health:
 - i. It is clear that long-term, regular marijuana use has many negative effects. However, there is little research to support negative effects of short-term or irregular use.
 - e. Effect of cannabis on weight:
 - i. Interestingly, in one sample of female weight management patients, lower rates of past year marijuana use were actually associated with higher BMI.
 - ii. Current research has actually demonstrated a lower prevalence of obesity in cannabis users as compared to non-users.
 - iii. There is a lack of empirical evidence to suggest a link between cannabis use and chronic overeating.
 - f. Recommendations:
 - i. For patients who do report irregular recreational marijuana use, or more recent problematic use, the employment of informed consent documents may be helpful
 - ii. For patients who have a history of non-adherence, the use of a behavioral contract may be helpful. A behavioral contract “spells out in clear terms the behavioral expectations of the team, and patients sign their agreement to those recommendations.”
 - iii. Patients assessed to be at increased risk for substance abuse or dependence may be required to attend a planned treatment intervention
- 2) **Vidot 2016**, (Not included in packet; [view online](#)) post operative marijuana use in bariatric surgery
- a. N=50, retrospective cohort study
 - b. A loss of controlled food intake was associated with current ($P = .02$) and increased post-WLS use ($P = .01$). Increased use and/or regular marijuana use predicted higher scores on eating disorder subscales compared with respective counterparts ($P < .05$). Current use did not significantly predict higher scores on the Yale Food Addiction Scale.
 - c. Unclear from presented data if there was any difference in post-operative BMI change among marijuana users compared to non-users
 - i. Rummell’s comments on the Vidot study: In terms of weight loss outcomes, a brief examination of patient BMI in Vidot et. al.’s sample reveals that patients who reported marijuana use within the 30 days to 1 year had the highest postsurgical BMI (39.6 and 37.0, respectively). Patients who had never used marijuana had an average BMI similar to that of the overall sample (35.3). Interestingly, patients who reported *increased* marijuana use since surgery had the *lowest* average postoperative BMI (30.4), also with the least amount of variation. This is reminiscent of previous research demonstrating lower rates of obesity in cannabis users compared with nonusers.

- d. Conclusions: Findings indicated marijuana use in post-WLS patients despite recommendations against use. A subgroup of WLS patients may be at risk for disordered eating post-WLS, particularly those who used marijuana before surgery, and should be closely monitored for several years post-WLS.

HERC staff summary:

The efficacy of marijuana for treatment of anorexia/cachexia related to cancer and HIV/AIDS appears to be mixed, and any positive effect appears to be small.

The following evidence was found regarding marijuana use and bariatric surgery outcomes:

- post-operative infections: little to no evidence that this is a concern (Vidot et al, 2016)
- post-operative weight gain: unclear evidence (Lutge et al, 2013) (Vidot et al 2014)
- post-operative loss of food control: weak evidence that marijuana users have more loss of food control after bariatric surgery than non-marijuana users (Vidot et al, 2016)
- post-operative complications: rare case studies demonstrating ACS with marijuana use (Casier et al, 2014), weak evidence to risk of infection, immunosuppression (Vidot et al, 2014), moderate evidence for risk of hyperemesis and chronic bronchitis (Vidot et al, 2014)
- There is an unclear relationship between marijuana use and BMI, and the data currently indicates that marijuana users have a lower BMI than non-marijuana users.

Based on the evidence above, there is no clear, compelling, consistent evidence that marijuana use would jeopardize the success of bariatric surgery or result in significant post-operative weight gain.

HERC staff recommendation:

- 1) Make no changes to GN8 BARIATRIC SURGERY
 - a. Continue to exclude marijuana abuse or dependence prior to bariatric surgery but allow casual use until more evidence is published about the effects of marijuana use on the outcomes of bariatric surgery
 - b. Consistent with major expert recommendations

GUIDELINE NOTE 8, BARIATRIC SURGERY

Line-325

Bariatric/metabolic surgery (limited to Roux-en-Y gastric bypass, and sleeve gastrectomy) is included on Line 325 when the following criteria are met:

- A) Age ≥ 18
- B) The patient has obesity with a:
 - 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
- C) 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.

- 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 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 illicit drugs. Tobacco abstinence to be confirmed in active smokers by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.
 - c) No mental or behavioral disorder that may interfere with postoperative outcomes¹.
 - d) Patient with 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 program²)
 - a) Patient found to be an appropriate candidate for surgery at initial evaluation and throughout period leading to surgery.
 - b) Received counseling by a credentialed expert on the team regarding the risks and benefits of the procedure³ 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 clinically supervised weight reduction program (including intensive nutrition and physical activity counseling as defined by the USPSTF).
 - 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 accreditation (as a comprehensive center or low acuity center) by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP).

Section 4.0

Coverage Guidances

Coverage Guidance Rescan 2016

Question: Coverage Guidance Rescan 2016

Question source: HERC Staff

Issue: Recommendations from the Routine HERC Coverage Guidance Topic Monitoring (rescan) Process. This will be the last time this sort of rescan occurs as the new administrative rules will place all topics on passive monitoring status in the future.

Recommendations: Update coverage guidance statuses as shown in the table below:

Topic	Rescan conducted?	Recommendation
Imaging for Low Back Pain	Yes	Reaffirm
Low Back Pain: NonPharm-Noninvasive	Yes	Reaffirm
Nonpharmacologic Interventions for Treatment-Resistant Depression	Yes	Reaffirm
Chronic Otitis Media with Effusion in Children	Yes	Passive monitoring (VbBS update)
Low Back Pain: Pharmacologic and Herbal	No	Passive monitoring
Planned Cesarean Section	No	Passive monitoring
Routine Ultrasound in Pregnancy	No	Passive monitoring
Neuroimaging for Dementia	No	Passive monitoring
Low Back Pain: Minimally Invasive and Non-Corticosteroid Percutaneous	No	Update in progress
Prenatal Genetic Testing	No	Retire (not practical to rescan with new process)
Indications for Hyperbaric Oxygen Therapy for Chronic Wounds and Burns	Yes	Reaffirm
Artificial Disk Replacement	Yes	Reaffirm
Hip Resurfacing	Yes	Reaffirm
Lumbar Discography	Yes	Reaffirm
Viscosupplementation for Osteoarthritis of the Knee	Yes	Reaffirm
Osteoporosis Screening by Dual-Energy X-ray Absorptiometry (DXA)	Yes	Reaffirm
Osteoporosis Monitoring by Dual-Energy X-ray Absorptiometry (DXA)	Yes	Reaffirm
Hip Procedures for Femoroacetabular Impingement Syndrome	Yes	Reaffirm
Treatment of Obstructive Sleep Apnea in Adults	Yes	Reaffirm
Knee Arthroscopy in Patients with Osteoarthritis	No	Passive monitoring
Upper Endoscopy for Gastroesophageal Reflux Disease (GERD)	No	Passive monitoring

Imaging for Low Back Pain – 2016 Rescanning Summary

Subcommittee

Evidence-based Guidelines Subcommittee (HERC Approved August 2012)

Coverage Recommendation (Box Language)

In patients with non-specific low back pain and an absence of “red flag” conditions:

- 1) Imaging (e.g., x-ray, CT, or MRI) should not be covered, and
- 2) Thermography, surface electromyography should not be covered.

If patients have persistent (> 1 month) low back pain and signs or symptoms of radiculopathy or spinal stenosis, appropriate imaging should be covered (MRI preferred, CT second choice) **only if** the patient is a potential candidate for surgery or epidural steroid injection (for suspected radiculopathy).

If patients have severe or progressive neurologic deficits, or clinicians suspect a serious underlying condition (e.g., cancer or infection) prompt workup with MRI (first choice) or CT should be covered.

Scope Statement

Population description	Adults with acute low back pain or acute exacerbations of chronic low back pain <i>Population scoping notes: None</i>
Intervention(s)	MRI, CT, plain x-rays, myelography, thermography <i>Intervention exclusions: None</i>
Comparator(s)	Usual care without imaging, other listed interventions
Outcome(s) (up to five)	Critical: Short-term function, long-term function, long-term risk of undergoing back surgery Important: Quality of life, adverse events (including incidental findings) <i>Considered but not selected for GRADE Table: Pain, reassurance</i>
Key questions	1. What is the comparative effectiveness of imaging for patients with acute low back pain or acute exacerbation of chronic low back pain? 2. Does the comparative effectiveness of imaging for patients with acute low back pain or acute exacerbation of chronic low back pain vary by: a. Age b. Co-morbid conditions c. Known structural abnormalities

	d. Duration of symptoms e. Response to prior treatments f. Presence of red-flag features g. Presence of radiculopathic pain h. Presence of abnormal neurologic signs or symptoms i. Candidacy for invasive interventions (e.g., surgery or percutaneous procedures) 3. What are the harms of imaging for patients with acute low back pain or acute exacerbation of chronic low back pain?
Contextual questions	1. Does the use of imaging in patients with low back pain affect the initial treatment strategy?

Newly Identified Evidence

	Suggests need to update CG?
American College of Radiology (2015)	No
American College of Radiology (2016)	No
Brinjikji et al. (2015)	No
Dagenais, Galloway, and Roffey (2014)	No
de Schepper et al. (2013)	No
Hayes (2013)	No
Hayes (2014)	No
Karel, Verkerk, Endenburg, Metselaar, and Verhagen (2015)	No
Mandl et al. (2015)	No
New Zealand National Health Committee (2015)	No
Raastad, Reiman, Coeytaux, Ledbetter, and Goode (2015)	No
Steffens et al. (2016)	No
Suri, Fry, and Gellhorn (2015)	No
Tawa, Rhoda, and Diener (2016)	No
van Rijn et al. (2012)	No
Wassenaar et al. (2012)	No
Webster, Bauer, Choi, Cifuentes, and Pransky (2013)	No
Williams et al. (2013)	No
Zhang et al. (2015)	No

Discussion

Imaging findings of lumbar spinal degenerative changes are common in asymptomatic individuals, increase with age, and correlate poorly with pain or function. Reviews continue to raise questions about the utility of routine imaging for low back pain (Karel et al., 2015) or even to guide specific treatments (Steffens et al., 2016; Tawa et al., 2016). While various sources disagree as to the appropriate timing of imaging for patients with persistent back pain in the absence of red flags, most recommend imaging at 1 to 12 months after the onset of symptoms. The presence of red flag features or diagnostic suspicion for back pain due to axial spondyloarthropathies remain indications for imaging. Overall, there is little new information from reviews or guidelines that suggest the need to update the current coverage guidance.

References

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Low Back Pain: Non-Pharmacologic Non-Invasive Interventions– 2016 Rescanning Summary

Subcommittee

Evidence-based Guidelines Subcommittee (HERC Approved June 2012, Reaffirmed November 2014)

Coverage Recommendation (Box Language)

For pain $\leq$ 4 weeks, self-care is recommended, and for those who do not improve with self-care, spinal manipulation is recommended for coverage.

For pain $>$ 4 weeks duration, the following treatments are recommended for coverage:

- Acupuncture
- Cognitive-behavioral therapy
- Exercise therapy
- Intensive interdisciplinary rehabilitation
- Massage therapy
- Progressive relaxation
- Spinal manipulation
- Yoga (viniyoga)

The following are not recommended for coverage for low back pain:

- Continuous or intermittent traction
- Transcutaneous electrical nerve stimulation

Scope Statement

Population description	Adults with acute, subacute, or chronic low back pain with or without radiculopathy <i>Population scoping notes: None</i>
Intervention(s)	Physical therapy, exercise therapy, home exercise programs, intensive interdisciplinary rehabilitation, massage therapy, progressive relaxation, yoga, cognitive-behavioral therapy, other behavioral health interventions, acupuncture (with or without electrical stimulation), spinal manipulation, continuous or intermittent traction, transcutaneous electrical nerve stimulation, interdisciplinary pain treatment programs, advice to remain active, combinations of the above <i>Intervention exclusions: None</i>
Comparator(s)	Other interventions for low back pain (including others listed above, alone or in combination), no treatment

Outcome(s) (up to five)	Critical: Short-term function, long-term function, long-term risk of undergoing surgery Important: Adverse events, change in utilization of comparators <i>Considered but not selected for GRADE Table: Short-term pain, long-term pain</i>
Key questions	1. What is the comparative effectiveness of non-pharmacological/non-invasive interventions for low back pain? 2. Does the comparative effectiveness of the interventions vary by: a. Duration of back pain b. Etiology of back or radicular pain (e.g., stenosis, disc herniation) c. Presence or absence of neurologic deficit d. Intensity and frequency of the intervention e. Previous back surgery f. Response to any prior intervention g. Risk level for poor functional prognosis h. Comorbidities (physical or behavioral) 3. What are the harms of non-pharmacological/non-invasive interventions for low back pain? 4. Which therapies or combinations of therapies are most cost-effective?
Contextual questions	1. Does the use of non-pharmacological/non-invasive interventions affect the subsequent use of health care resources?

Newly Identified Evidence

	Suggests need to update CG?
Ainpradub, Sitthipornvorakul, Janwantanakul, and van der Beek (2016)	No
Andronis et al. (2016)	No
Bervoets, Luijsterburg, Alessie, Buijs, and Verhagen (2015)	No
Blanchette et al. (2016)	No
Canadian Agency for Drugs and Technologies in Health (2014)	No
Chang, Holt, Sklar, and Groessl (2016)	No
Chen and Wang (2014)	No
Chou et al. (2016)	Possibly
Chuter, Spink, Searle, and Ho (2014)	No
Daffada, Walsh, McCabe, and Palmer (2015)	No

Dailey et al. (2014)	Possibly
Franke, Franke, and Fryer (2014)	No
Franke, Fryer, Ostelo, and Kamper (2015)	No
Furlan, Giraldo, Baskwill, Irvin, and Imamura (2015)	Possibly
Garg, Garg, Turin, and Chowdhury (2016)	No
Glazov, Yelland, and Emery (2016)	No
Gomes-Neto et al. (2016)	No
Gordon and Bloxham (2016)	No
Hall et al. (2016)	No
Hidalgo, Detrembleur, Hall, Mahaudens, and Nielens (2014)	No
Holden, Davidson, and O'Halloran (2014)	No
Huang et al. (2015)	No
Jauregui et al. (2016)	No
Kalin, Rausch-Osthoff, and Bauer (2016)	No
Kamper et al. (2015)	Possibly
Kuss, Becker, Quint, and Leonhardt (2015)	No
Lawford, Walters, and Ferrar (2016)	Possibly
Lee et al. (2014)	No
Lopez-de-Uralde-Villanueva et al. (2016)	No
Macedo et al. (2016)	No
McCaskey, Schuster-Amft, Wirth, Suica, and de Bruin (2014)	No
Meng and Yue (2015)	No
Menke (2014)	No
Merepeza (2014)	No
Nelson (2016)	No
O'Connor et al. (2015)	Possibly
O'Keeffe et al. (2016)	No
Oltean et al. (2014)	No
Parreira Pdo, Costa Lda, Hespanhol, Lopes, and Costa (2014)	No
Patti et al. (2015)	No
Poquet et al. (2016)	No
Richmond et al. (2015)	No
Ruddock, Sallis, Ness, and Perry (2016)	No
Saltychev, Eskola, and Laimi (2014)	No
Saragiotto, Yamato, and Maher (2015)	No
Saragiotto et al. (2016)	No
Smith, Littlewood, and May (2014)	No
Straube et al. (2016)	No
Steele, Bruce-Low, and Smith (2015)	No
Traeger et al. (2015)	Possibly
Vanti et al. (2015)	No
Wang, Wanyan, Tian, and Hu (2015)	No
Wells, Kolt, Marshall, Hill, and Bialocerkowski (2014)	Possibly

Yamato et al. (2016)	No
Yuan, Guo, Liu, Sun, and Zhang (2015)	No
Yuan et al. (2016)	No
Yue et al. (2014)	No
Zaina, Tomkins-Lane, Carragee, and Negrini (2016)	No

Discussion

The literature on non-pharmacologic, non-invasive treatments for low back is extensive. In general, the level of evidence for different interventions varies widely. Most of the available evidence with positive results suggest short-term improvements in pain more than function, and long-term outcomes of any type are sparsely reported. Massage therapy may not be effective, particularly for functional outcomes (Furlan et al., 2015). Bracing for subacute low back pain is supported by an evidence-based guideline (Dailey et al., 2014). On-line delivery of cognitive behavioral therapy appears to be effective (Garg et al., 2016). There is mixed evidence on short-term functional outcomes with laser therapy (Glazov et al., 2016; Huang et al., 2015). There is evidence in support of multidisciplinary biopsychosocial rehabilitation (Kamper et al., 2015) and walking (Lawford et al., 2016; O'Connor et al., 2015). In the acute setting, education and reassurance may be beneficial (Traeger et al., 2015). There is mixed evidence on Pilates, but it is not clearly superior to other forms of exercise therapy (Patti et al., 2015; Wells et al., 2014; Yamato et al., 2016). There is divergent evidence and opinions on the effective components of exercise therapy, though several reviews find no differences between various exercise therapy approaches. Neither mattresses nor insoles have sufficient evidence of effectiveness (Canadian Agency for Drugs and Technologies in Health, 2014; Chuter et al., 2014). The most comprehensive review available (Chou et al., 2016) largely supports the current coverage guidance, though tai chi and Iyengar yoga also show evidence for improved functional outcomes.

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Non-pharmacologic Interventions for Treatment-Resistant Major Depression – 2016 Rescanning Summary

Subcommittee

Evidence-based Guidelines Subcommittee (HERC Approved August 2012, Reaffirmed November 2014)

Coverage Recommendation (Box Language)

In patients with an episode of major depressive disorder who have failed at least two or more pharmacologic treatments the following treatments is recommended for coverage:

- 1) Repetitive transcranial magnetic stimulation
- 2) Electroconvulsive therapy

Vagus nerve stimulation is not recommended for coverage.

Scope Statement

Population description	Adults and children with treatment-resistant major depression <i>Population scoping notes: None</i>
Intervention(s)	Electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), vagal nerve stimulation (VNS), deep brain stimulation (DBS), psychotherapy <i>Intervention exclusions: None</i>
Comparator(s)	Usual care, adjunctive pharmacologic treatments (e.g., lithium, anticonvulsants, antipsychotics, ketamine), other listed interventions
Outcome(s) (up to five)	Critical: Mortality, remission of major depression, improvement in depression symptom scores including functional measures Important: Quality of life, adverse effects/harms <i>Considered but not selected for GRADE Table:</i> Time to remission of major depression

Key questions	1. What is the comparative effectiveness of non-pharmacologic interventions for treatment-resistant depression? 2. Does the comparative effectiveness of non-pharmacologic interventions for treatment-resistant depression vary by: a. Age b. Gender c. Duration of symptoms d. Number, type and duration of previous treatment attempts e. Single-episode vs. recurrent major depressive disorder f. Co-morbid conditions g. Ability to adhere to initial treatment plan 3. What are the harms of non-pharmacologic interventions for treatment-resistant major depression?
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Newly Identified Evidence

	Suggests need to update CG?
Berlim et al. (2014)	No
Brunoni et al. (2016)	Yes
CADTH (2014)	No
CADTH (2015)	No
Donaldson, Gordon, Melvin, Barton, and Fitzgerald (2014)	No
Fitzgerald and Segrave (2015)	No
Gaynes et al. (2014)	No
Hayes (2014a)	No
Hayes (2014b)	No
OHTAC (2016a)	No
OHTAC (2016b)	No
UCHTAU (2014)	No
Kedzior, Azorina, and Reitz (2014)	No
Kedzior, Gellersen, Brachetti, and Berlim (2015)	No
Kedzior, Reitz, Azorina, and Loo (2015)	No
Leggett et al. (2015)	No
Lepping et al. (2014)	Yes
Liu, Zhang, Zhang, and Li (2014)	No
McGirr et al. (2015)	No
Meron, Hedger, Garner, and Baldwin (2015)	No

Milev et al. (2016)	No
Morishita, Fayad, Higuchi, Nestor, and Foote (2014)	No
Naesstrom, Blomstedt, and Bodlund (2016)	No
NICE (2015a)	No
NICE (2015b)	No
Nordenskjold, Martensson, Pettersson, Heintz, and Landen (2016)	No
Palm, Hasan, Strube, and Padberg (2016)	No
Perera et al. (2016)	No
Serafini et al. (2015)	No
VHA/DOD (2016)	No
Vallejo-Torres et al. (2015)	No
Zhang et al. (2015)	No

Discussion

In general, the summary literature continues to support the use of ECT and rTMS, though one review questioned the clinical relevance of the improvements observed with rTMS (Lepping et al., 2014). One review found positive results with the use of deep TMS (Kedzior, Gellersen, et al., 2015), though that is based only on nine observational studies with a total of 150 patients. The evidence on transcranial direct current stimulation is mixed and the technology is still regarded as experimental by NICE (Brunoni et al., 2016; Meron et al., 2015; NICE, 2015b; Palm et al., 2016). There was little new summary literature on vagal nerve stimulation. Deep brain stimulation continues to be regarded as experimental. The VA/DOD guideline endorses the use of ECT or rTMS (VA/DOD, 2016), while a Canadian guideline regards rTMS as first-line, ECT as second-line, and VNS or tDCS as third-line options for treatment resistant depression (Milev et al., 2016).

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Chronic Otitis Media with Effusion in Children – 2016 Rescanning Summary

Subcommittee

Evidence-based Guidelines Subcommittee (HERC Approved October 2012, Reaffirmed November 2014)

Coverage Recommendation (Box Language)

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) is not recommended for coverage for children with children with otitis media with effusion (OME) (without another appropriate diagnosis).

There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented persistent hearing loss is greater than or equal to 25dB in the better hearing ear, referral for tympanostomy surgery is recommended for coverage, given short, but not long-term, improvement in hearing.

Formal audiometry is indicated for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing initially upon diagnosis. Children with chronic OME who are not at risk for language or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy is not recommended for coverage at the time of the first pressure equalization tube insertion.

Tympanostomy surgery is recommended for coverage for patients with craniofacial anomalies, Down's syndrome, cleft palate, and patients with speech and language delay along with hearing loss based on an individualized treatment plan.

Scope Statement

Population description	Children with chronic otitis media with effusion with or without hearing loss <i>Population scoping notes: None</i>
Intervention(s)	Antibiotics, other medications (including antihistamines, decongestants, and oral/nasal steroids), tympanostomy, pressure equalization tubes, adenoidectomy with or without tonsillectomy, eustachian tube autoinflation, hearing aids <i>Intervention exclusions: None</i>

Comparator(s)	No treatment, usual care (including monitoring with regular audiometry or tympanometry), other listed interventions
Outcome(s) (up to five)	Critical: Language or speech delays Important: Harms, missed school and work (for parents), persistent clinically significant hearing loss <i>Considered but not selected for GRADE Table: Quality of life, academic performance</i>
Key questions	1. What is the comparative effectiveness of the treatments for chronic otitis media with effusion in children? 2. Does the effectiveness of treatments for chronic otitis media with effusion in children vary based on: a. Age b. Duration of the effusion c. Presence and degree of clinically significant hearing loss at diagnosis d. Presence of predisposing conditions (e.g., craniofacial anomalies) e. Previous treatment (e.g., conservative management, medications) 3. What are the harms of treatments for chronic otitis media with effusion in children?

Newly Identified Evidence

	Suggests need to update CG?
Aval, Pabla, and Flood (2013)	No
Berkman et al. (2013)	No
Boonacker et al. (2014)	Yes
Heidemann et al. (2016)	No
Kuo et al. (2014)	No
Mikals and Brigger (2014)	Yes
Mohiuddin, Schilder, and Bruce (2014)	No
Perera, Glasziou, Heneghan, McLellan, and Williamson (2013)	No
Rosenfeld et al. (2016)	Yes
Trinidad, Page, and Dornhoffer (2016)	No
Venekamp et al. (2016)	Yes
Wallace et al. (2014)	Yes
Washington HTA (2015)	No

Discussion

In general, the literature supports the 2014 findings that interventions for chronic otitis media result in short-term improvements in hearing and resolution of the effusion, but that long-term differences are negligible or non-existent. Since 2014, there is new evidence that adenoidectomy, with or without other interventions, may also improve short-term outcomes particularly in children over the age of 4 years (Boonacker et al., 2014; Mikals & Brigger, 2014; Rosenfeld et al., 2016; Wallace et al., 2014). There is also a recent Cochrane review that found that antibiotics were effective for resolution of effusion at 2-3 months, but with higher rates of diarrhea, vomiting, and skin rash (Venekamp et al., 2016).

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Hyperbaric Oxygen Therapy for Chronic Wounds and Burns – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved November 2014)

Coverage Recommendation (Box Language)

Hyperbaric oxygen therapy is recommended for coverage (strong recommendation) for diabetic wounds of the lower extremities in patients who meet all of the following criteria:

- Patient has Type 1 or Type 2 diabetes and has a lower extremity wound that is due to diabetes,
- Patient has a wound classified as Wagner grade III or higher, and
- Patient has failed an adequate course of standard wound therapy including arterial assessment, with no measurable signs of healing after at least thirty days.

Hyperbaric oxygen therapy is recommended for coverage for late radiation tissue injury, and gas gangrene (*strong recommendation*).

Hyperbaric oxygen therapy is recommended for coverage for compromised surgical flaps and grafts, and for crush injuries (*weak recommendation*).

Scope Statement

Population description	Patients with chronic wounds, non-healing surgical wounds or compromised surgical flaps/grafts, thermal burns <i>Population scoping notes: None</i>
Intervention(s)	Hyperbaric oxygen therapy <i>Intervention exclusions: None</i>
Comparator(s)	Usual wound care, skin substitutes, antibiotic therapy, skin and tissue grafts, negative pressure wound treatment, multiple interventions
Outcome(s) (up to five)	Critical: Deep/invasive soft tissue or bone infections, complete wound or tissue healing, quality of life Important: Adverse effects, time to complete wound or tissue healing <i>Considered but not selected for GRADE Table: None</i>

Key questions	1. What is the comparative effectiveness of hyperbaric oxygen therapy for treatment of the listed conditions? 2. Does the comparative effectiveness of hyperbaric oxygen therapy vary by: a. Type of wound or tissue damage b. Size of wound or tissue damage c. Duration of wound or tissue damage d. Comorbidities e. Treatment setting f. Age of patient g. Duration of therapy h. Number of sessions i. Concurrent or previous wound therapy 3. What are the harms of hyperbaric oxygen therapy?
Contextual questions	1. What (if any) other treatments should be tried prior to use of hyperbaric oxygen therapy to optimize cost-effective treatment of these conditions? 2. How does hyperbaric oxygen therapy affect inpatient hospital utilization?

Newly Identified Evidence

	Suggests need to update CG?
Braun, Fisk, Lev-Tov, Kirsner, and Isseroff (2014)	No
Dauwe, Pulikkottil, Lavery, Stuzin, and Rohrich (2014)	No
Elraiyah et al. (2016)	No
Hayes (2016)	No
Hingorani et al. (2016)	No
Huang et al. (2015)	No
NICE (2015)	No
Khan et al. (2015)	No
Kranke et al. (2015)	No
Levett, Bennett, and Millar (2015)	No
Lima, Oliveira, Carvalho, Cimerman, and Savio (2014)	No
National Pressure Ulcer Advisory Council (2014)	No
Peters et al. (2016)	No
Reddy (2015)	No
Rollason et al. (2016)	No
Santema et al. (2015)	No

Stansby, Avital, Jones, and Marsden (2014)	No
Stoekenbroek et al. (2014)	No
Yang et al. (2015)	No

Discussion

There are no new evidence reviews or guidelines that would suggest the need to substantially change the current coverage guidance.

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Artificial Disk Replacement – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved August 2012, Reaffirmed November 2014)

Coverage Recommendation (Box Language)

Artificial disc replacement is recommended for coverage only when all of the following criteria are met:

Lumbar artificial disc replacement

- 1) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
- 2) Patients must be 60 years or under;
- 3) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
 - Failure of at least six months of conservative treatment
 - Skeletally mature patient
 - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Cervical artificial disc replacement

- 1) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
 - Skeletally mature patient
 - Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

Scope Statement

Population description	Adults with uncomplicated chronic cervical or lumbar back pain
Intervention(s)	Artificial disk replacement <i>Intervention exclusions: None</i>
Comparator(s)	Other interventions for neck and back pain, no treatment

Outcome(s) (up to five)	Critical: Long-term function, utilization of other surgical procedures (e.g., spinal fusion) Important: Short-term function, harms (including development of adjacent segment disease), utilization of non-surgical interventions (e.g. opioids) <i>Considered but not selected for GRADE Table: Short-term pain, long-term pain</i>
Key questions	1. What is the comparative effectiveness of artificial disk replacement for the treatment of chronic cervical or lumbar back pain? 2. Does the comparative effectiveness of artificial disk replacement vary by: a. Age b. Etiology of chronic cervical or lumbar back pain c. Duration of back pain d. Location or severity of degenerative changes e. Type of artificial disk f. Previous back surgery g. Number of levels treated h. Presence of radiculopathy, radicular symptoms or myelopathy i. Response to previous treatments 3. What are the harms of artificial disk replacement?

Newly Identified Evidence

	Suggests need to update CG?
Alvin & Mroz (2014)	No
Alvin et al. (2014)	No
Ament, Yang, Nunley, Stone, & Kim (2014)	No
Aragones, Hevia, & Barrios (2015)	No
Bakar, Lubelski, Abdullah, & Mroz (2014)	No
Blue Cross Blue Shield Association (2014)	No
Boselie, Willems, van Mameren, de Bie, & van Santbrink (2016)	No
Canadian Agency for Drugs and Technologies in Health (2014)	No
Colorado Division of Workers' Compensation (2014a)	No
Colorado Division of Workers' Compensation (2014b)	No
Ding et al. (2016)	No
Gao et al. (2015)	No

Hiratzka et al. (2015)	No
Hu, Lv, Ren, & Johansen (2016)	No
Jia et al. (2014)	No
Jiang et al. (2016)	No
Kang, Shi, Gu, Yang, & Gao (2015)	No
Kuang, Chen, Wang, Li, & Lu (2016)	No
Lewis, Attiah, Malhotra, Burnett, & Stein (2014)	No
Li et al., 2015; Luo, Gong, Huang, Yu, & Zou (2015)	No
Luo, Huang, et al. (2015)	No
Manchikanti & Hirsch (2015)	No
McAnany et al. (2014)	No
Molinari, Pagarigan, Dettori, Molinari, & Dehaven (2016)	No
Muheremu, Niu, Wu, Muhanmode, & Tian (2015)	No
National Institute for Health and Care Excellence (2014)	No
National Institute for Health and Care Excellence (2016)	No
Nie, Chen, Wang, & Zeng (2015)	No
Noshchenko et al. (2015)	No
Rao & Cao (2014)	No
Rao et al. (2015)	No
Ren, Song, Xue, & Yang (2014)	No
Shriver et al. (2016)	No
Thavaneswaran & Vandeppeer (2014)	No
Veruva, Steinbeck, Toth, Alexander, & Kurtz (2014)	No
Wu et al., (2015)	No
Xie, Liu, Ding, Li, & Ma (2016)	No
Yao, Liang, Xia, & Jia (2016)	No
Zhang et al. (2015)	No
Zhao et al. (2015)	No
Zhong, Li, et al. (2016)	No
Zhong, Zhu, Zhuang, Wu, & Chen (2016)	No
Zhong, Zhu, Zhuang, Wu, & Chen (2016)	No
Zhou, Qu, Dong, Kang, & Zhao (2015)	No
Zhu, Tian, et al. (2016)	No
Zhu, Zhang, Liu, Wu, & Zhu (2016)	No
Zou et al. (2016)	No

Discussion

Most of the newly identified summary evidence shows that cervical disc replacement is either equivalent to or superior to anterior cervical discectomy with fusion. Additionally, disc replacement may be associated with fewer adverse effects and a reduced need for reoperation. Emerging evidence suggests that two-level disc replacement may have similar outcomes to one-level disc replacement, but

others judge the evidence insufficient at this point. There were few new studies of lumbar disc replacement, but those that were identified support its use as an alternative to lumbar fusion in patients who have failed conservative management.

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Lumbar Discography – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved August 2012, Reaffirmed November 2014)

Coverage Recommendation (Box Language)

Lumbar discography is not recommended for coverage for patients with low back pain and uncomplicated lumbar degenerative disc disease.

Scope Statement

Population description	Adults with uncomplicated chronic lumbar back pain with or without prior back surgery <i>Population scoping notes: Most studies exclude patients with signs of nerve root impingement, spinal stenosis, spinal instability, objective motor deficits, fractures, infectious discitis, ankylosing spondylitis, low back pain due to malignancy, scoliosis, and kyphosis</i>
Intervention(s)	Lumbar discography with or without provocative testing <i>Intervention exclusions: None</i>
Comparator(s)	Usual care, other tests to diagnose discogenic causes of back pain or predict response to lumbar surgery (e.g., lumbar x-rays, lumbar computerized tomography, lumbar magnetic resonance imaging, myelography, facet joint blocks, orthotic immobilization, external fixation)
Outcome(s) (up to five)	Critical: Long-term function, change in utilization of surgery Important: Harms, prognostic accuracy for surgical outcomes, short-term function <i>Considered but not selected for GRADE Table: None</i>
Key questions	1. What is the comparative effectiveness of lumbar discography for the diagnosis and treatment planning of lumbar back pain? 2. Does the comparative effectiveness of lumbar discography vary by: a. Pretest probability of discogenic lumbar back pain b. Use of or characteristics of provocative testing c. Response to non-invasive or minimally-invasive treatments d. Previous back surgery

3. What are the harms of lumbar discography?

Newly Identified Evidence

	Suggests need to update CG?
Patel et al. (2016)	No
Eck et al. (2014)	No
Ong, Chua, and Vissers (2016)	No
TOP (2015)	No
Willems, Staal, Walenkamp, and de Bie (2013)	No
Manchikanti, Benyamin, et al. (2013)	No
Manchikanti, Abdi, et al. (2013)	No

Discussion

The use of lumbar discography for patients with uncomplicated low back pain remains controversial and is not widely endorsed by professional society guidelines. There is no new, high quality data published since the topic was last reviewed in 2014, and in particular the effects of provocative discography on utilization of and prognostication for surgical intervention remain unclear.

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DRAFT

Hip Resurfacing – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved October 2012, Reaffirmed November 2014)

Coverage Recommendation (Box Language)

Hip resurfacing is recommended for coverage for patients who are likely to outlive a traditional prosthesis and who would otherwise require a total hip replacement, and should only be done by surgeons with specific training in this technique.

The following criteria should be required:

- Diagnosis of osteoarthritis or inflammatory arthritis,
- Individual has failed nonsurgical management, and
- The device is FDA approved

Patients who are candidates for hip resurfacing must not have FDA contraindications including:

- Patients with active or suspected infection in or around the hip joint, or sepsis
- Patients who are skeletally immature
- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Patients with bone stock inadequate to support the device, including severe osteopenia or a family history of severe osteoporosis or osteopenia
- Patients with osteonecrosis or avascular necrosis with >50% involvement of the femoral head
- Patients with multiple cysts of the femoral head
- Females of childbearing age
- Patients with known moderate-to-severe renal insufficiency
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
- Patients who are severely overweight
- Patients with known or suspected metal sensitivity

Scope Statement

Population description	Adults with uncomplicated degenerative conditions of the hip <i>Population scoping notes: None</i>
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Intervention(s)	Hip resurfacing <i>Intervention exclusions: None</i>
Comparator(s)	Total hip arthroplasty, hip osteotomy, walking aids, anti-inflammatory medication, physical therapy, exercise programs, corticosteroid injections, viscosupplementation, oral medications supplements, topical medications, stem cell therapy, acupuncture, chiropractic manipulation
Outcome(s) (up to five)	Critical: Long-term function, utilization of total hip arthroplasty Important: Short-term function, harms, utilization of non-surgical interventions (e.g., opioids) <i>Considered but not selected for GRADE Table: Pain</i>
Key questions	1. What is the comparative effectiveness of hip resurfacing for the treatment of degenerative conditions of the hip? 2. Does the comparative effectiveness of hip resurfacing vary by: a. Etiology of degenerative changes b. Proportion of the intra articular surface that is resurfaced c. Duration or severity of degenerative changes d. Previous surgery and treatment e. Age f. Weight g. Gender h. Type of device used for hip resurfacing 3. What are the harms of hip resurfacing?

Newly Identified Evidence

	Suggests need to update CG?
Clarke et al. (2015)	No
Haughom, Erickson, Hellman, & Jacobs (2015)	No
Koutras, Antoniou, Talias, & Heep (2015)	No
Marshall et al. (2014)	No
National Institute for Health and Care Excellence (2014)	No
Reito, Lainiala, Elo, & Eskelinen (2016)	No

Discussion

Two new reviews find that hip resurfacing is inferior to total hip arthroplasty (THA), with one of the reviews also concluding that resurfacing is not cost-effective (dominated by THA). One review finds an increased risk of adverse events among women undergoing resurfacing procedures compared to men. Metal-on-metal resurfacing procedures have an associated risk of metallosis. However, on balance, the evidence would still likely support the use of hip resurfacing in the narrow clinical scenarios envisioned in the current coverage guidance. A NICE clinical guideline in 2014 concluded that resurfacing has a higher risk of revision procedures and hardware loosening while THA is associated with a higher risk of infection; NICE recommends either procedure so long as the device has a revision rate of less than 5% at 10 years.

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Viscosupplementation for Osteoarthritis of the Knee – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved October 2012, Reaffirmed November 2014)

Coverage Recommendation (Box Language)

Viscosupplementation should not be covered for the treatment of pain associated with Osteoarthritis (OA) of the knee

Scope Statement

Population description	Adults with osteoarthritis of the knee <i>Population scoping notes: None</i>
Intervention(s)	Viscosupplementation <i>Intervention exclusions: None</i>
Comparator(s)	Physical therapy, home exercise programs, aquatic exercise programs, medications (e.g., NSAIDs, acetaminophen, topical analgesics, opioids, glucosamine, chondroitin), arthroscopic knee procedures, corticosteroid injections, off-loading braces or orthoses, osteotomy, total knee arthroplasty, sham procedures, acupuncture
Outcome(s) (up to five)	Critical: Utilization of total knee replacement, Short-term function, long-term function, Important: Utilization of nonsurgical interventions, harms <i>Considered but not selected for GRADE Table: Short-term and long-term pain</i>
Key questions	1. What is the comparative effectiveness of viscosupplementation for osteoarthritis of the knee? 2. Does the comparative effectiveness of viscosupplementation for osteoarthritis of the knee vary by: a. Severity of osteoarthritis b. Fluoroscopic guidance c. Presence of specific radiographic features

	d. Response to non-invasive or minimally-invasive treatments e. Age f. Obesity g. Type of viscosupplement h. Baseline functional status
	3. What are the harms of viscosupplementation for osteoarthritis of the knee?

Newly Identified Evidence

	Suggests need to update CG?
Bannuru, Brodie, Sullivan, & McAlindon (2016)	No
Bannuru, Osani, Vaysbrot, & McAlindon (2016)	No
Bannuru et al. (2015)	No
Blue Cross Blue Shield (2014)	No
Bruyere et al. (2014)	No
Chang et al. (2014)	No
Department of Veterans Affairs and Department of Defense (2014)	No
Gallagher et al. (2015)	No
Hatoum, Fierlinger, Lin, & Altman (2014)	No
Jevsevar, Donnelly, Brown, & Cummins (2015)	No
Juni et al. (2015)	No
Lai et al. (2015)	No
Laudy, Bakker, Rekers, & Moen (2015)	No
McAlindon et al. (2014)	No
Meheux, McCulloch, Lintner, Varner, & Harris (2016)	No
Monticone et al. (2016)	No
Newberry et al. (2015)	No
National Institute for Health and Care Excellence (2014a)	No
National Institute for Health and Care Excellence (2014b)	No
Pai, Allgar, & Giannoudis (2014)	No
Richette et al. (2015)	No
Sadabad, Behzadifar, Arasteh, Behzadifar, & Dehghan (2016)	No
Strand, McIntyre, Beach, Miller, & Block (2015)	No
Wang & He (2015)	No
Xing et al. (2016)	No
Zhao et al. (2016)	No

Discussion

There is some discordance in the conclusions of the newly identified evidence reviews, but when limited to only the highest quality study designs with greater than 50 patients, sham controls, and double-blinding, the effects of viscosupplementation do not reach levels of clinical significance. In the few studies that examined delay in TKA, there was no apparent benefit to viscosupplementation. Some reviews suggest that injections of platelet-rich plasma may be superior to HA injections. NICE guidelines state that intraarticular hyaluronate should not be offered; VA/DOD guidelines state that there is insufficient evidence to recommend for or against viscosupplementation.

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Hip Surgery Procedures for Femoroacetabular Impingement Syndrome – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved January 2014)

Coverage Recommendation (Box Language)

Surgery for femoroacetabular impingement (FAI) syndrome is recommended (*weak recommendation*) for coverage in patients who meet all of the following criteria:

- Adult patients, or adolescent patients who are skeletally mature with documented closure of growth plates; and
- Other sources of pain have been ruled out (e.g., lumbar spine pathology, SI joint dysfunction, sports hernia); and
- Pain unresponsive to physical therapy and other non-surgical management and conservative treatments (e.g., restricted activity, cortisone injections, nonsteroidal anti-inflammatory drugs) of at least three months duration, or conservative therapy is contraindicated; and
- Moderate-to-severe persistent hip or groin pain that significantly limits activity and is worsened by flexion activities (e.g., squatting or prolonged sitting); and
- Positive impingement sign (i.e., sudden pain on 90 degree hip flexion with adduction and internal rotation or extension and external rotation); and
- Radiographic confirmation of FAI morphology (e.g., pistol-grip deformity, alpha angle greater than 50 degrees, coxaprofunda, and/or acetabular retroversion); and
- Do not have advanced osteoarthritis (i.e., Tönnis grade 2 or 3) or severe cartilage damage (i.e., Outerbridge grade III or IV).

Scope Statement

Population description	Adults and adolescents with femoroacetabular impingement (FAI) syndrome <i>Population scoping notes: None</i>
Intervention(s)	Surgical procedures for FAI (e.g., hip arthroscopy, hip arthroscopy combined with a mini-open approach, open dislocation of the hip) <i>Intervention exclusions: None</i>
Comparator(s)	Observation, usual care, physical therapy, anti-inflammatory medications, exercise programs, corticosteroid injections, oral supplements, viscosupplementation, acupuncture, chiropractic and osteopathic manipulation, other listed interventions

Outcome(s) (up to five)	Critical: Long-term function, incidence of severe hip osteoarthritis Important: Short-term function, quality of life, harms <i>Considered but not selected for GRADE Table: None</i>
Key questions	1. What is the comparative effectiveness of surgery for femoroacetabular impingement syndrome? 2. Does the comparative effectiveness of hip surgery procedures for femoroacetabular impingement syndrome vary by: a. Age b. Weight c. Gender d. Physical activity level e. Means of establishing preoperative diagnosis of FAI f. Type of FAI (i.e. cam impingement vs. pincer impingement) g. Severity and/or duration of condition h. Previous treatments 3. What are the harms of surgery for femoroacetabular impingement syndrome?

Newly Identified Evidence

	Suggests need to update CG?
Alradwan et al. (2012)	No
Casartelli, Leunig, Maffiuletti, & Bizzini (2015)	No
Collins, Ward, & Youm (2014)	No
Cvetanovich et al. (2015)	No
de Sa et al. (2016)	No
Fairley et al. (2016)	No
Forster-Horvath, von Rotz, Giordano, & Domb (2016)	No
Griffin, Kinnard, Formby, McCabe, & Anderson (2016)	No
Harris, Erickson, Bush-Joseph, & Nho (2013)	No
Horner et al. (2016)	No
Kemp et al. (2012)	No
MacDonald et al. (2016)	No
Nwachukwu et al. (2016)	No
Saadat et al. (2014)	No
Sardana et al. (2015)	No

Shearer, Kramer, Bozic, & Feeley (2012)	No
Tibor & Leunig (2012)	No
Wall et al. (2014)	No
Zhang, Chen, & Wang (2016)	No

Discussion

There is no new high quality data regarding the effectiveness of surgery for FAI compared with non-surgical treatments. Nearly all of the existing data comes from non-comparative case series that suggest patients with FAI improve after surgery, particularly in younger athletes. There continues to be some debate in the literature regarding the details of surgical interventions, but, on-balance, most of the reviews favor arthroscopic over open approaches and labral reconstruction over labral debridement. Evidence also suggests that the likelihood of surgical success drops with increasing age and in presence of established arthritic changes. There appears to be no role for “prophylactic” procedures in asymptomatic individuals.

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Treatment of Obstructive Sleep Apnea in Adults – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved January 2014)

Coverage Recommendation (Box Language)

Coverage of treatment for Obstructive Sleep Apnea (OSA) in adults should be limited, as follows:

CPAP is recommended for coverage initially when all of the following conditions are met:

- 12 week ‘trial’ period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour (*strong recommendations*); or if between 5 and 14 events with additional symptoms (*weak recommendations*) including one or more of the following:
 - Excessive daytime sleepiness (Epworth Sleepiness Scale score > 10), or
 - Documented hypertension, or
 - Ischemic heart disease, or
 - History of stroke;
- Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and
- Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

CPAP coverage subsequent to the initial 12 weeks should be based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

Mandibular advancement devices (oral appliances) are recommended for coverage for those for whom CPAP fails or is contraindicated (*weak recommendation*).

Intensive weight loss programs (if provided in the benefit package) are recommended for coverage for patients with obesity and obstructive sleep apnea.

Surgery for sleep apnea for adults is not recommended for coverage (*weak recommendation*).

Scope Statement

Population description	Adults with obstructive sleep apnea (OSA) <i>Population scoping notes: Excludes children, people with central sleep apnea</i>
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Intervention(s)	Non-invasive positive pressure ventilation (NIPPV) (e.g., Continuous Positive Pressure Airway devices (CPAP)), mandibular advancement devices, intensive weight loss interventions, nasooropharyngeal surgical procedures <i>Intervention exclusions: None</i>
Comparator(s)	No treatment, usual care, other listed interventions
Outcome(s) (up to five)	Critical: Mortality, major adverse cardiovascular events, fatigue-related accidents Important: Quality of life, harms <i>Considered but not selected for GRADE Table: Change in A1c, improvement in symptom scales, remission of hypertension, improvement in apnea-hypopnea index (AHI), depression</i>
Key questions	1. What is the comparative effectiveness of treatments for obstructive sleep apnea in adults? 2. Does the comparative effectiveness of treatments for obstructive sleep apnea vary by: a. Severity of OSA b. Gender c. Weight or body mass index d. Comorbidities e. Type of equipment used for NIPPV f. Level of adherence to prescribed treatment g. Response to prior interventions h. Customization of equipment 3. What are the harms of treatments for obstructive sleep apnea?
Contextual questions	1. What effective strategies exist to improve adherence (in specific populations)? 2. What is the most cost-effective treatment strategy given real-world adherence rates?

Newly Identified Evidence

	Suggests need to update CG?
Abdullatif et al. (2016)	No
Aiello et al. (2016)	No

Anastasopoulos, Chalkias, Iakovidou, & Xanthos (2016)	No
Ashrafian et al. (2015)	No
Baba, Mohan, Metta, & Mador (2015)	No
Bartolucci et al. (2016)	No
Birkbak, Clark, & Rod (2014)	No
Bordier, Lataste, Hofmann, Robert, & Bourenane (2016)	No
Canadian Agency for Drugs and Technologies in Health, (2014)	No
Camacho, Certal, et al. (2015)	No
Camacho et al. (2014)	No
Camacho et al. (2016)	No
Camacho, Teixeira, et al. (2015)	No
Certal et al. (2015)	No
Chapman, Vakulin, Hedner, Yee, & Marshall (2016)	Possibly
Choi, Cho, Kim, Suh, & Cho (2016)	No
Fonseca, Pereira, & Caseiro (2015)	No
Fu et al. (2016)	No
Guo et al. (2016)	No
Ha, Hirai, & Tsoi (2014)	No
Handler, Hamans, Goldberg, & Mickelson, Hedner (2015)	No
Iftikhar, Kline, & Youngstedt (2014)	No
Ishii, Roxbury, Godoy, Ishman, & Ishii (2015)	No
Justin, Chang, Camacho, & Brietzke (2016)	No
Kim, Koo, Lee, & Lee (2016)	No
King & Cuellar (2016)	No
Knudsen, Laulund, Ingerslev, Homoe, & Pinholt (2015)	No
Kuan et al. (2016)	Possibly
H. T. Liu et al. (2016)	Possibly
Liu, Cao, Guo, & Dai (2016)	No
Lv, Jiang, Huang, Zhang, & Chen (2016)	Possibly
Meccariello et al. (2016)	No
Miller, Nguyen, Ong, & Gillespie (2016)	No
Mitchell et al. (2014)	No
Murphey, Kandl, Nguyen, Weber, & Gillespie (2015)	No
National Institute for Health Research (2016)	No
Nigam, Pathak, & Riaz (2016)	No
Okuno et al. (2014)	No
Pietzsch, Liu, Garner, Kezirian, & Strollo (2015)	No
Quintas-Neves, Preto, & Drummond (2016)	No
Ramar et al. (2015)	No
Riaz et al. (2015)	No
Rotenberg, Vicini, Pang, & Pang (2016)	No

Serra-Torres, Bellot-Arcis, Montiel-Company, Marco-Algarra, & Almerich-Silla (2016)	No
Shantha & Pancholy (2015)	No
Sharples et al. (2016)	No
Song, Chang, et al. (2016)	No
Song, Wei, et al. (2016)	No
Sukhal, Khalid, & Tulaimat (2015)	Possibly
Trakada et al. (2015)	No
Tsui, Yang, Cheung, & Leung (2016)	No
Veer, Yang, Green, & Kotecha (2014)	No
Wang et al. (2015)	No
Wu et al. (2015)	No
Yang & Sawyer (2016)	No
Zaghi et al. (2016)	No
Zhu et al. (2015)	No

Discussion

Overall, there is little new summary evidence that would necessitate updating the current coverage guidance. The literature that does exist is limited by the use of mostly non-randomized study designs and failure to consider longer term patient-important health outcomes (nearly all studies report surrogate outcomes like AHI or blood pressure). While there is new summary literature regarding the use of medications (stimulants or intranasal corticosteroids) these were examined in comparison to placebo and don't offer comparative effectiveness information. The only new pertinent guideline that was identified supports the use of oral appliances in those patients who cannot tolerate treatment with CPAP.

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Osteoporosis/Osteopenia Monitoring by Dual-Energy X-ray Absorptiometry (DXA) – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved June 2014)

Coverage Recommendation (Box Language)

Osteoporosis screening by dual-energy X-ray absorptiometry (DXA) is recommended for coverage only for women aged 65 or older, and for men or younger women whose 10-year risk of major osteoporotic fracture is equal to or greater than 9.3 percent. Fracture risk should be assessed by the World Health Organization's FRAX tool (*strong recommendation*).

Routine osteoporosis screening by DXA is not recommended for coverage in men (*weak recommendation*).

The frequency of subsequent monitoring for development of osteoporosis should not be based on DXA scores alone. If rapid change in bone density is expected, more frequent DXA scanning is appropriate (for example, in patients taking glucocorticoids, those with a history of rapid weight loss, those with medical conditions that could result in secondary osteoporosis, etc.).

If there has been no significant change in an individual's risk factors, monitoring of individuals with low bone density by repeat DXA scanning is recommended for coverage (*weak recommendation*) only at the following frequencies:

- Once every two years for those with osteoporosis or advanced osteopenia (T-score of -2.00 or lower)
- Once every four years for moderate osteopenia (T-score between -1.50 and -1.99)
- Once every ten years for mild osteopenia (T-score between -1.01 and -1.49)
- Once every fifteen years for those with normal bone density

Repeat testing should only be covered if the results will influence clinical management. For purposes of monitoring osteoporosis medication therapy, testing at intervals of less than two years is not recommended for coverage (*weak recommendation*).

Scope Statement

Population description	Adults with a personal history of osteoporosis or osteopenia <i>Population scoping notes: None</i>
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Intervention(s)	Monitoring of bone mineral density (BMD) using dual-energy x-ray absorptiometry (DXA) <i>Intervention exclusions: None</i>
Comparator(s)	No routine monitoring of BMD, monitoring of BMD using alternative tests
Outcome(s) (up to five)	Critical: Hip fractures, other osteoporotic fractures Important: Progression of osteopenia to osteoporosis, quality of life, adverse events <i>Considered but not selected for GRADE Table: None</i>
Key questions	1. What is the comparative effectiveness of DXA for monitoring bone mineral density in patients with osteoporosis? 2. Does the comparative effectiveness of DXA for monitoring of osteoporosis vary by: a. Severity of osteoporosis at initial diagnosis or last study b. Age c. Gender d. Race/ethnicity e. Prior or ongoing use of medications known to alter bone density f. Other risk factors (e.g., history of rapid weight loss, comorbidities, BMI, alcohol consumption, smoking, family history) g. Frequency of monitoring h. Site of measurements 3. What are the harms of DXA for monitoring bone mineral density for osteoporosis?

Newly Identified Evidence

	Suggests need to update CG?
Hoiberg, Rubin, Hermann, Brixen, & Abrahamsen (2016)	No
Jefferson et al. (2016)	No
E. Kilic & S. Ozgocmen (2015)	No
G. Kilic & S. Ozgocmen (2015)	No
Lee et al. (2016)	No
Mandl et al. (2015)	No
Michigan Quality Improvement Consortium (2014)	No

Minniti, Davini, Gualano, & Gianino (2014)	No
Scottish Intercollegiate Guidelines Network (2015)	No
Washington State Health Care Authority (2014)	No

Discussion

There was no new summary evidence regarding the optimal interval for osteoporosis monitoring with DXA.

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- Hoiberg, M. P., Rubin, K. H., Hermann, A. P., Brixen, K., & Abrahamsen, B. (2016). Diagnostic devices for osteoporosis in the general population: A systematic review. *Bone*, 92, 58-69. DOI: 10.1016/j.bone.2016.08.011 .
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- Lee, J. H., Lee, Y. K., Oh, S. H., Ahn, J., Lee, Y. E., Pyo, J. H., ... Kim, D. Y. (2016). A systematic review of diagnostic accuracy of vertebral fracture assessment (VFA) in postmenopausal women and elderly men. *Osteoporosis International*, 27(5), 1691-1699. DOI: 10.1007/s00198-015-3436-z.
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- Scottish Intercollegiate Guidelines Network. (2015). *Management of osteoporosis and the prevention of fragility fractures*. Retrieved from <http://www.sign.ac.uk/pdf/SIGN142.pdf>

Washington State Health Care Authority. (2014). HTA report: Screening and monitoring tests for osteopenia/osteoporosis. Olympia, WA: Health Technology Assessment Program. Retrieved from http://www.hca.wa.gov/assets/program/osteo_final_report_102014.pdf

Osteoporosis/Osteopenia Screening by Dual-Energy X-ray Absorptiometry (DXA) – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved June 2014)

Coverage Recommendation (Box Language)

Osteoporosis screening by dual-energy X-ray absorptiometry (DXA) is recommended for coverage only for women aged 65 or older, and for men or younger women whose 10-year risk of major osteoporotic fracture is equal to or greater than 9.3 percent. Fracture risk should be assessed by the World Health Organization's FRAX tool (*strong recommendation*).

Routine osteoporosis screening by DXA is not recommended for coverage in men (*weak recommendation*).

Scope Statement

Population description	Adults without a personal history of osteoporosis or osteopenia <i>Population scoping notes: None</i>
Intervention(s)	Screening for osteoporosis using dual-energy x-ray absorptiometry (DXA) <i>Intervention exclusions: None</i>
Comparator(s)	No screening, use of fracture risk assessment tools
Outcome(s) (up to five)	Critical: Hip fractures, other osteoporotic fractures Important: Development of osteoporosis, quality of life, adverse events <i>Considered but not selected for GRADE Table: None</i>
Key questions	1. What is the comparative effectiveness of DXA for screening for osteoporosis? 2. Does the comparative effectiveness of DXA for screening of osteoporosis vary by: a. Age b. Gender c. Race/ethnicity d. Prior use or concurrent of medications known to alter bone density e. Other risk factors (e.g., history of rapid weight loss, medical conditions, patient history, BMI, alcohol consumption, smoking, family history)

	f. Frequency of screening g. Site of measurements 3. What are the harms of DXA for screening for osteoporosis?
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Newly Identified Evidence

	Suggests need to update CG?
Hoiberg, Rubin, Hermann, Brixen, & Abrahamsen (2016)	No
Jefferson et al. (2016)	No
E. Kilic & S. Ozgocmen (2015)	No
G. Kilic & S. Ozgocmen (2015)	No
Lee et al. (2016)	No
Mandl et al. (2015)	No
Michigan Quality Improvement Consortium (2014)	No
Minniti, Davini, Gualano, & Gianino (2014)	No
Scottish Intercollegiate Guidelines Network (2015)	No
Washington State Health Care Authority (2014)	No

Discussion

In general, there is no new summary evidence on the role for DXA screening since the coverage guidance was last reviewed. Guidelines from SIGN suggest DXA screening for women over the age of 50 with a 10 year FRAX risk of >10%. There is some summary evidence and guidelines regarding the use of DXA in certain conditions (axial spondyloarthropathies, rheumatoid arthritis, Rett syndrome), but this information would not substantially alter the current coverage guidance. There is emerging evidence that quantitative ultrasound may be comparable to DXA for assessing BMD.

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- Hoiberg, M. P., Rubin, K. H., Hermann, A. P., Brixen, K., & Abrahamsen, B. (2016). Diagnostic devices for osteoporosis in the general population: A systematic review. *Bone*, 92, 58-69. DOI: 10.1016/j.bone.2016.08.011.
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