

MINUTES

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

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

Members Absent: Irene Crosswell, RPh

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

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

Call to Order

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

Minutes Approval

[Meeting materials](#), pages 4-11

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

Director's Report

Membership Update

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

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

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

Other Business

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

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

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

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

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

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

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

GUIDELINE NOTE 155 ELECTRIC TUMOR TREATMENT FIELDS FOR GLIOBLASTOMA
Line 299

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

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

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

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

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

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

Coverage Guidance Evidence Submission Policy Clarification

[Meeting materials](#), pages 569-570

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

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

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

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

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

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

Coverage Guidance Topic: Tobacco Cessation In Pregnancy

[Meeting materials](#), pages 571-651

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

The scope of this coverage guidance looked at:

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

Evidence sources included Cochrane and AHRQ systematic reviews.

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

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

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

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

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

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

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

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

Further discussion led to deleting all instances of “partner support.”

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

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

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

Approved Coverage Guidance

HERC Coverage Guidance

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

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

The following interventions are not recommended for coverage:

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

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

Multisector Interventions

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

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

No or insufficient evidence is available for the following:

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

Changes to the Prioritized List of Health Services

Modify Guideline Note 4 as follows:

GUIDELINE NOTE 4, TOBACCO DEPENDENCE, INCLUDING PREGNANT WOMEN

Lines 1, 5

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

Inclusion on this line follows the minimum standard criteria as defined in the Oregon Public Health Division “Standard Tobacco Cessation Coverage” (based on the Patient Protection and Affordable Care Act), available here:

<https://public.health.oregon.gov/PreventionWellness/TobaccoPrevention/Pages/pubs.aspx>. The USPSTF has also made “A” recommendations for screening, counseling, and treatment of pregnant and nonpregnant adults, included in Guideline Note 106.

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

Modify Guideline Note 99 as follows:

GUIDELINE NOTE 99, ROUTINE PRENATAL ULTRASOUND

Lines 1,39,41,67

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

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

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

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

Changes to multisector interventions

MULTISECTOR INTERVENTIONS: TOBACCO PREVENTION AND CESSATION, INCLUDING PREGNANT WOMEN

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

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

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

TASK FORCE FINDINGS ON TOBACCO USE

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

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

| Intervention | Task Force Finding |
|--|---|
| Reducing Tobacco Use Initiation | |
| Increasing the unit price of tobacco products |  |
| Mass media campaigns when combined with other interventions |  |
| Smoke-free policies |  |
| Increasing Tobacco Use Cessation | |
| Increasing the unit price of tobacco products |  |
| Mass media campaigns when combined with other interventions |  |
| Mass-reach health communication interventions |  |
| Mobile phone-based interventions |  |
| Multicomponent interventions that include client telephone support |  |
| Smoke-free policies |  |
| Provider reminders when used alone |  |
| Provider reminders with provider education |  |
| Reducing client out-of-pocket costs for cessation therapies |  |
| Internet-based interventions |  |
| Mass media – cessation contests |  |
| Mass media – cessation series |  |
| Provider assessment and feedback |  |
| Provider education when used alone |  |
| Reducing Exposure to Environmental Tobacco Smoke | |
| Smoke-free policies |  |
| Community education to reduce exposure in the home |  |
| Restricting Minors’ Access to Tobacco Products | |
| Community mobilization with additional interventions |  |
| Sales laws directed at retailers when used alone |  |
| Active enforcement of sales laws directed at retailers when used alone |  |
| Community education about youth’s access to tobacco products when used alone |  |
| Retailer education with reinforcement and information on health consequences when used alone |  |
| Retailer education without reinforcement when used alone |  |
| Laws directed at minors’ purchase, possession, or use of tobacco products when used alone |  |
| Decreasing Tobacco Use Among Workers | |
| Smoke-free policies |  |
| Incentives and competitions to increase smoking cessation combined with additional interventions |  |
| Incentives and competitions to increase smoking cessation when used alone |  |

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

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

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

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

Coverage Guidance Topic: Skin Substitutes for Chronic Skin Ulcers

[Meeting materials](#), pages 652-760

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

Public Comment

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

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

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

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

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

Items for Next Meeting

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

Adjournment

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

DRAFT

Appendix A

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

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

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

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

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

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

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

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

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE AND MULTISECTOR INTERVENTION REPORT: TOBACCO CESSATION DURING PREGNANCY

Approved 8/11/2016

HERC Coverage Guidance

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

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

The following interventions are not recommended for coverage:

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

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

Note: Definitions for strength of recommendation are provided in Appendix A *GRADE Informed Framework Element Description*.

Multisector Interventions

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

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

No or insufficient evidence is available for the following:

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

Oregon Health Plan Prioritized List changes Tobacco Cessation During Pregnancy

The Health Evidence Review Commission approved the following changes to the Prioritized List of Health Services on August 11, 2016, based on the approved coverage guidance, “Tobacco Cessation During Pregnancy.” The changes will take effect on the Prioritized list of Health Services for the Oregon Health Plan on October 1, 2015.

- 1) Modify Guideline Note 4 as follows

GUIDELINE NOTE 4, TOBACCO DEPENDENCE, INCLUDING PREGNANT WOMEN

Lines 1, 5

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

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

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

- 2) **Modify Guideline Note 99 as follows:**

GUIDELINE NOTE 99, ROUTINE PRENATAL ULTRASOUND

Lines 1,39,41,67

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

- A) One ultrasound in the first trimester for the purpose of identifying fetal aneuploidy or anomaly (between 11 and 13 weeks of gestation) and /or dating confirmation. In some instances, if a patient’s LMP is truly unknown, a dating ultrasound may be indicated prior to an aneuploidy screen

Oregon Health Plan Prioritized List changes

Tobacco Cessation During Pregnancy

- B) One ultrasound for the purpose of anatomy screening after 18 weeks gestation. [For women using tobacco during pregnancy, additional counseling around smoking impacts on the fetus is included during this ultrasound.](#)

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

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

3) Modify the MULTISECTOR INTERVENTIONS: TOBACCO PREVENTION AND CESSATION to include interventions for pregnancy:

MULTISECTOR INTERVENTIONS: TOBACCO PREVENTION AND CESSATION, INCLUDING PREGNANT WOMEN

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

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

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

Oregon Health Plan Prioritized List changes

Tobacco Cessation During Pregnancy

TASK FORCE FINDINGS ON TOBACCO USE

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

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

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

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

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

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

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

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

GUIDELINE NOTE 60, OPIOIDS PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE

Lines 351,366,407,532

Opioid medications are only included on these lines under the following criteria:

~~The following restrictions on opioid treatment apply to all diagnoses included on these lines.~~

For acute injury, acute flare of chronic pain, or after surgery:

- 1) During the first 6 weeks ~~after the acute injury, flare or surgery~~, opioid treatment is included on these lines ONLY:
 - a) When each prescription is limited to 7 days of treatment, AND
 - b) For short acting opioids only, AND
 - c) When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
 - d) When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
 - e) There is documented ~~lack of current or prior~~ verification that the patient is not high risk for opioid misuse or abuse.
- 2) Treatment with opioids after 6 weeks, up to 90 days after the initial injury/flare/surgery, ~~requires the following~~ is included on these lines ONLY:
 - a) With D documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools.
 - b) ~~Must be~~ When prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
 - c) With V verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve:
 - i) Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
 - ii) Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
 - iii) Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
 - d) Each prescription must be limited to 7 days of treatment and for short acting opioids only
- 3) Chronic opioid treatment (>90 days) after the initial injury/flare/surgery is not included on these lines except for the taper process described below. ~~Further opioid treatment after 90 days may be considered is included on these lines ONLY when there is a significant change in status, such as a clinically significant verifiable new injury or surgery. In such cases, use of opioids is limited to a maximum of an additional 7 days. In exceptional cases, use up to 28 days may be included on these lines, subject to the criteria in #2 above.~~

Transitional coverage for patients on long-term opioid therapy as of July 1, 2016

~~For patients with chronic pain from diagnoses on these lines currently treated with long term opioid therapy, opioids must be tapered off using~~ For patients on covered chronic opioid therapy as of July 1, 2016, opioid medication is included on these lines only from July 1, 2016 to December 31, 2016. During the period from January 1, 2017 to December 31, 2017, continued coverage of opioid medications requires an individual treatment plan developed by January 1, 2017 which includes a taper with a quit date an end to opioid therapy no later than January 1, 2018. Taper plans must include nonpharmacological treatment strategies for managing the patient's pain based on Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE. If a patient has developed dependence and/or addiction related to their opioids, treatment is available on Line 4 SUBSTANCE USE DISORDER.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: METABOLIC AND BARIATRIC SURGERY

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

HERC Coverage Guidance

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

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

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

Metabolic and bariatric surgery is not recommended for coverage in:

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

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

RATIONALE FOR GUIDANCE DEVELOPMENT

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

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

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

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: NONINVASIVE TESTING FOR LIVER FIBROSIS IN PATIENTS WITH CHRONIC HEPATITIS C

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

HERC Coverage Guidance

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

Imaging tests:

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

Blood tests (only if imaging tests are unavailable):

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

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

Imaging tests:

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

Magnetic resonance elastography is recommended for coverage for $\geq F2$ 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 (*weak recommendation*).

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

The following tests are not recommended for coverage for the detection of liver fibrosis to guide treatment decisions with antivirals in chronic hepatitis C (*strong recommendation*):

Imaging tests

- Real time tissue elastography

Blood tests (proprietary):

- Hepascore® (FibroScore®)
- FibroSure® (FibroTest®)

Blood tests (non-proprietary):

- Age-platelet index
- AST-platelet ratio index (APRI)
- AST-ALT ratio
- Cirrhosis discriminant score (Bonacini index)
- FIB-4
- Fibro- α score
- FibroIndex
- Fibronectin discriminant score
- FibroQ
- Fibrosis–cirrhosis index
- Fibrosis index
- Fibrosis probability index (Sud index)
- Fibrosis–protein index
- Fibrosis Routine Test
- Forns index
- Globulin–albumin ratio
- Göteborg University Cirrhosis Index (GUCI)
- HALT-C model (Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis)
- King’s score
- Lok index
- MP3 score
- Pohl index
- Sabadell NIHCED index (Non-Invasive Hepatitis-C–Related Cirrhosis Early Detection)
- Significant fibrosis index
- Zeng index

Note: Definitions for strength of recommendation are provided in Appendix A *GRADE Informed Framework Element Description*.

RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as they seek to improve patient experience of care, population health and the cost-effectiveness of health care. In the era of the Affordable Care Act and health system transformation, reaching these goals may require a focus on population-based health interventions from a variety of sectors as well as individually-focused clinical care. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that happen outside of the typical clinical setting.

HERC selects topics for its reports to guide public and private payers based on the following principles: