

Quality and Health Outcomes Committee

February 8, 2016

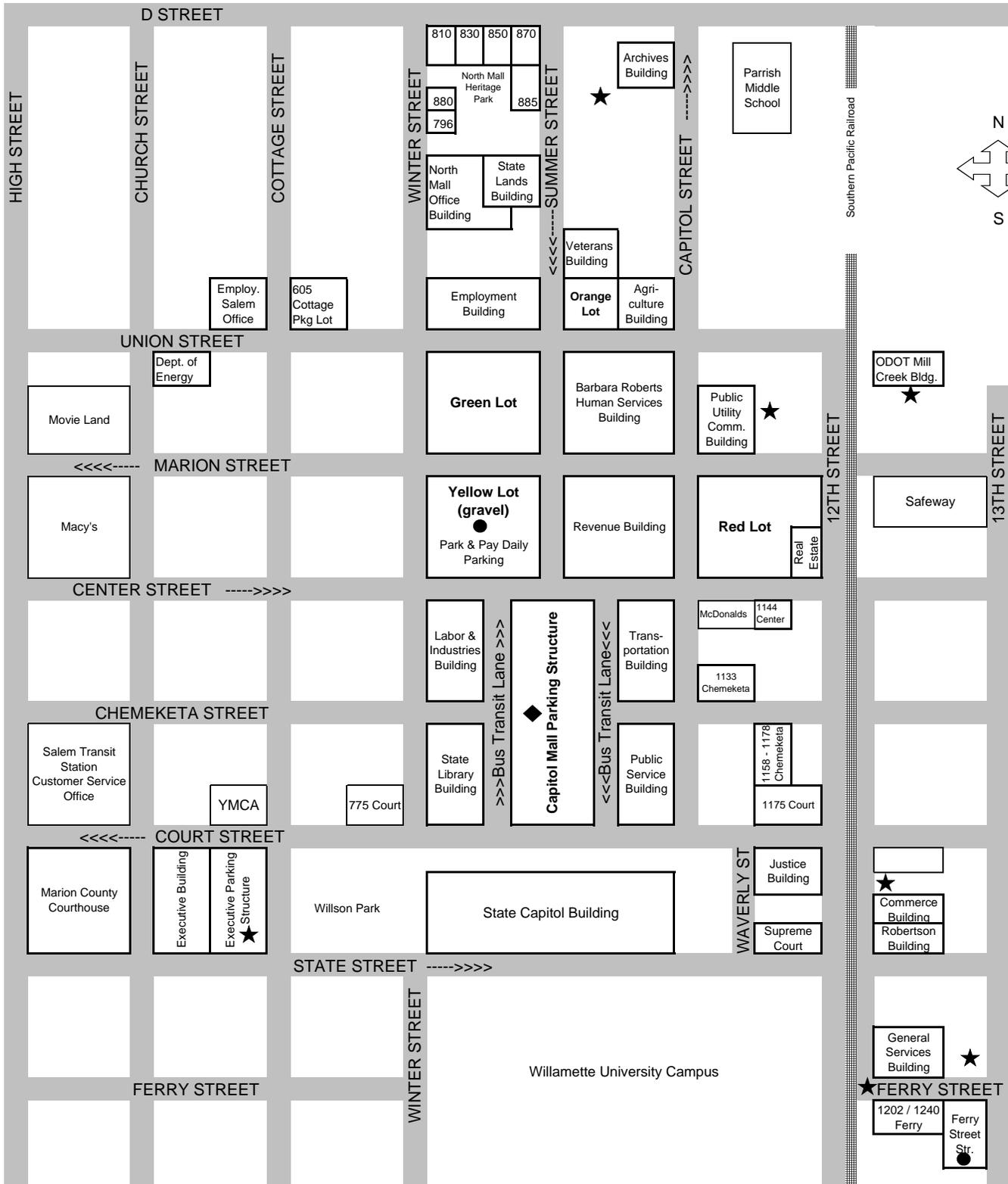
HSB Building Room 137A-D, Salem, OR

Toll free dial-in: **888-278-0296** Participant Code: **310477**

Parking: [Map](#) ° Phone: 503-378-5090 x0

Clinical Director Workgroup			
Time	Topic	Owner	Related Documents (page#)
9:00 – 9:10	Welcome / Introductions -Consent Agenda	Mark Bradshaw	-Meeting Minutes (1 – 9) -PH Update/leading causes of death report (10 – 27) -Actionline Flyer (28)
9:10 – 9:20	Metrics Update	Sarah Bartelmann	-Metrics Update (29)
9:20 – 9:30	Metrics Targeted TA Prioritization	Anona Gund	-CCO Needs Assessment Calls (30)
9:30 – 9:45	P&T update	Ted Williams	P&T committee meeting materials
9:45 – 10:10	HERC Update	Cat Livingston	-HERC Meeting Minutes (31 - 38) -Nitrous Oxide use for Labor Pain Management Documents (39 – 63) -Proton Beam Therapy Documents (64 – 98) -Digital Breast Tomosynthesis Documents (99 – 102) -Scope Statements for HERC Coverage Guidances (103 – 158)
10:10 – 10:30	Transformation Center: Clinical Innovators Program	Emilee Coulter-Thompson	-Call for Applications Presentation (159 – 162) -Applications Flier (163)
10:30 – 10:50	Clinical Items from the floor	All	
10:50 – 11:00	BREAK		
Learning Collaborative Session			
11:00 – 12:30	Non-Opioid Treatment Options	Panel	-Statewide PIP on Opioid Safety Presentation (164 – 169) -Opiates Approach Presentation (170 – 176)
12:30 – 1:00	LUNCH		
Quality and Performance Improvement Workgroup			
1:00 – 1:10	QPI Update – Introductions	Jennifer/Lisa	
1:10 – 2:10	Metrics <ul style="list-style-type: none"> • Contraceptive • Immunization • Tobacco 	All	OHA Metrics site
2:10 – 2:40	PIPs	All	-CCO Performance Improvement Projects (177)
2:40 – 3:00	Items from the Floor	All	
3:00	Adjourn		

SALEM CAPITOL MALL AREA



- ★ State of Oregon Meters - OK to use Agency issued one-day permit
- ◆ Capitol Mall Structure Meters - OK to use Agency Issued one-day permit
- Yellow Lot & Ferry Structure Rooftop Visitor Spaces - OK to use Agency issued one-day permit

MEETING NOTES

Quality & Health Outcomes Committee (QHOC)

January 11, 2016

Website: <http://www.oregon.gov/oha/healthplan/Pages/CCO-Quality-and-Health-Outcomes-Committee.aspx>

Chair- Mark Bradshaw (All Care)

Co-Chair- Jennifer Johnstun (Primary Health)

Attendees: *(in person or by phone)*

Anne Alftine (JCC); Gary Allen (Advantage Dental); Tracy Anastas (OHSU); Susan Arbor (MAP); Joell Archibald (OHA); Bruce Austin (OHA); Maggie Bennington-Davis (Health Share); Summer Boslaugh (OHA); Bill Bouska (OHA); Stuart Bradley (WVCH); Mark Bradshaw (All Care); Stacy Brbali (JCC); Lisa Bui (OHA); Jim Calvert (Cascade Health Alliance); Emileigh Canales (FamilyCare); Barbara Carey (Health Share); Jody Carson (Acumentra); Christine Castle (CareOregon); Roger Citron (OHA/HSD); Tom Cogswell (OHA); Cheryl Cohen (HealthShare); Laurence Colman (GOBHI); Bruce Croffy (FamilyCare); Eric Davis (JD Health); Chandra Elser (HealthShare); Kevin Ewanchyna (IHN/CCO); Linda Fanning (Acumentra); David Fischer (OHA/HSD); Ruth Galster (UHA); Bennett Garner (FamilyCare); Jim Gaudino (OHSU); David Geels (WOAH); Walter Hardin (Tuality); Rosanne Harksen (OHA), Jenna Harms (Yamhill CCO); Maria Hatcliffe (PacificSource); Laura Heesacker (JCC); Theresa Heidt (YCCO); Hank Hickman (OHA); Holly Jo Hodges (WVP/WVCH); Andrew Huff (CareOregon); Todd Jacobsen (GOBHI); Jennifer Johnstun (Primary Health); Charmaine Kinney (Mult. Co./Health Share); Cynthia Lacro (EOCCO); Deborah Larkins (DHS); Robin Leatherwood (Architrave); Lynnea Lindsey-Pengelly (Trillium); Alison Little (PacificSource); Cat Livingston (HERC); Andrew Luther (OHMS); Laura Matola (All Care); Roxanne McAnally (OHA); Tracy Muday (WOAH); Chris Norman (MAP); Colleen O'Hare (Trillium); Laureen Oskochil (Acumentra); Paolo Paz (Tuality); Ellen Pinney (OHA); Jordan Rawlins (Moda/EOCCO); Rose Rice (UHA); Jim Rickards (OHA); Kathy Savicki (MVBCN); Stefan Shearer (CareOregon); Nancy Siegel (Acumentra); Debbie Standridge (UHA); Dayna Steringer (WOAH/Advantage Dental); Anna Stern (WVCH); Kristin Swafford (PSU); Jaclyn Testani (CPCCO); Corinne Thayer (ODS); Jennifer Valentine (OHA); Mark

Whitaker (Providence); Diana White (PSU); and Dustin Zimmerman (OHA)

By phone:

Ellen Altman, Lyle Jackson, Deborah Loy, Ben Messner, Rebecca Ross, Melinda West, NW Medical Center, OHA, UHA, WOAHA

CLINICAL DIRECTORS SESSION

1. Introductions & Announcements

Introductions/
Announcements

- Lisa Bui shared parking instructions with all.
- Introductions were made around the room and from the phone.
- Jim Rickards was introduced as the new Chief Medical Officer by Dr. Kim Wentz.

Review of November
Notes

Notes from the November QHOC meeting were not available this month. They will be available by the February QHOC meeting.

Older Adult BH
Investment: (Nirmala
Dhar, Diana White, and
Kristen Swafford)

Serving Older Adults with Behavioral Needs:

- Senior Mental Health Investment Report;
- 2014 recommendations;
- Accomplishments- infrastructure/training;
- Current Focus : Primary Care;
- Primary care, aging, and behavioral health;
- Support for primary care providers & clinics;
- Primary care trainings overview;

	<ul style="list-style-type: none"> ▪ Partnering for progress; <p>Behavioral Health System Information:</p> <ul style="list-style-type: none"> ▪ Senior behavioral health investment; ▪ Why focus on aging? ▪ What is senior behavioral health? ▪ Older Adult Behavioral Health Specialists' functions; <p>Older Adult Behavioral Health Specialists Contact List (hand-out)</p>
<p>Hospital Performance Program: Sara Kleinschmit</p>	<ul style="list-style-type: none"> ▪ HTPP background; ▪ Timing; ▪ Funding; ▪ Incentive payments; ▪ Hospital Performance Metrics Advisory Committee function; ▪ Detailed domains and measures; ▪ Future of the HTPP; ▪ HTPP next steps; ▪ Opioid measure under review;
<p>HERC: (Cat Livingston)</p>	<ul style="list-style-type: none"> ▪ Diagnostic imaging for back pain; ▪ Repeat imaging for low back pain; ▪ Out-of-hospital births; ▪ Nitrous oxide use for labor pain management; ▪ Skin substitutes for chronic skin ulcers- what's recommended/what's not; ▪ Bariatric surgery- centers of excellence, children and adolescents, age disparity;

	<ul style="list-style-type: none"> ▪ Question: Advanced MRI for cancer- is the table acceptable or would another format be more useful? ▪ Tobacco cessation prior to surgical procedures – choice 1 or 2; 	
Other	Jim Rickards shared his goals and plans as the new Chief Medical Officer for OHA;	
TOPIC	DISCUSSION	ACTION ITEM(S)
Older Adult Behavioral Health Investment	Discussed primary care needs of a population that will be booming in the near future and why there is a need to focus on this group.	<u>Action Item:</u> Send contact information.
Jim Rickards, CMO		<u>Action item:</u> Send out Jim’s contact information
From the Floor	EPSDT issues of general concern.	<u>Action Item:</u> E-mail conversation of this matter to attendees.
JOINT LEARNING SESSION		
	Behavioral Health Integration	
Quality and Performance Improvement Session (2.5 hrs.)		
Introductions		
Complaints/Grievances: Tressa Perlicek	<ul style="list-style-type: none"> ▪ The first quarter has been reported in; ▪ Ann Brown will be taking leadership over this with a desired goal of more accuracy; ▪ The new updated format should be in use by now; ▪ Standardized training would be helpful. The idea is to create a workgroup with at least one representative from each CCO participating; 	

	<ul style="list-style-type: none"> At this time, continue to send reports to David Fischer;
<p>Statewide PIP: Diabetes-SPMI-Final Data Report: Susan Arbor</p>	<p>Statewide PIP – Baseline SFY 12, Remeasurements SFY 14 & SFY 15:</p> <ul style="list-style-type: none"> Overall, there were no increases though some plans may have. There were a variety of reasons given for the stats; This is the last time to discuss this PIP; <p>Statewide PIP for Opioid use/doses:</p> <ul style="list-style-type: none"> CDC recommendation is 90mg; A monthly report was overwhelmingly chosen over quarterly; Would like to have name, DOB, prime ID, and prescribing physician information included; Desire is to go by the calendar year for baseline and subsequent CMS reporting; CY 2014 is the baseline year;
<p>QAPI- Discussion of Elements: Lisa Bui</p>	<ul style="list-style-type: none"> Health National Disparities Report discussed; Reviewed the draft 2015 QAPI Evaluation Tool;
<p>Items from the floor: All</p>	<ul style="list-style-type: none"> PIP reports due at the end of this month; FamilyCare is revamping their NOA and is asking for samples from other CCOs; Protocol tool for OARs- Is there something similar to ISPA?
<p>Next Meeting</p>	
<p>Monday, February 8, 2016 9:00 am - 3:30 pm <i>HSB Conference Room 137 A-D</i> Toll free dial-in: 888-278-0296 Participant Code: 310477 Parking: Map Office: 503-378-5090 x0</p>	

Applied Behavioral Analysis
Training for Coordinated Care Organizations

March 18, 8:00 - 5:00

Location: Trillium Behavioral Health
Oregon Research Institute Building
1776 Millrace Drive
Eugene Oregon 97403

A Conference Call number will be provided at a later date

Morning 8:00 – 12:00:

Wendy Machalicek, Ph.D., BCBA-D Special Education, Associate Professor of Special Education
at U of O

1. Brief Background of ABAABA Clinical Guidelines
2. Service Authorization and Utilization management review criteria
3. ABA provider information
4. Care Coordination issues: Developmental Disabilities, schools, Early Intervention Programs

Afternoon 1:00 – 5:00:

Lea Forsman, Ph.D. Operations and Policy Analyst Child Behavioral Health

1. Overview ABA benefit in Oregon Health Plan
2. State planning and implementation process
3. OHA experience in prior authorization
4. Billing and payment

1/11/16: Behavioral Health Directors Meeting

- Attendance: Bruce Abel, Stacey Brubaker, Cheryl Cohen, Karen Weiner, Shelby Sanford, Mike Franz, Stan Gilbert, Laurence Colman, Lynnea Lindsey-Pengelly, David Geels.
- On Phone: Ron Lagergen, Ralph Summers, Karla McCafferty.

Guest: Cherryl Ramirez (AOCMHP), Mike Morris (OHA/HSD)

1. Discussion on need to give regular report back to QHOC on work in BH Directors meeting. Agreed to include meeting minutes in QHOC packet and Lynnea will give brief highlights during QHOC meeting.
2. Certified Community Behavioral Health Statewide planning process. General discussion about the potential upside and downside of pursuing CCBHC certification.
 - Pursuing CCBHC certification may be more of a heavy lift for some orgs than others. Some orgs appear to be choosing alternate options including Behavioral Health Home tier options or getting better inclusion of MH services through PCPCH model; allowing increased flexibility by orgs that may not be able to meet aspects required as CCBHCs.
 - Cherryl Ramirez (AOCMHP) reports that informal survey indicated that more non-profit orgs and sub-contractors are interested in CCBHC status than County based programs (CMHPs). CMHPs do see that many of the elements of CCBHCs are worth achieving even if certification is not immediate goal.
 - Mike Morris as OHA project lead for CCBHC gave overview:
 - i. 24 States received planning grants; only 8 States will actually get ok to implement. Due to Oregon's Health Transform efforts we may have advantage.
 - ii. A minimum of two sites need to be fully developed prior to submission of application; one urban, one rural with a max of up to 30.
 - iii. Perspective payment is a part of the modelling, similar to basis of FQHCs. This is obvious benefit of CCBHC. May need sign Tech Assist to manage cost reporting requirements. Payments for quality metrics may also be included.
 - iv. Technical Assistance is being provided by Feds including PPS, Research /Project Evaluation, etc.
 - v. Currently OHA hiring project lead and other staff to oversee the project.

- vi. CCBHC's can meet some requirements through a direct contact with other org but others must be met by organization itself. Substance use treatment is one such service that must be provided by CCBHC itself.
- Related meetings/updates:
 - i. HSD stakeholder meeting is being held on January 13th; announcement has gone out.
 - ii. Trillium (per Bruce) will be hosting a CCBHC forum on Friday January 22, 2016 that will be facilitated by Dale Jarvis (2pm – 5pm) in Eugene. This is for orgs that are moving forward with CCBHC process.
3. Integration of Behavioral Health services.
- Challenges of integrating Behavioral Health into PCPCHs. Need to develop expertise/training in Behaviorist functioning within Primary care settings; facilitate billing for both BH and Health codes; incentivize this role/function (utilizing encounter data, coding flexibility, etc); promoting the benefits such as streamline documentation standards; develop coordination/referral process to access more comprehensive BH care including ACT teams/ Wraparound.
 - Trillium using auto adjudication for those members coming in for brief treatment (I.e. Less than 5 sessions, CCO TBD) that eliminates the use of enrollment requirements, but still incentivizes (financially) this practice (don't de-incentivize brief treatment that produces positive outcomes).
 - Look at Colorado Advancing Care Together Initiative for more information on integration of BH into Physical health.
4. Psychiatric Consultation Codes. Bruce requesting input re CPT code that would be available for telephone consult between Primary care provider and Psychiatrist. Because there is no face to face eval the usual Consultation codes would not work. Bruce handed out code option that is being used in Minnesota that might work and has already received CMS approval. Question whether similar could be ok in Oregon (see: Minnesota Department of Human Services Provider Manual – Psychiatric Consultation to Primary Care). This code allows for non-face to face consultation, case does not need to be open and both sides can bill.
- Mike Morris will take the handout back and determine who to take it to in order to advance this option for consultation billing.
5. Update on USDOJ status: Nothing definitive yet. Attorney still negotiating agreement.
6. Applied Behavioral Analysis: Continued expression by group of multiple concerns about implementation of ABA through the CCOs. Concerns continue to related to: severe lack of providers of service in Oregon to deliver service at all levels; lack of good data to base future utilization of service; move away from traditional providers of this service at DD services, schools, ESD who have been doing this work for years and are not properly

qualified or interested in doing as a primary function. OHA continues to sound the “its working fine” under FFS but there is considerable skepticism on this by Bx Health directors.

- Next ABA Workgroup meeting is scheduled for 2/4/2016 2pm at the Cherry Heights training offices. This will be the first all stakeholder meeting- all Bx Health Directors can attend. Lea Forsman is facilitating.
 - Trillium also us developing a training on Autism and ABA with a professor at U of O. Tentatively schedule for March 18, 2016; 8a to 5p. All are invited –will send out info as details are finalized.
7. Agreement between CCOs on when high need youth transfer across CCOs - disc pended to next meeting. Karen will facilitate...



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Quality and Health Outcomes Committee Public Health Division updates – February 2016

Data and Reports

2015 Updates to State Health Profile: Oregon's State Health Profile includes a broad set of indicators that offer a snapshot of the health of people in our state. This information helps us understand the health of our communities, celebrate and learn from successes and identify areas for improvement. The State Health Profile page includes reports for the entire population in Oregon and, in many cases, for populations residing in CCO areas. State Health Profile reports are available at:

<https://public.health.oregon.gov/About/Pages/HealthStatusIndicators.aspx>.

Prescribing and Overdose Data: The Public Health Division has posted an interactive tool that contains state and county level data on controlled substance prescribing and drug overdose health outcomes (hospitalizations and deaths). This data dashboard is available at: <http://public.health.oregon.gov/PreventionWellness/SubstanceUse/Opioids/Pages/data.aspx>.

Marijuana Report: Marijuana Use, Attitudes and Health Effects in Oregon: In November 2014, Oregon voters passed Measure 91 to legalize non-medical retail marijuana sale in the state. The Oregon Health Authority's Public Health Division created this report to provide current data on marijuana-related public health surveys and other measures. This report summarizes readily available data sources that describe marijuana use, attitudes and health effects. These data shed light on the public health impacts of marijuana use and create a baseline in order to monitor trends over time. The report is available at:

<http://public.health.oregon.gov/PreventionWellness/marijuana/Documents/oha-8509-marijuana-report.pdf>

Resources and Updates

2016 Meaningful Care Conference: Registration is now open for the Meaningful Care Conference: LGBTQI Healthcare in an Era of Health Transformation. The **2016 Meaningful Care Conference** is the effort of a group of LGBTQI-focused community programs who have joined together to promote cultural competency for healthcare and social service providers working with members of the LGBTQI (lesbian, gay, genderqueer, bisexual, trans*, queer, questioning, intersex) community. This key step in local efforts will improve health care utilization, satisfaction, and outcomes for LGBTQI consumers through expanding access to culturally competent care. This year's conference will focus on the rapidly changing healthcare

landscape and what it means for the LGBTQI community. For more information or to register, please go to the website: www.oregonlgbtqhealth.org/mcc

National Prediabetes Awareness Campaign: Last month, a national prediabetes awareness campaign was launched by the Ad Council in collaboration with the CDC, American Diabetes Association, and American Medical Association. The campaign's public service announcements (PSAs) encourage people to visit <https://doihaveprediabetes.org> to find out their prediabetes risk. The website features a short quiz, lifestyle tips, and links to prevention programs across the country that are recognized by CDC as part of the National Diabetes Prevention Program (www.cdc.gov/diabetes/prevention). The PSAs can be viewed on the campaign's YouTube channel (<https://www.youtube.com/channel/UCFG5XgDdJHkz2aW7UJ2in7A>). For more information contact andrew.d.epstein@state.or.us.

March 2016 Lifestyle Coach Training for National Diabetes Prevention Program: For organizations interested in offering a CDC-recognized lifestyle change program to prevent diabetes among patients, employees or community members, a lifestyle coach training will be presented March 4-5 in Portland through Emory University's Diabetes Training and Technical Assistance Center. The cost for participation in this two-day training is \$750 per person. Registration is available at: <http://www.cvent.com/d/2fqpcy>. For more information contact Don Kain at kaind@ohsu.edu.

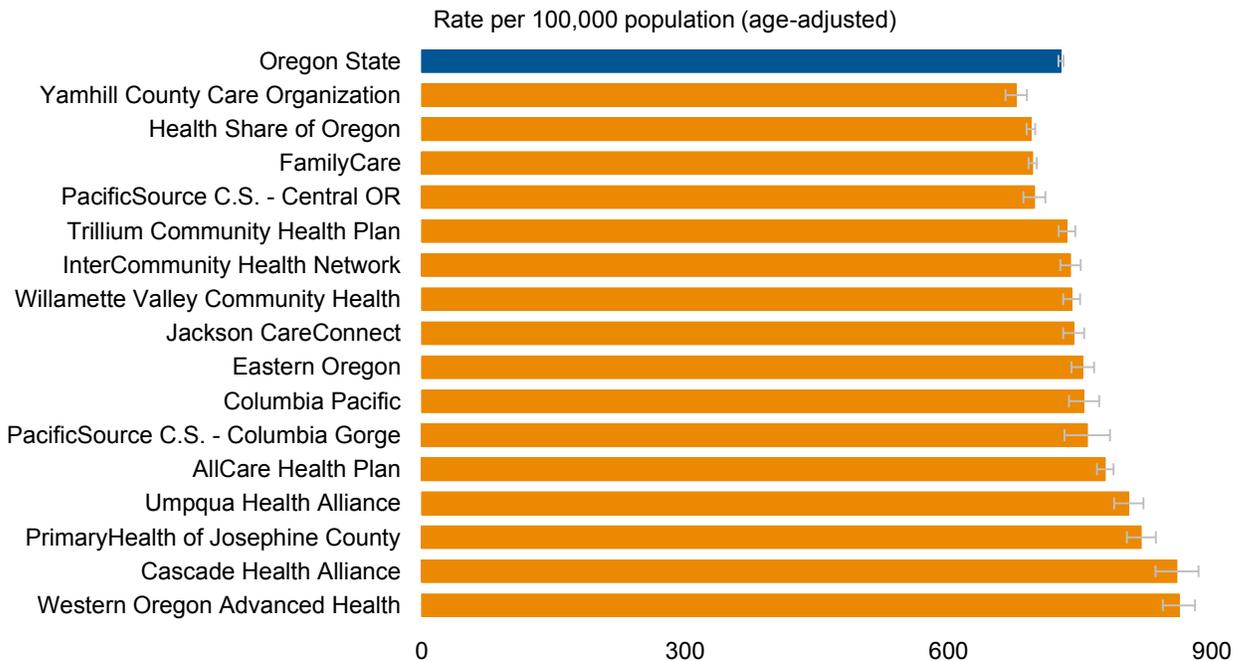
National Council on Aging Panel Discussion: Centralized and Coordinated Referral and Enrollment Processes: Partnering with a health care organization is important, but it doesn't ensure that chronic disease self-management education (CDSME) workshops will be filled. Foresight and collaborative planning are required to develop processes for obtaining and tracking referrals, enrolling participants in workshops, and filling seats. Join a panel discussion featuring three experts in the field who will share their strategies for implementing centralized and coordinated referral and enrollment processes, including data management, that have led to their success in working with health care systems. This panel is part of the *Community-Integrated Health Care Webinar Series*. For more information visit: <https://cc.readytalk.com/cc/s/registrations/new?cid=u6v8cszge4w1>

Immunization Resources: Resources and tools to help health care providers and others improve childhood and adolescent immunization rates are now available on the Public Health Division's AFIX Resources webpage. These tools, which include a self-assessment and sample quality improvement plans, allow providers to identify the root causes for low immunization rates within their clinic and plan effective strategies to address these root causes. Resources and tools are available at: <https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/Immunization/ProviderResources/Pages/AFIXResource.aspx>

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

All causes of death

Gray lines represent confidence intervals

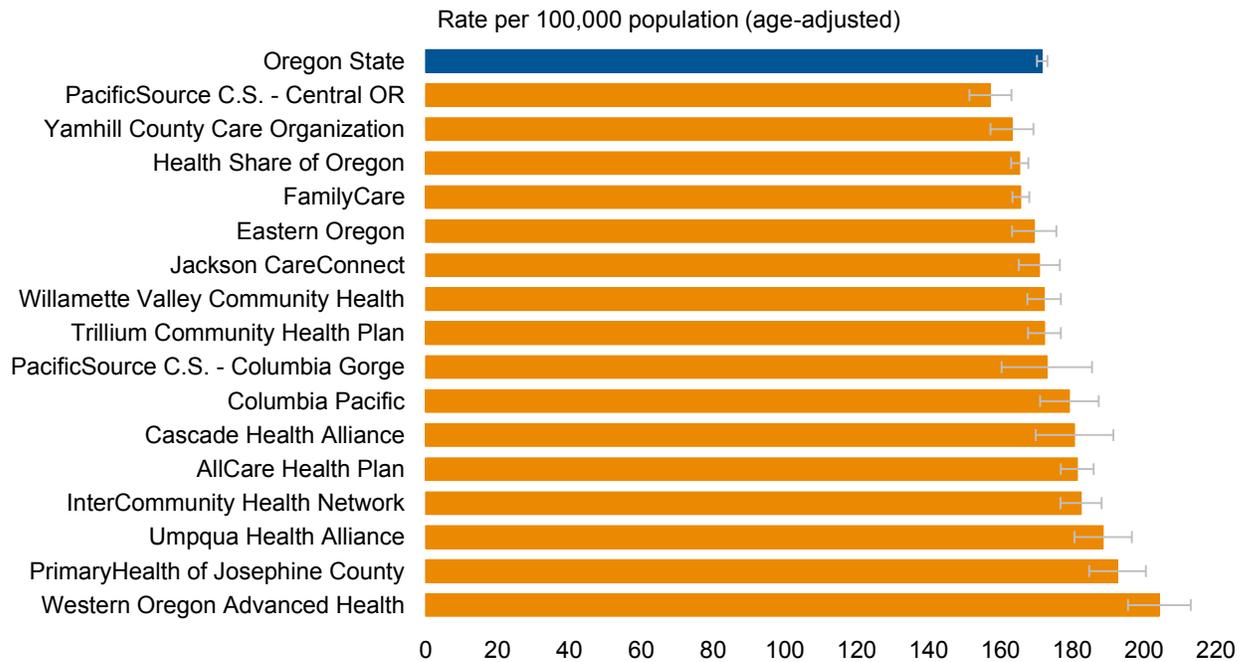


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	778.7	3,657	311,502
Cascade Health Alliance	860.4	684	63,344
Columbia Pacific	754.4	1,057	111,554
Eastern Oregon	753.0	1,840	194,198
FamilyCare	696.1	11,813	1,701,228
Health Share of Oregon	694.0	11,348	1,644,682
InterCommunity Health Network	738.9	2,234	247,856
Jackson CareConnect	742.6	2,127	203,606
PacificSource C.S. - Central OR	697.9	1,671	204,793
PacificSource C.S. - Columbia Gorge	758.2	470	47,224
PrimaryHealth of Josephine County	819.8	1,377	105,492
Trillium Community Health Plan	735.2	3,354	368,142
Umpqua Health Alliance	805.4	1,264	101,647
Western Oregon Advanced Health	862.6	1,207	85,375
Willamette Valley Community Health	740.4	3,302	399,019
Yamhill County Care Organization	677.4	1,717	234,279
Oregon State	728.2	32,287	3,833,035

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Cancer

Gray lines represent confidence intervals

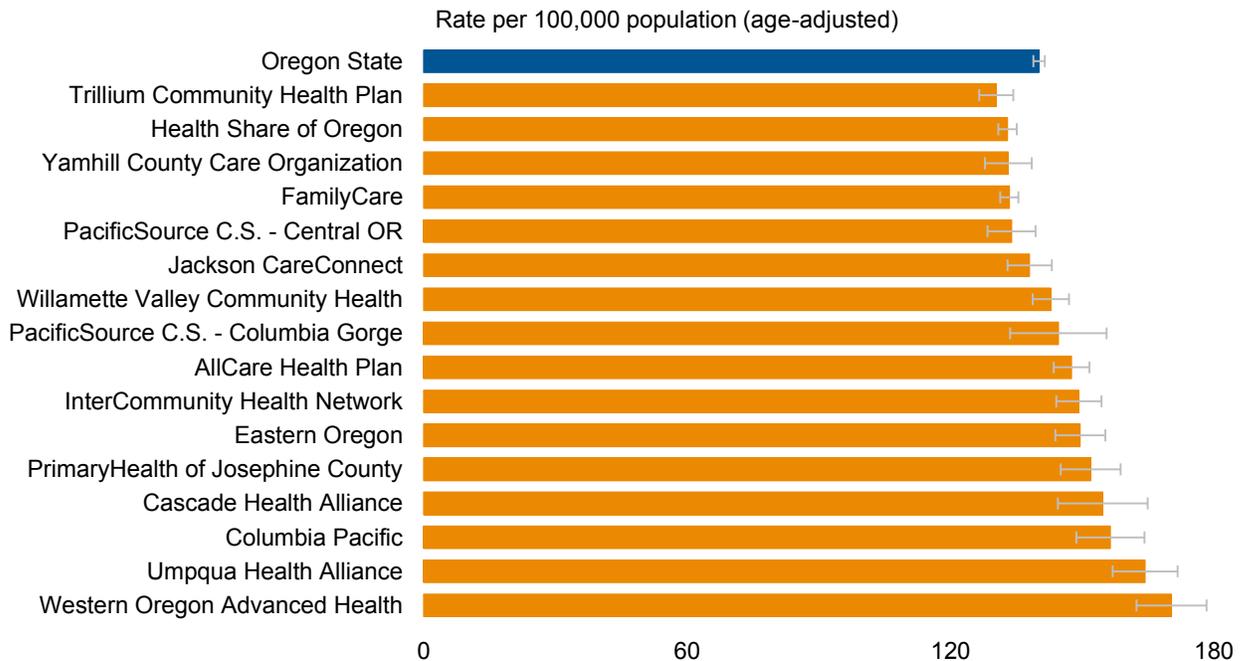


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	181.4	860	311,502
Cascade Health Alliance	180.7	153	63,344
Columbia Pacific	179.3	264	111,554
Eastern Oregon	169.5	419	194,198
FamilyCare	165.7	2,773	1,701,228
Health Share of Oregon	165.4	2,667	1,644,682
InterCommunity Health Network	182.5	560	247,856
Jackson CareConnect	170.9	490	203,606
PacificSource C.S. - Central OR	157.3	392	204,793
PacificSource C.S. - Columbia Gorge	172.9	103	47,224
PrimaryHealth of Josephine County	192.7	328	105,492
Trillium Community Health Plan	172.3	787	368,142
Umpqua Health Alliance	188.7	307	101,647
Western Oregon Advanced Health	204.3	300	85,375
Willamette Valley Community Health	172.2	760	399,019
Yamhill County Care Organization	163.3	408	234,279
<i>Oregon State</i>	<i>171.6</i>	<i>7,615</i>	<i>3,833,035</i>

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Heart Disease

Gray lines represent confidence intervals

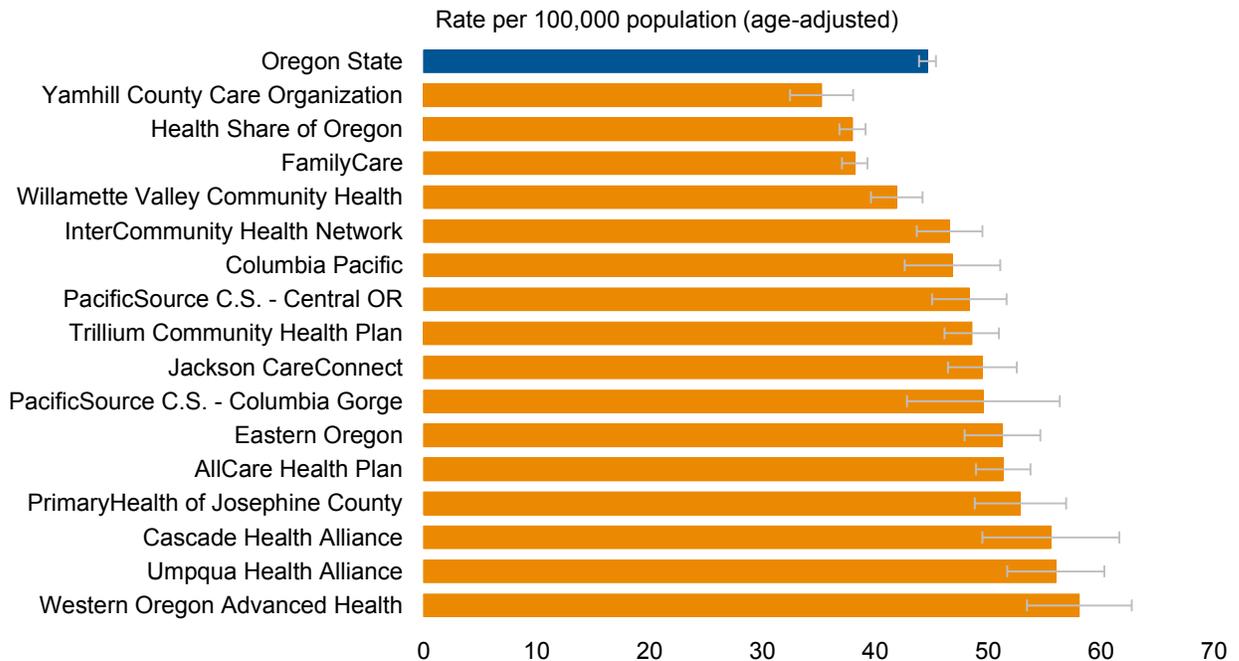


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	147.6	728	311,502
Cascade Health Alliance	154.7	126	63,344
Columbia Pacific	156.5	222	111,554
Eastern Oregon	149.6	377	194,198
FamilyCare	133.4	2,281	1,701,228
Health Share of Oregon	133.0	2,190	1,644,682
InterCommunity Health Network	149.3	460	247,856
Jackson CareConnect	138.0	412	203,606
PacificSource C.S. - Central OR	133.9	325	204,793
PacificSource C.S. - Columbia Gorge	144.6	95	47,224
PrimaryHealth of Josephine County	152.0	271	105,492
Trillium Community Health Plan	130.4	614	368,142
Umpqua Health Alliance	164.3	271	101,647
Western Oregon Advanced Health	170.4	250	85,375
Willamette Valley Community Health	142.9	653	399,019
Yamhill County Care Organization	133.2	345	234,279
Oregon State	140.2	6,340	3,833,035

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Chronic lower respiratory diseases

Gray lines represent confidence intervals

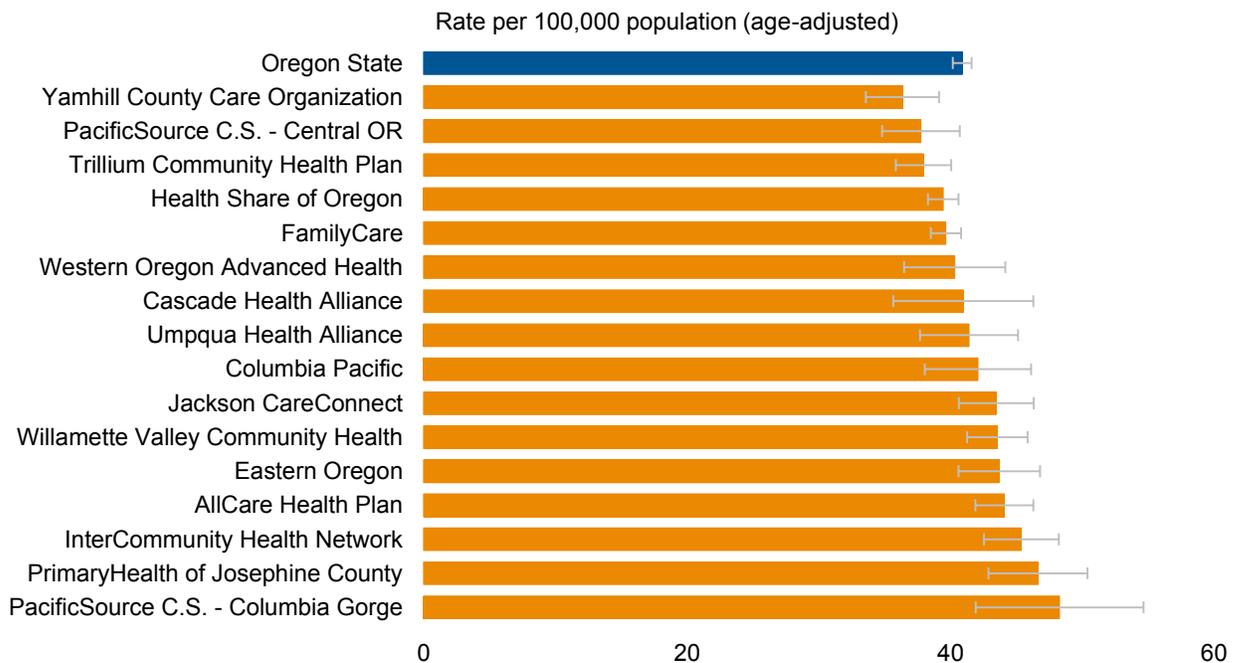


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	51.3	250	311,502
Cascade Health Alliance	55.6	46	63,344
Columbia Pacific	46.8	67	111,554
Eastern Oregon	51.3	128	194,198
FamilyCare	38.2	618	1,701,228
Health Share of Oregon	38.0	592	1,644,682
InterCommunity Health Network	46.6	142	247,856
Jackson CareConnect	49.5	144	203,606
PacificSource C.S. - Central OR	48.4	118	204,793
PacificSource C.S. - Columbia Gorge	49.6	29	47,224
PrimaryHealth of Josephine County	52.9	94	105,492
Trillium Community Health Plan	48.6	223	368,142
Umpqua Health Alliance	56.0	93	101,647
Western Oregon Advanced Health	58.1	87	85,375
Willamette Valley Community Health	41.9	183	399,019
Yamhill County Care Organization	35.3	87	234,279
<i>Oregon State</i>	<i>44.6</i>	<i>1,957</i>	<i>3,833,035</i>

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Cerebrovascular diseases

Gray lines represent confidence intervals

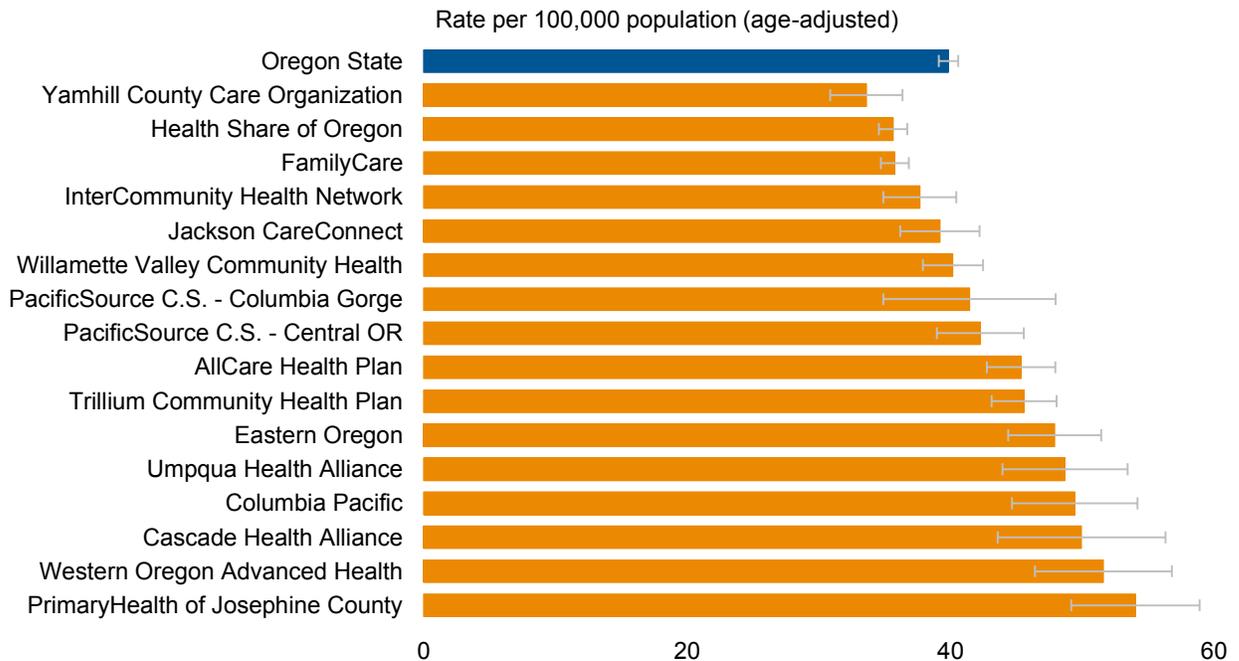


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	44.1	220	311,502
Cascade Health Alliance	41.0	33	63,344
Columbia Pacific	42.1	59	111,554
Eastern Oregon	43.7	110	194,198
FamilyCare	39.7	668	1,701,228
Health Share of Oregon	39.5	640	1,644,682
InterCommunity Health Network	45.4	139	247,856
Jackson CareConnect	43.5	130	203,606
PacificSource C.S. - Central OR	37.8	89	204,793
PacificSource C.S. - Columbia Gorge	48.3	32	47,224
PrimaryHealth of Josephine County	46.7	85	105,492
Trillium Community Health Plan	38.0	179	368,142
Umpqua Health Alliance	41.4	68	101,647
Western Oregon Advanced Health	40.3	60	85,375
Willamette Valley Community Health	43.6	197	399,019
Yamhill County Care Organization	36.4	94	234,279
Oregon State	40.9	1,836	3,833,035

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Accidents (unintentional injuries)

Gray lines represent confidence intervals

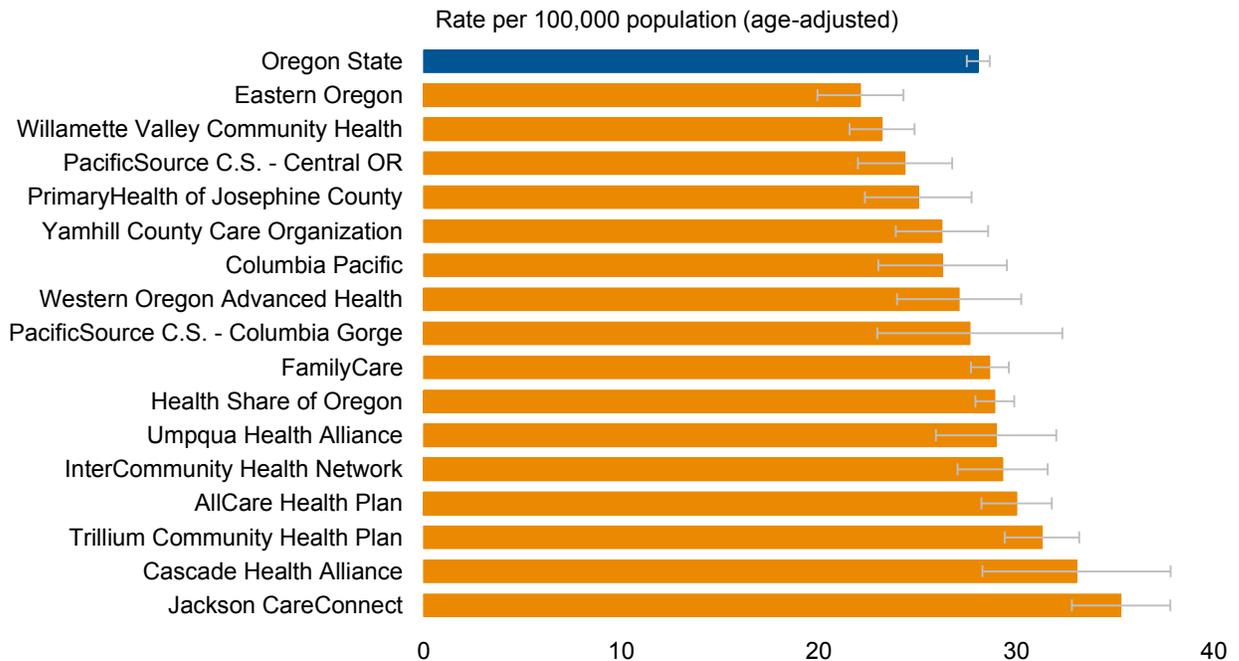


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	45.4	167	311,502
Cascade Health Alliance	50.0	34	63,344
Columbia Pacific	49.4	59	111,554
Eastern Oregon	47.9	101	194,198
FamilyCare	35.8	622	1,701,228
Health Share of Oregon	35.7	598	1,644,682
InterCommunity Health Network	37.7	102	247,856
Jackson CareConnect	39.2	93	203,606
PacificSource C.S. - Central OR	42.3	90	204,793
PacificSource C.S. - Columbia Gorge	41.5	22	47,224
PrimaryHealth of Josephine County	54.1	67	105,492
Trillium Community Health Plan	45.6	187	368,142
Umpqua Health Alliance	48.7	58	101,647
Western Oregon Advanced Health	51.6	54	85,375
Willamette Valley Community Health	40.2	168	399,019
Yamhill County Care Organization	33.6	83	234,279
<i>Oregon State</i>	<i>39.9</i>	<i>1,652</i>	<i>3,833,035</i>

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Alzheimer's disease

Gray lines represent confidence intervals

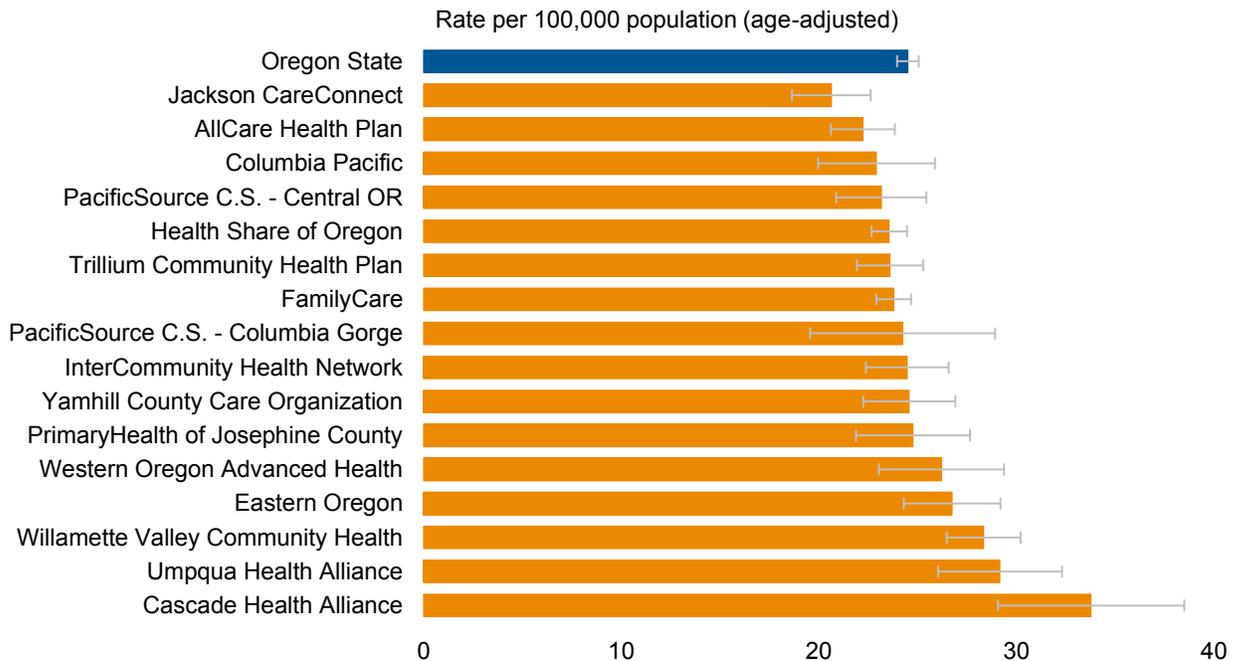


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	30.0	156	311,502
Cascade Health Alliance	33.1	26	63,344
Columbia Pacific	26.3	36	111,554
Eastern Oregon	22.1	56	194,198
FamilyCare	28.7	488	1,701,228
Health Share of Oregon	28.9	473	1,644,682
InterCommunity Health Network	29.3	91	247,856
Jackson CareConnect	35.3	111	203,606
PacificSource C.S. - Central OR	24.4	57	204,793
PacificSource C.S. - Columbia Gorge	27.7	19	47,224
PrimaryHealth of Josephine County	25.0	47	105,492
Trillium Community Health Plan	31.3	151	368,142
Umpqua Health Alliance	29.0	50	101,647
Western Oregon Advanced Health	27.1	41	85,375
Willamette Valley Community Health	23.2	108	399,019
Yamhill County Care Organization	26.2	69	234,279
Oregon State	28.1	1,280	3,833,035

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Diabetes

Gray lines represent confidence intervals

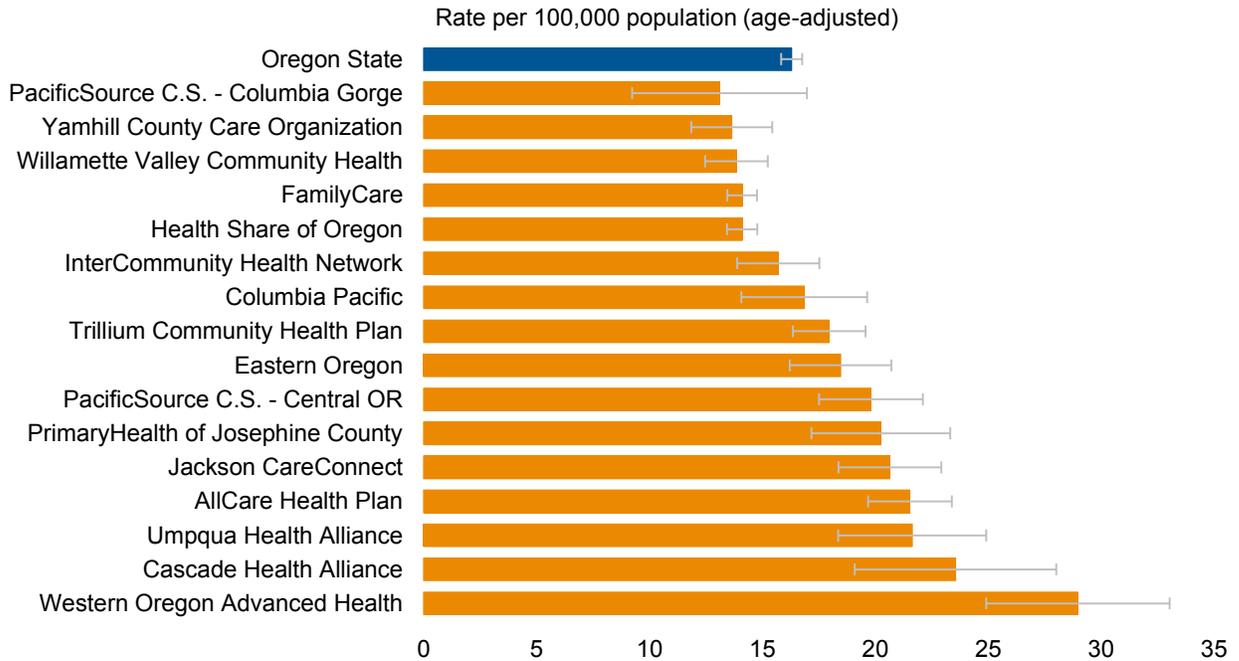


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	22.2	104	311,502
Cascade Health Alliance	33.8	28	63,344
Columbia Pacific	22.9	33	111,554
Eastern Oregon	26.8	65	194,198
FamilyCare	23.8	400	1,701,228
Health Share of Oregon	23.6	381	1,644,682
InterCommunity Health Network	24.5	74	247,856
Jackson CareConnect	20.6	59	203,606
PacificSource C.S. - Central OR	23.2	57	204,793
PacificSource C.S. - Columbia Gorge	24.3	15	47,224
PrimaryHealth of Josephine County	24.8	40	105,492
Trillium Community Health Plan	23.6	108	368,142
Umpqua Health Alliance	29.2	47	101,647
Western Oregon Advanced Health	26.2	38	85,375
Willamette Valley Community Health	28.4	126	399,019
Yamhill County Care Organization	24.6	61	234,279
Oregon State	24.5	1,087	3,833,035

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Suicide

Gray lines represent confidence intervals

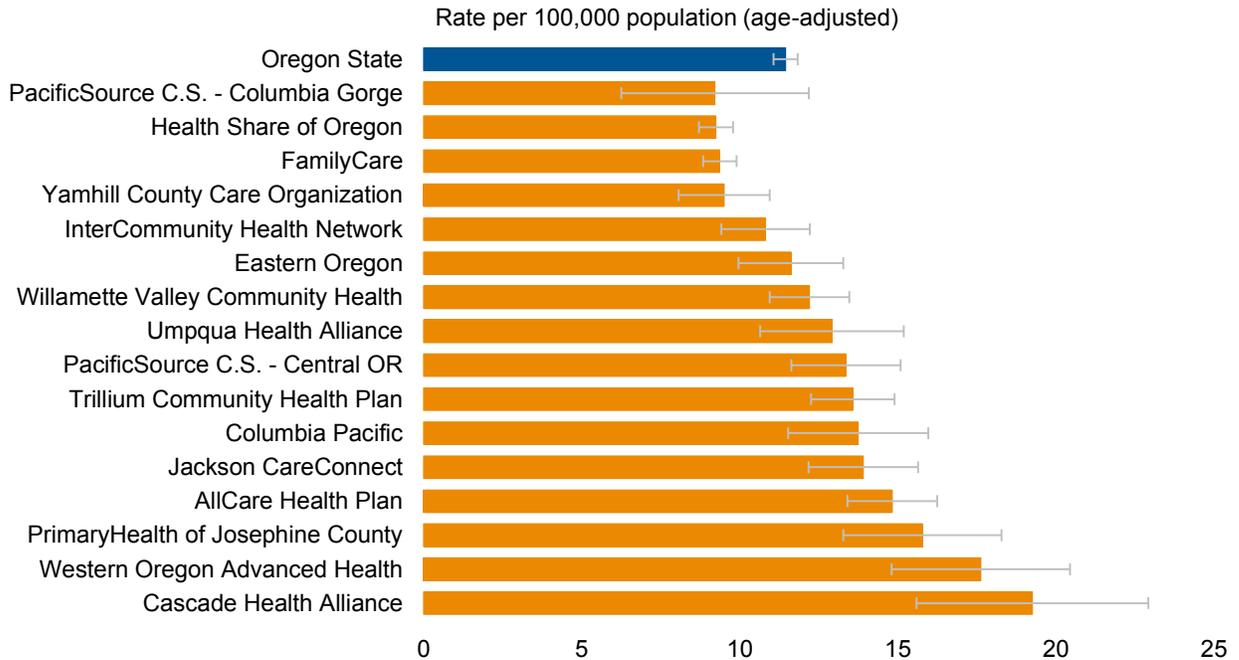


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	21.5	74	311,502
Cascade Health Alliance	23.6	15	63,344
Columbia Pacific	16.9	20	111,554
Eastern Oregon	18.5	37	194,198
FamilyCare	14.1	250	1,701,228
Health Share of Oregon	14.1	243	1,644,682
InterCommunity Health Network	15.7	41	247,856
Jackson CareConnect	20.7	45	203,606
PacificSource C.S. - Central OR	19.8	41	204,793
PacificSource C.S. - Columbia Gorge	13.1	6.3	47,224
PrimaryHealth of Josephine County	20.3	24	105,492
Trillium Community Health Plan	18.0	69	368,142
Umpqua Health Alliance	21.6	24	101,647
Western Oregon Advanced Health	29.0	28	85,375
Willamette Valley Community Health	13.9	55	399,019
Yamhill County Care Organization	13.7	32	234,279
Oregon State	16.3	652	3,833,035

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Chronic liver disease and cirrhosis

Gray lines represent confidence intervals

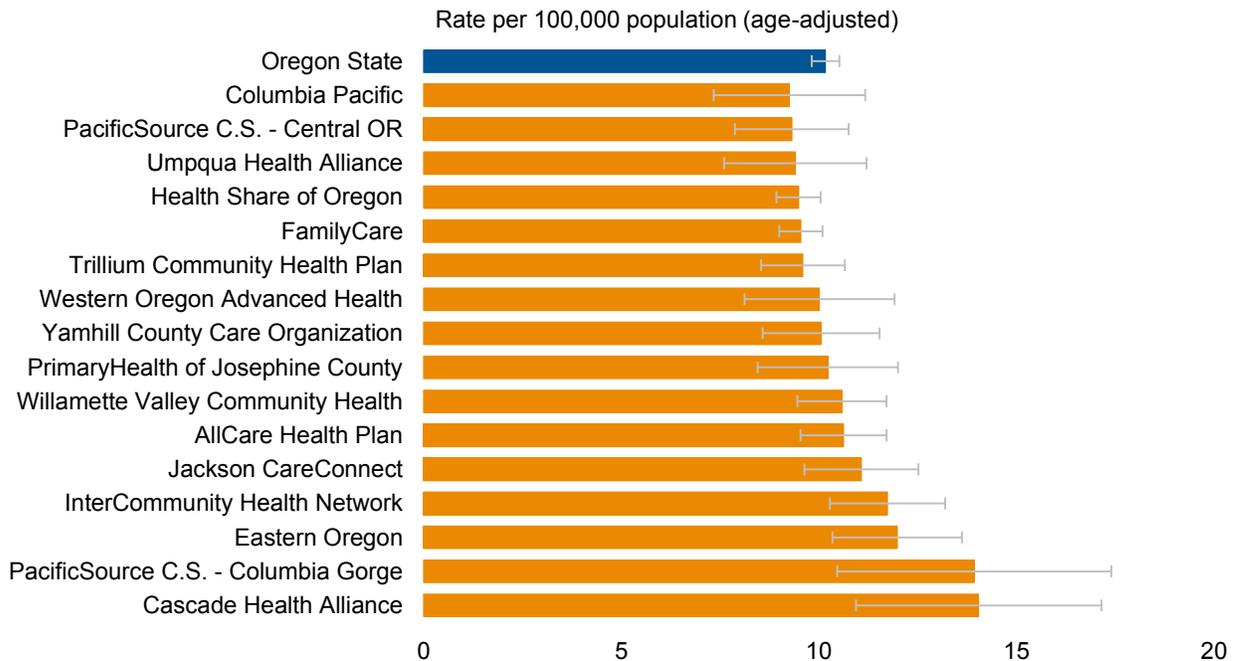


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	14.8	60	311,502
Cascade Health Alliance	19.3	15	63,344
Columbia Pacific	13.8	21	111,554
Eastern Oregon	11.6	27	194,198
FamilyCare	9.4	171	1,701,228
Health Share of Oregon	9.3	164	1,644,682
InterCommunity Health Network	10.8	33	247,856
Jackson CareConnect	13.9	36	203,606
PacificSource C.S. - Central OR	13.4	33	204,793
PacificSource C.S. - Columbia Gorge	9.2	5.3	47,224
PrimaryHealth of Josephine County	15.8	22	105,492
Trillium Community Health Plan	13.6	58	368,142
Umpqua Health Alliance	12.9	18	101,647
Western Oregon Advanced Health	17.6	21	85,375
Willamette Valley Community Health	12.2	51	399,019
Yamhill County Care Organization	9.5	24	234,279
Oregon State	11.5	508	3,833,035

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Influenza and pneumonia

Gray lines represent confidence intervals

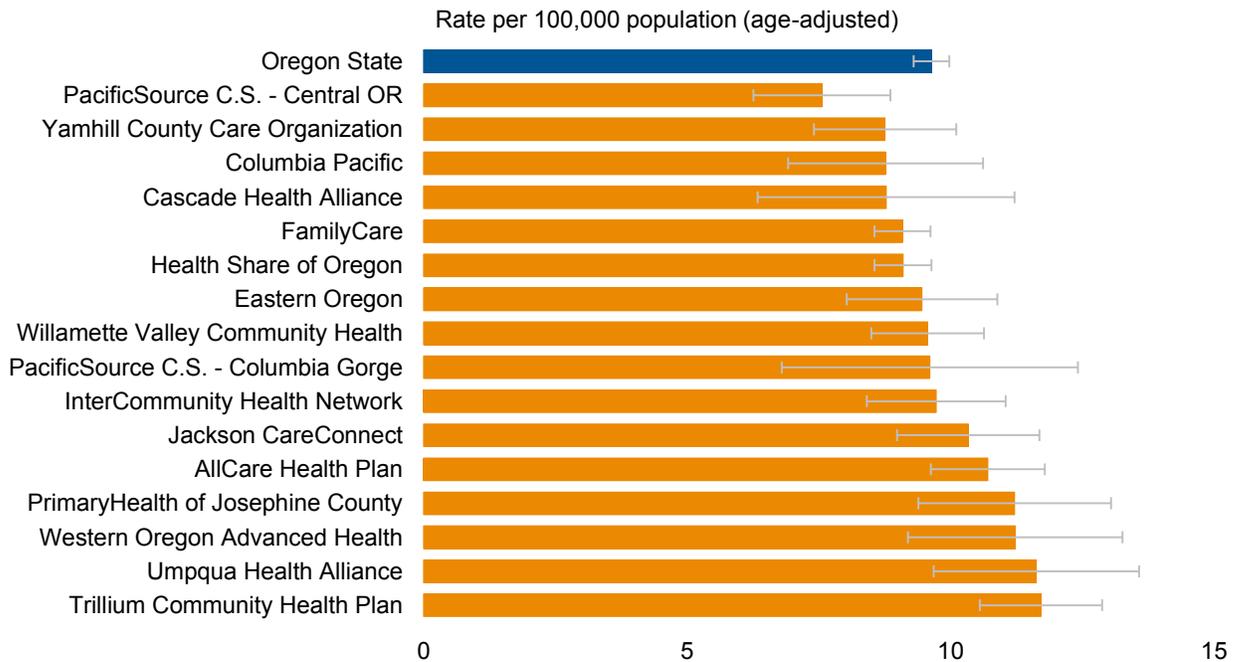


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	10.6	52	311,502
Cascade Health Alliance	14.1	11	63,344
Columbia Pacific	9.3	13	111,554
Eastern Oregon	12.0	29	194,198
FamilyCare	9.6	163	1,701,228
Health Share of Oregon	9.5	156	1,644,682
InterCommunity Health Network	11.7	35	247,856
Jackson CareConnect	11.1	33	203,606
PacificSource C.S. - Central OR	9.3	23	204,793
PacificSource C.S. - Columbia Gorge	13.9	9	47,224
PrimaryHealth of Josephine County	10.2	18	105,492
Trillium Community Health Plan	9.6	45	368,142
Umpqua Health Alliance	9.4	15	101,647
Western Oregon Advanced Health	10.0	15	85,375
Willamette Valley Community Health	10.6	48	399,019
Yamhill County Care Organization	10.1	25	234,279
<i>Oregon State</i>	<i>10.2</i>	<i>458</i>	<i>3,833,035</i>

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Hypertension and hypertensive renal disease

Gray lines represent confidence intervals

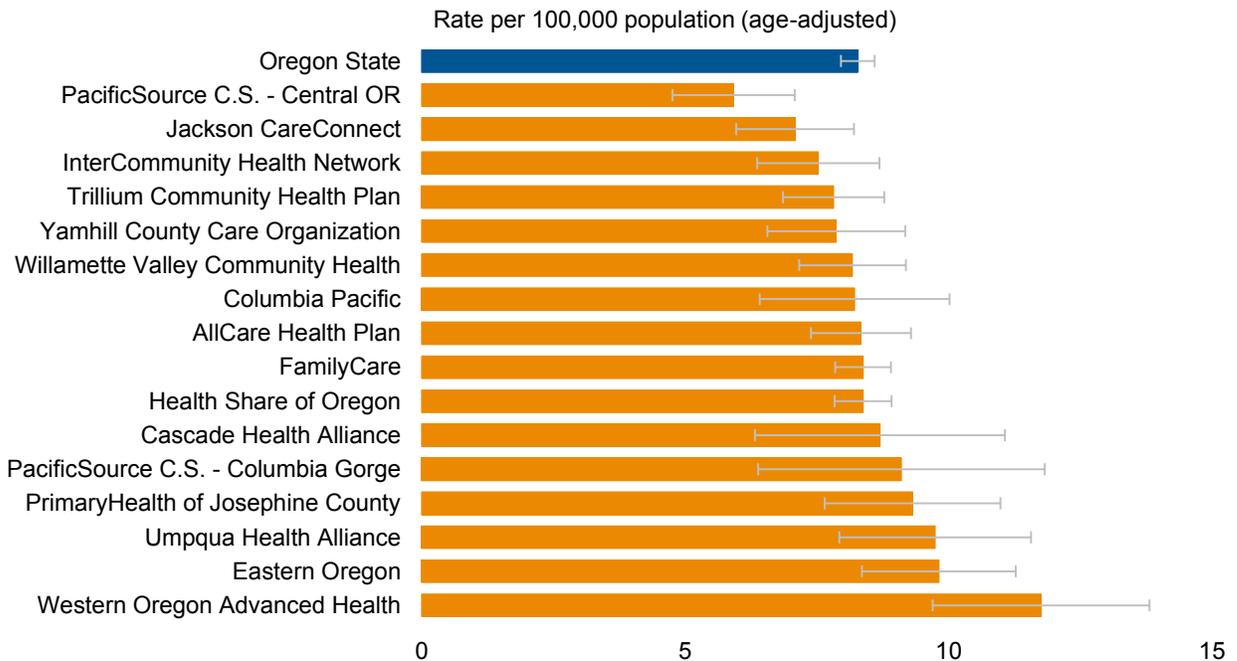


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	10.7	54	311,502
Cascade Health Alliance	8.8	7	63,344
Columbia Pacific	8.8	12	111,554
Eastern Oregon	9.5	24	194,198
FamilyCare	9.1	159	1,701,228
Health Share of Oregon	9.1	153	1,644,682
InterCommunity Health Network	9.7	30	247,856
Jackson CareConnect	10.3	32	203,606
PacificSource C.S. - Central OR	7.6	18	204,793
PacificSource C.S. - Columbia Gorge	9.6	6.4	47,224
PrimaryHealth of Josephine County	11.2	21	105,492
Trillium Community Health Plan	11.7	56	368,142
Umpqua Health Alliance	11.6	20	101,647
Western Oregon Advanced Health	11.2	17	85,375
Willamette Valley Community Health	9.6	44	399,019
Yamhill County Care Organization	8.8	23	234,279
<i>Oregon State</i>	<i>9.6</i>	<i>444</i>	<i>3,833,035</i>

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Kidney disease

Gray lines represent confidence intervals

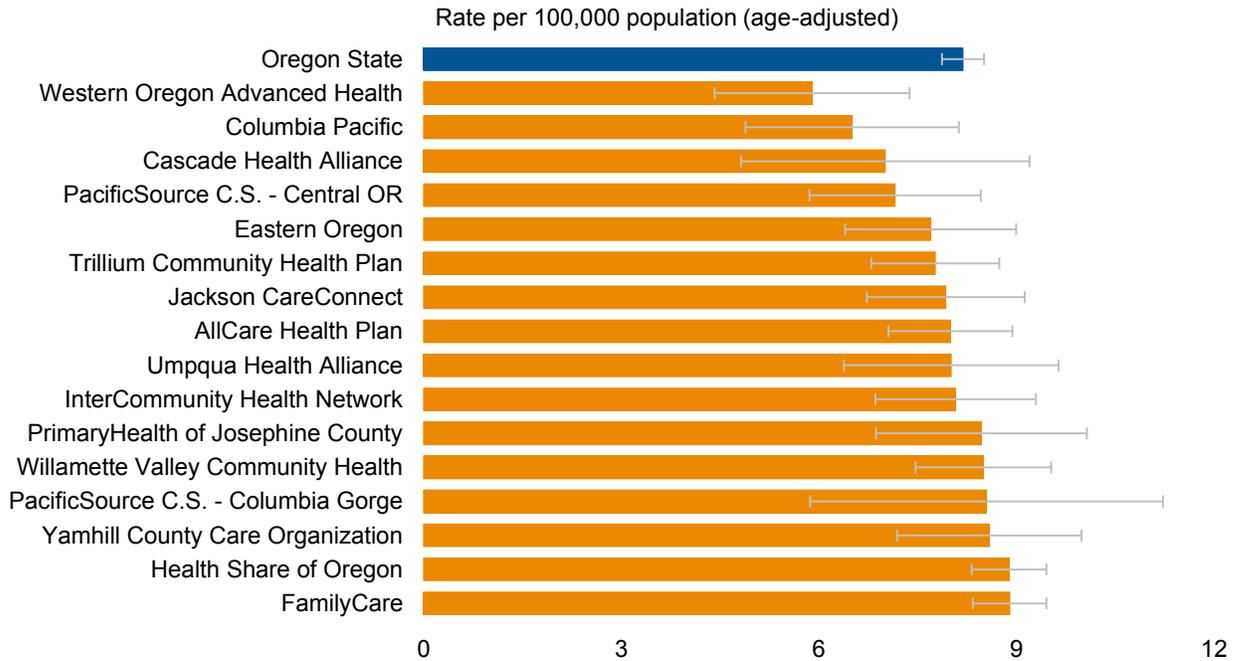


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	8.3	42	311,502
Cascade Health Alliance	8.7	7	63,344
Columbia Pacific	8.2	11	111,554
Eastern Oregon	9.8	25	194,198
FamilyCare	8.4	139	1,701,228
Health Share of Oregon	8.4	134	1,644,682
InterCommunity Health Network	7.5	23	247,856
Jackson CareConnect	7.1	22	203,606
PacificSource C.S. - Central OR	5.9	14	204,793
PacificSource C.S. - Columbia Gorge	9.1	6.1	47,224
PrimaryHealth of Josephine County	9.3	17	105,492
Trillium Community Health Plan	7.8	36	368,142
Umpqua Health Alliance	9.8	16	101,647
Western Oregon Advanced Health	11.8	18	85,375
Willamette Valley Community Health	8.2	36	399,019
Yamhill County Care Organization	7.9	20	234,279
Oregon State	8.3	370	3,833,035

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Parkinson's disease

Gray lines represent confidence intervals

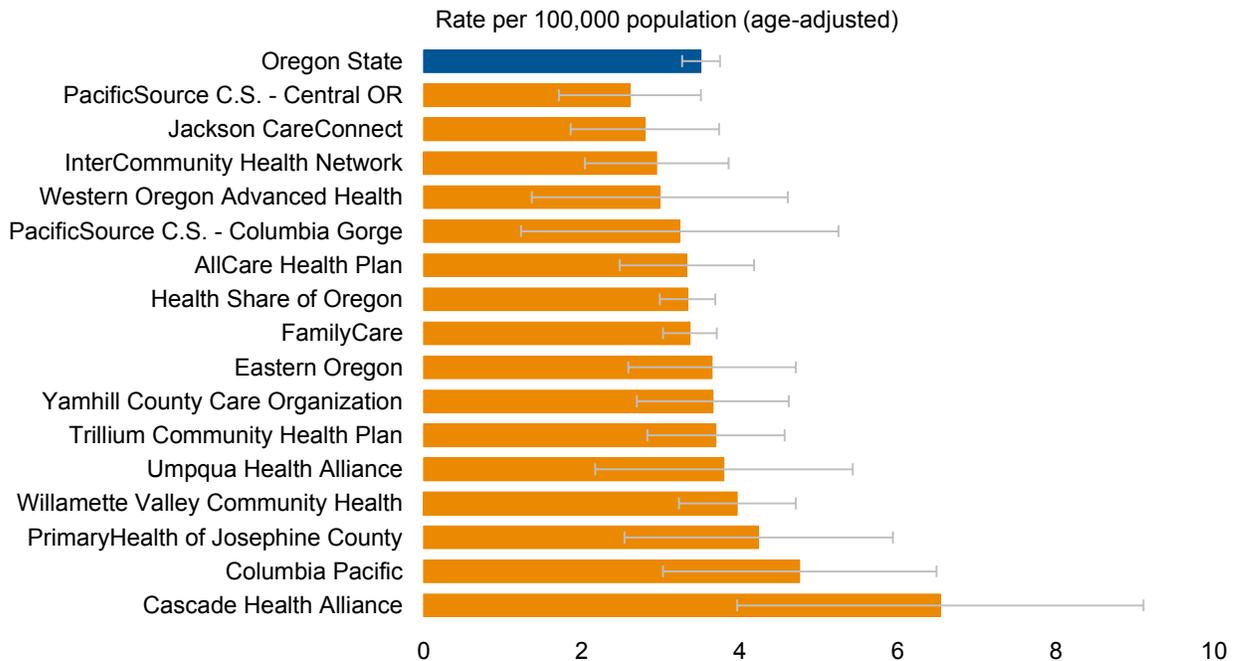


Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	8.0	40	311,502
Cascade Health Alliance	7.0	5.6	63,344
Columbia Pacific	6.5	9	111,554
Eastern Oregon	7.7	19	194,198
FamilyCare	8.9	141	1,701,228
Health Share of Oregon	8.9	135	1,644,682
InterCommunity Health Network	8.1	24	247,856
Jackson CareConnect	7.9	24	203,606
PacificSource C.S. - Central OR	7.2	17	204,793
PacificSource C.S. - Columbia Gorge	8.6	5.6	47,224
PrimaryHealth of Josephine County	8.5	15	105,492
Trillium Community Health Plan	7.8	35	368,142
Umpqua Health Alliance	8.0	13	101,647
Western Oregon Advanced Health	5.9	9	85,375
Willamette Valley Community Health	8.5	37	399,019
Yamhill County Care Organization	8.6	21	234,279
Oregon State	8.2	355	3,833,035

Leading causes of death in regions covered by Coordinated Care Organizations, 2007–2013

Perinatal conditions

Gray lines represent confidence intervals



Coordinated Care Organization <i>(Data represent entire population of CCO regions - not just enrolled population)</i>	Rate per 100,000 population (age-adjusted)	Deaths (average annual)	Population (average annual)
AllCare Health Plan	3.3	8	311,502
Cascade Health Alliance	6.5	3.6	63,344
Columbia Pacific	4.8	4.1	111,554
Eastern Oregon	3.7	6.6	194,198
FamilyCare	3.4	53	1,701,228
Health Share of Oregon	3.3	50	1,644,682
InterCommunity Health Network	3.0	5.7	247,856
Jackson CareConnect	2.8	4.9	203,606
PacificSource C.S. - Central OR	2.6	4.6	204,793
PacificSource C.S. - Columbia Gorge	3.2†	1.4	47,224
PrimaryHealth of Josephine County	4.2	3.4	105,492
Trillium Community Health Plan	3.7	10	368,142
Umpqua Health Alliance	3.8	3.0	101,647
Western Oregon Advanced Health	3.0	1.9	85,375
Willamette Valley Community Health	4.0	16	399,019
Yamhill County Care Organization	3.7	8	234,279
Oregon State	3.5	118	3,833,035

† = rates with a relative standard error > 30% should be considered unreliable

About the Data

Data Source: Oregon Death Certificate Data

Date: August 25, 2015

ACTIONLINE

DOES THIS SOUND FAMILIAR?

- *How can my alcohol/drug treatment program comply with HIPAA's HITECH Act amendments?*
- *We want to participate in a health information exchange without violating 42 C.F.R. Part 2 and HIPAA. Can you help?*
- *What information may we share through our electronic health record system?*
- *We were just served with a subpoena. How should we respond?*
- *The police have arrived with a search warrant. Can we let them in?*

The Oregon Health Authority (OHA) has subscribed to the Legal Action Center's Actionline (through June 2016) to support CCOs and their affiliated providers. The Center is nationally recognized and has extensive expertise answering questions about the confidentiality of alcohol/drug program records. Actionline lawyers share their expertise on the:

- Confidentiality of alcohol and drug treatment and prevention records under both 42 C.F.R. Part 2 and HIPAA; and
- Federal anti-discrimination laws that protect people with substance use disorders in employment, housing, and zoning.

The Actionline service will provide regulatory guidance, interpretation, and clarification of Part 2 and HIPAA. CCOs, CCO providers, and substance use treatment providers can call toll free, at (800) 223-4044 on any business day between 10 a.m. and 2 p.m. PST. Callers simply need to identify that they are calling from Oregon and ask to speak to the attorney on call. Upon request, the Center's lawyers can also provide an opinion in writing.

The services are free of charge and there is no limit on the number of calls that can be placed through June 2016. Consultations with the Center may be considered confidential, lawyer-client discussions. The Center might report to OHA the names of the agencies who obtained the service and aggregate amount of service provided, but will not disclose information that would directly or indirectly indicate the substance of any consultation.

Note: The Actionline service does not include advice about corporate legal issues for programs, general legal services for clients, or state law issues. Neither does it include representation on any issue.

Metrics Update

QHOC, February 8, 2016

Reports

The 2015 Mid-Year CCO metrics report was published January 20th; for the first time this report includes measures stratified for members with disability, members with mental health diagnoses, and members with severe and persistent mental illness. The report is available at www.oregon.gov/oha//Metrics/

The 2014 Medicaid Behavioral Risk Factor Surveillance System (MBRFSS) survey report was also released on January 20th. The report is available at www.oregon.gov/oha/analytics/Pages/MBRFSS.aspx

Dashboards

The January dashboard was released on Jan 27th for Sept 1, 2014 – Aug 31, 2015 data. The final samples for the 2015 chart review measures were also released in January.

There will not be a February dashboard, to allow time to convert the dashboard to ICD10. The dashboard will resume March 30th for Dec 1, 2014 – Nov 30, 2015 data. Beginning in March, the data lag will be reduced by one month.

Immunization Data from ALERT

OHA intends to provide quarterly files to CCOs with data from the ALERT immunization registry for all their enrolled members, beginning in March. Files will be posted for each CCO along with the monthly metrics dashboard. Each CCO must complete a data use agreement by March 25th to receive these files.

The DUA can be found online at

www.oregon.gov/oha/analytics/MetricsTAG/ALERT%20data%20use%20agreement.pdf

please return to metrics.questions@state.or.us

Clinical Quality Measures

All CCOs have successfully submitted their Year Three Data Proposals; OHA has reviewed and approved all proposals. Year Three data submissions are due no later than April 1st.

PCPCH Enrollment Update

OHA has modified the online survey for PCPCH enrollment data to collect information on the number of members (if any) who are assigned to NCQA-recognized medical homes that are not also OHA-recognized PCPCHs. These data will be used to determine if any future modifications to the measure are needed.

Save the Date: Colorectal Roundtable

On Wednesday, April 20th from 9 – 3 at the Multnomah Athletic Club, the American Cancer Society will host a roundtable focused on increasing colorectal cancer screening. The agenda will include innovation, best practices, patient voice, panel presentations and small group discussions on disparities, and health plan and clinical quality improvement. For more information, please contact Bridget Kiene at 503.795.3993 or Bridget.Keine@cancer.org

Dear CCO Partners:

During the Transformation Center's recent strategic planning interviews with CCO stakeholders, many CCOs expressed interest in receiving technical assistance from the Transformation Center for the following incentive metrics: **childhood immunizations, tobacco cessation and adolescent well-care visits.**

Our next step is to hold **informal conference calls**--starting next week--with representatives from interested CCOs for each of these three metrics to identify specific technical assistance needs and possible areas where the Transformation Center could provide support. During the calls, we will facilitate a round-robin discussion and group brainstorm for participants to share current challenges and needs, including:

- What type of assistance would be the most helpful?
- What have you tried that has or hasn't worked?
- Which specific resources or expert consultants would you recommend?

We will use the strategies identified in the OHA guidance documents for these metrics as a framework for these conversations:

- [Childhood Immunizations Resource Guide](#)
- [Strategies for Reducing Tobacco Use](#)
- [Adolescent Well-Care Visits Guidance Document](#)

This invitation is being sent to the CCO stakeholders we interviewed in December, the innovator agents, and CCO medical directors and quality improvement coordinators that did not participate in the interviews. Feel free to forward this invitation to any key staff working on these metrics who you think should participate.

We offered conference call options for each of the three metrics last week, and we are offering additional conference-call options this week.

Childhood Immunizations

- Thursday, February 11, 9-10 a.m.
- 866-390-1828; participant code: 4628003

Tobacco Cessation

- Wednesday, February 10, 1-2 p.m.
- 866-390-1828; participant code: 4628003

Adolescent Well-Care Visits

- Thursday, February 11, 1-2 p.m.
- 877-336-1829, participant code: 3100151

Participation in these calls is optional, and RSVPs are not necessary. The specific technical assistance strategies offered will depend on the needs identified and resources available.

If you have any questions, please send them to: metrics.questions@state.or.us

In addition, please note that the Transformation Center will also be providing technical assistance for the colorectal cancer screening incentive metric, which will involve a different process. If you would like to participate, please notify us through the same email address: metrics.questions@state.or.us.

We look forward to speaking with you!
OHA Transformation Center

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
January 14, 2016

Members Present: Susan Williams, MD; Chair Pro Tempore; Beth Westbrook, PsyD; Irene Crowell, RPh; Mark Gibson; Gerald Ahmann, MD, PhD; Derrick Sorweide, DO; Chris Labhart; Holly Jo Hodges, MD; Gary Allen, DMD.

Members Absent: Som Saha, MD, MPH, Chair; Wiley Chan, MD; Leda Garside, RN, MBA; Wiley Chan, MD; Vern Saboe, DC.

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

Also Attending: Jesse Little, Kim Wentz, MD, MPH, (Oregon Health Authority); Erica Pettigrew, MD (OHSU); Valerie King, MD MPH, Adam Obley, MD, MPH, Craig Mosbaek (OHSU Center for Evidence Based Policy); Nancy Noe (Johnson & Johnson); Renee Taylor (Dexcom).

Call to Order

Susan Williams, MD, Chair Pro Tempore of the Health Evidence Review Commission (HERC), called the meeting to order and role was called.

Minutes Approval

MOTION: To approve the minutes of the November 12, 2015 meeting as presented. CARRIES 10-0.

Director's Report

Membership update

Darren Coffman thanked Dr. Gerald Ahmann for his years of service, noting this is his last meeting. Dr. Kevin Olson, VbBS Chair (and former Health Services Commission member) was nominated by Governor Kate Brown to fill the post vacated by Dr. Ahmann and will have a Senate confirmation hearing in February.

Coffman thanked an absent Dr. Vern Saboe for his years of service and noted that Saboe will now be moving from the Evidence-based Guidelines Subcommittee to the Value-based Benefits Subcommittee. Governor Brown nominated Dr. Kimberly Tippens (naturopath and acupuncturist) to fill the complementary and alternative medicine post on HERC (also to be Senate confirmed in February). Dr. Tippens will also serve on the Evidence-based Guidelines Subcommittee.

Prioritized List update

Staff determined there is not a need for a possible additional Prioritized List for 2016; the errata process to correct issues with ICD-10-CM conversion is working well.

Statewide back pain guidelines

Coffman discussed retiring three evidence-based clinical guidelines on back pain. He stated the Commission stopped work on clinical guidelines in 2012 to focus on coverage guidances. Coverage guidances have been developed from the following three clinical guidelines and so they are no longer needed.

- Guideline on the Evaluation and Management of Low Back Pain (October 2011)
- Guideline for Advanced Imaging for Low Back Pain (April 2012)
- Guideline for Percutaneous Interventions for Low Back Pain (June 2012)

MOTION: To retire the three guidelines on the management of back pain. Carries: 10-0.

ICD-10-CM coding changes for meeting materials and guideline inclusion

Staff will change the ICD-10 codes in all meeting materials and guidelines to remove terminal “x’s” which are there to indicate that all further digit “daughter” codes are included. The ICD-10 codes will terminate at the digit that includes all daughter codes. Codes will remain in guidelines only when absolutely necessary.

Biennial Review topics (1/1/2018)

The 2018 biennial review is starting. Smits is requesting suggestions for topics. Topics proposed to date include obesity (subject of a new taskforce), merging the two low birth weight lines into a single prematurity line, and review of coverage for uncomplicated inguinal hernia. Coffman added the project should be wrapped up this calendar year.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes

[Meeting materials page 73-117](#)

Ariel Smits reported the VbBS met earlier in the day, January 14, 2016. She summarized the subcommittee’s recommendations.

RECOMMENDED CODE MOVEMENT (effective 10/1/16)

- Move the diagnosis code for Barrett’s esophagus without dysplasia from an uncovered line to a covered line with a guideline change allowing long-term proton pump inhibitor therapy
- Move the diagnosis codes for Barrett’s esophagus with dysplasia from an uncovered line to the covered esophageal cancer line, a line title was change to reflect this inclusion
- Move the eosinophilic esophagitis diagnosis code from one covered line to another
- Move several conditions of the mouth with no treatment from a covered line to an uncovered line
- Add procedure codes for acupuncture and chiropractic/osteopathic manipulation to the scoliosis line
- Move the procedure code for placement of artificial discs from the scoliosis line to the covered back surgery line
- Delete the procedure codes for epidural steroid injections from the back conditions line and add to the Services Recommended for Non-Coverage Table

- Delete the procedure codes for maintenance of intrathecal pumps from the back condition lines
- Various straightforward coding changes

RECOMMENDED GUIDELINE CHANGES (effective 10/1/16)

- Edit the wording of the guideline regarding disease of the lips to clarify the included ICD-10 codes
- Edit the surgical back guideline to remove the requirement for 6 months of conservative therapy prior to a patient being eligible for surgery on the uncovered back surgery line; add epidural steroid injections to the list of uncovered procedures
- Edit the guideline for advanced imaging for low back conditions to specify that repeat imaging is only covered for significant changes in a patient's condition, and to return to the old definition of radiculopathy as neurologic changes rather than just radiating pain
- The epidural steroid injection guideline and the intrathecal pump maintenance guideline were deleted

MOTION: To accept the VbBS recommendations on Prioritized List changes not related to coverage guidances, as stated. See the VbBS minutes of 1/14/16 for a full description. Carries: 10-0.

Topic Rescan for 2013 Approved Coverage Guidances

[*Meeting materials page 119-232*](#)

Livingston led the discussion. The process calls for the identification of Population, Intervention, Comparator, Outcomes (PICO) and Key Questions (KQ) for each topic, followed by posting for public comment for 7 days and a review of the literature search results. EbGS and HTAS have reviewed each topic.

The Commission discussed the scope documents ([meetings materials pages 119-232](#)). There was limited discussion and no change to the proposed documents.

Retire this coverage guidance and defer to United States Preventive Services Task Force (USPSTF):

- Cervical cancer screening

Reassess the need to review pending completion of an outside report:

- Coronary artery calcium scoring (CACs) - delay pending AHRQ review
- Coronary computed tomography angiography (CCTA) - delay pending AHRQ review
- Treatment of attention deficit/hyperactivity disorder in children (ADHD) - delay pending NICE review

Review and update now, according to priority order:

- Recurrent acute otitis media
- Continuous glucose monitoring in diabetes mellitus
- Diagnosis of sleep apnea in adults

Reaffirm the current coverage guidance and rescan in another two years:

- Neuroimaging headache
- Induction of labor

- Carotid endarterectomy
- Self-monitoring of blood glucose for Type 1 & Type 2 Diabetes
- PET scanning for breast cancer
- MRI for breast cancer diagnosis
- Vertebroplasty, sacroplasty and kyphoplasty

MOTION: To approve the recommendations on the need to update the 2013 approved coverage guidances as presented. Carries 10-0.

Coverage Guidance Topic: Nitrous Oxide Use for Labor Pain Management

[Meeting materials page 234-266](#)

Livingston and Valerie King, MD from the Center for Evidence-based Policy, reviewed the evidence resulting in the draft coverage guidance from the Evidence-based Guidelines Subcommittee (EbGS).

The primary evidence source is from an Agency for Healthcare Research and Quality (AHRQ) report, retrievable from:

http://www.effectivehealthcare.ahrq.gov/ehc/products/260/1175/CER67_NitrousOxideLaborPain_Final_Report_20120817.pdf

Clinical Background:

- In the U.S., pain relief during childbirth is most commonly delivered through epidural anesthesia.
- 61% of women who had singleton vaginal births elected epidural anesthesia.
- Other pain control options include opioids, hydrotherapy, sterile water injections, psychoprophylaxis, and labor support as well as inhaled nitrous oxide.
- Inhaled nitrous oxide is widely used for childbirth pain relief outside of the United States.
- Nitrous oxide (N₂O) is a non-flammable, tasteless, odorless gas.
- For childbirth-related pain, N₂O is typically administered as a 50% nitrous oxide/50% oxygen mixture.
- Nitrous oxide reduces the sensation of pain and provides some anti-anxiety effects.
- In comparison to epidural anesthesia, women using N₂O retain full mobility.
- Nitrous oxide is rapidly cleared from the maternal system with normal respiration.
- Because the effects of N₂O wear off quickly, other pain management methods can be used soon after N₂O.
- Nitrous oxide can be used in the first or second stages of labor and is indicated for women intending a vaginal birth.
- Nitrous oxide can also be used in the third stage of labor for immediate postpartum procedures (e.g., perineal repair, manual placenta removal).
- Costs in the Portland-Metro region:
 - Epidural: \$1,050-\$2,400
 - Nitrous oxide: \$15-\$100

Evidence Summary: King read through the GRADE-Informed Framework ([meeting materials pages 235-237](#)).

Summary:

- Nitrous oxide is often used in dentistry and can be used by most pregnant women for pain in labor, as an alternative to or in addition to other pain-relieving measures.
- There do not appear to be any ill effects for infants.
- Women can experience unpleasant side effects such as nausea, vomiting, and lightheadedness.
- Most women who use nitrous oxide find it helpful and would want it again in another birth.
- The benefits of nitrous oxide seem to outweigh any harms.
- There is little recent published data about its use in U.S. settings, but there are an increasing number of new use locations.

Discussion:

Livingston said many implementation barriers such as licensure, payment, monitoring, and billing codes exist that are not HERC's tasks to tackle. Westbrook asked if there is a way to encourage providers to include options of pain management at the informed consent phase. For example, a person may not know an epidural is not available when having a home-birth. None were put forth.

MOTION: To approve the proposed coverage guidance for Nitrous Oxide Use for Labor Pain Management as recommended by EbGS. Carries 10-0.

MOTION: To approve the proposed guideline and coding changes for the Prioritized List as recommended by VbBS. Carries 10-0.

Approved Coverage Guidance:

HERC Coverage Guidance

Nitrous oxide for labor pain is recommended for coverage (*weak recommendation*).

Changes for the Prioritized List of Health Services:

- 1) Advise HSD to consider reimbursement options for the use of nitrous oxide.
- 2) Add a new guideline note:

GUIDELINE NOTE XXX NITROUS OXIDE FOR LABOR PAIN

Line 1

Nitrous oxide for labor pain is included on this line.

Coverage Guidance Topic: Indications for Proton Beam Therapy
[Meeting materials page 268-367](#)

Obley presented the proposed coverage guidance from the Health Technology Assessment Subcommittee (HTAS).

Proton beam therapy is a different way to deliver radiation in cancer treatment and in certain non-malignant conditions. The benefit is protons are less likely to damage surrounding tissue. It is twice as

expensive as conventional radiation. It may be used as a primary treatment with curative intent or as salvage treatment in recurrent disease.

Obley read through the Evidence Summary document ([Meeting materials page 274](#)):

Evidence Summary

- Bone cancer – low quality evidence of effectiveness, unknown risk, higher cost
- Brain, spinal, and paraspinal tumors – very low quality evidence of incremental benefit and higher costs
- Esophageal cancer – no evidence on effectiveness, unknown risk, higher cost
- Head and neck cancers – very low quality evidence of comparable benefits, fewer harms, higher costs, but patient preference
- Liver cancer – low quality evidence of comparable benefits and harms, higher costs
- Lung cancer – low quality evidence of comparable benefits, similar risk, higher cost
- Ocular tumors – moderate quality evidence of greater benefits with fewer harms
- Pediatric cancers – very low quality evidence of comparable benefits, fewer harms, potential health impact over decades
- Prostate cancer – low quality evidence of similar benefits, similar risk, higher cost
- Ocular hemangiomas – very low quality evidence of comparable benefits and harms
- Other benign tumors – no evidence on effectiveness, unknown risk compared to alternative, higher cost

Livingston read the GRADE-Informed Framework ([meeting materials page 288-290](#)) and highlighted what translated to the recommended box language. Public comment was received in support of PBT for many cancer conditions including cancers of the brain, spine, paraspine, breast, head and neck, prostate, lung, liver and pediatric cancers. Among core issues raised by experts/public are recurrent cancers, definition of pediatric, and longevity of benefit. There are no treatment centers in Oregon; patients would have to travel to Seattle or another clinic outside of Oregon.

There was some discussion about the definition of “pediatric.” Wentz said the American Academy of Pediatrics considers pediatric up to 21. Hodges asserted age 19 is used for DME. Sorweide added, when this issue came up with the experts, they said if a person develops a brain tumor between age 18 and 21, it is considered a pediatric tumor rather than an adult-onset tumor.

MOTION: To approve the proposed coverage guidance for Indications for Proton Beam Therapy as recommended by HTAS. Carries 10-0.

MOTION: To approve the proposed guideline and coding changes for the Prioritized List recommended by VbBS. Carries 10-0.

Approved Coverage Guidance:

HERC Coverage Guidance

Proton beam therapy (PBT) is recommended for coverage for malignant ocular tumors (*strong recommendation*).

Proton beam therapy is recommended for coverage (*weak recommendation*) for:

- malignant brain, spinal, skull base, paranasal sinus, and juxtaspinal tumors
- pediatric malignant tumors (incident cancer under age 21)

Proton beam therapy is not recommended for coverage for cancer of the bone, breast, oropharynx, nasopharynx, esophagus, liver, lung, or prostate or for gynecologic or gastrointestinal cancers, lymphoma, sarcoma, thymoma, seminoma, arteriovenous malformation or ocular hemangiomas (*weak recommendation*).

Changes for the Prioritized List of Health Services:

1) Add proton beam therapy codes (77520, 77522, 77523, 77525) to the following lines:

- a. 97 CHILDHOOD LEUKEMIAS
- b. 133 GRANULOMATOSIS WITH POLYANGIITIS
- c. 195 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
- d. 205 CANCER OF BONES
- e. 242 ACUTE PROMYELOCYTIC LEUKEMIA
- f. 280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
- g. 292 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX
- h. 402 ACUTE MYELOID LEUKEMIA
- i. 403 MYELOID DISORDERS

2) Remove proton beam therapy codes from Line 377 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS

3) Add a new guideline note

GUIDELINE NOTE XXX PROTON BEAM THERAPY FOR CANCER

Lines 97, 117, 130, 133, 195, 205, 242, 280, 292, 299, 377, 402, 403

Proton beam therapy is included on lines 117 CANCER OF EYE AND ORBIT, 130 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD and 299 CANCER OF BRAIN AND NERVOUS SYSTEM.

Proton beam therapy is included on lines 133, 205, and 292 only for: malignant skull base, paranasal sinus (including lethal midline granuloma), spinal, and juxtaspinal tumors.

Proton beam therapy is additionally included on lines 97, 195, 242, 280, 402, and 403 only for pediatric malignant tumors (incident cancer under age 21.)

Elective Surgery and Tobacco Cessation

Williams asked Commissioners to share their thoughts about requiring smoking cessation for a period of time before any elective surgery, which the commission indicated that wanted to discuss further at the November meeting.

Hodges said elective surgery is everything that does not have to be done straight from the Emergency Department. Sorweide expressed concerned that we may be asked to study and supply a risk assessment for each and every procedure. Gibson said he thinks this focus on surgical outcomes is an investment in the health of the population. Williams shared her worry about appeals, lawsuits and potentially denying access to care for patients with addictions. Livingston shared concern about treatment of patients with the additional challenged of mental illness issues.

The commission asked staff to consider further and bring options to the next meeting.

Public Comment

There was no public comment at this time.

Adjournment

Meeting adjourned at 3:40 pm. Next meeting will be from 1:30-4:30 pm on Thursday, March 10, 2016 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon.

Oregon Health Plan Prioritized List changes Nitrous Oxide Use for Labor Pain Management

The Health Evidence Review Commission approved the following changes to the Prioritized List of Health Services on January 14, 2016, based on the approved coverage guidance, “Nitrous Oxide Use for Labor Pain Management.” The changes will take effect on the Prioritized list of Health Services for the Oregon Health Plan on October 1, 2016.

HERC Decision:

- 1) Advise HSD to consider reimbursement options for the use of nitrous oxide.
- 2) Add a new guideline note

GUIDELINE NOTE XXX NITROUS OXIDE FOR LABOR PAIN

Line 1

Nitrous oxide for labor pain is included on this line.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: NITROUS OXIDE USE FOR LABOR PAIN MANAGEMENT

Approved January 14, 2016

HERC Coverage Guidance

Nitrous oxide for labor pain is recommended for coverage (*weak recommendation*).

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

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.

GRADE-INFORMED FRAMEWORK

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

Coverage question: Should nitrous oxide (50% N2O) be recommended for coverage for labor pain management?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
Fetal/neonatal adverse effects <i>(Critical outcome)</i>	No significant differences in Apgar scores at 1 and 5 minutes, or umbilical cord gasses after birth when maternal N2O is compared to epidural anesthesia use. ●●●○ <i>(Moderate certainty, based on multiple RCTs and other studies with consistent findings)</i>	Use of N2O is likely to be cost-saving compared to epidural anesthesia. The cost of N2O is low. Use of N2O is associated with lower rates of assisted vaginal birth and cesarean delivery, and shorter length of stay on labor and delivery units.	High variability: Some women would want this additional option because of the reduced risk of caesarean section or assisted delivery. Concerns about harms would be mitigated because they could easily discontinue it and consider an epidural if adverse events occur or if analgesia is insufficient. Other	There is no specific CPT code for this service, other than an anesthesia code, so reimbursement to providers may require use of a non-specific code that may require manual review.
Mode of birth <i>(Critical outcome)</i>	Compared to women using epidural anesthesia, for those using N2O: 15 to 34 more women per 100 are likely to have an unassisted vaginal birth; 9 to 27 fewer women per 100 would experience assisted vaginal (forceps/vacuum) birth; and there would be about 6 fewer Cesarean births per 100 compared to those using epidural anesthesia for labor pain. ●○○○ <i>(Low certainty based on prospective cohort and cross sectional studies with consistent findings)</i>			

Coverage question: Should nitrous oxide (50% N2O) be recommended for coverage for labor pain management?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
Maternal adverse effects <i>(Important outcome)</i>	Women may experience unpleasant side effects when using N2O. (These data come from studies of women using N2O as the sole form of labor analgesia and are not compared to any other methods.) Nausea (0-28%), vomiting (0-14%), dizziness/lightheadedness (3-23%), and drowsiness/sleepiness (0-67%) were commonly reported side effects. Effects dissipated quickly when N2O use is stopped. ●●○○ <i>(Moderate certainty based on multiple RCTs and other studies with consistent findings)</i>		women may prefer epidural anesthesia because of its greater effect in reducing labor pain.	
Maternal satisfaction <i>(Important outcome)</i>	70 to 80% of women who used N2O said they would want to use it in a subsequent pregnancy compared to 45 to 88% of women who would request an epidural again. (These data come from studies where multiple labor pain management modalities are readily available and women using N2O or epidural were asked if they would want to use that method for a future birth.) ●●○○ <i>(Low certainty based on prospective cohort and cross-sectional studies with consistent findings)</i>			
Use of neuraxial (e.g., epidural) anesthesia <i>(Important outcome)</i>	When multiple pain management methods are available for women 13% to 79% will use N2O, compared to 34 to 42% who will select epidural anesthesia. There is no direct evidence on whether			

Coverage question: Should nitrous oxide (50% N2O) be recommended for coverage for labor pain management?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
	availability or use of N2O changes the use of neuraxial anesthesia. ●○○○ (Very low certainty based on cross-sectional studies with consistent findings)			
Rationale: On balance, there are potential benefits to the use of N2O and no serious harms to its use. Costs are low and variable maternal preferences argue for increased availability of N2O for management of labor pain. Coverage is recommended because of the potential benefits of fewer cesarean and assisted deliveries, the lack of significant harms, maternal preferences, and low costs. The recommendation is a weak recommendation because there are few studies available for benefit outcomes, and the external validity of the data and its applicability in U.S. settings is limited. The confidence in the quality of evidence for most outcomes is low to moderate certainty.				
Recommendation: Nitrous oxide for labor pain is recommended for coverage (<i>weak recommendation</i>).				

Note: GRADE-informed framework elements are described in Appendix A. Appendix B provides a GRADE Evidence Profile.

EVIDENCE OVERVIEW

Clinical background

Annually, approximately 45,000 births occur in Oregon (Oregon Health Authority, 2015) and childbirth pain is a major concern among women (Likis et al., 2012). Pain relief is most commonly delivered through epidural anesthesia in the United States, with 61% of women who had singleton births through vaginal delivery electing an epidural anesthesia (Centers for Disease Control and Prevention, 2011; Likis, et al., 2012). For women interested in other types of pain relief or in delaying the timing of an epidural, there are several options including inhaled nitrous oxide (N₂O, also known as “laughing gas”), other inhaled anesthetic gases, opioids, paracervical or pudendal block, transcutaneous electrical nerve stimulation, hydrotherapy, sterile water injections, and psychoprophylaxis (Likis et al., 2012).

Inhaled nitrous oxide is a non-invasive form of pain relief. Commonly used in dentistry, nitrous oxide provides a diminished sense of pain and provides some antianxiety effects (Likis et al., 2012). In comparison to epidural anesthesia, women using nitrous oxide for pain management retain their full mobility. Individuals experience the maximum effect of nitrous oxide 30 to 60 seconds after inhalation. The effects of nitrous oxide wear off quickly and other types of pain management methods can be used in a relatively short time period after the use of nitrous oxide (Likis et al., 2012).

In the Portland-Metro region, an epidural adds an additional \$1,050 to \$2,400 to the cost of a hospital birth (Providence Health Services, 2015). The use of nitrous oxide costs significantly less with estimates ranging from \$15 to \$100 per patient.

Indications

Inhaled nitrous oxide can be used in the first or second stages of labor and is indicated for pregnant women in labor intending a vaginal birth. Nitrous oxide can also be used in the third stage of labor to assist with managing pain that may occur during immediate postpartum procedures (e.g., perineal repair, manual placenta removal).

Technology description

Inhaled nitrous oxide is widely used for childbirth pain relief outside of the United States and is a common form of non-invasive pain relief during childbirth (Klomp, van Poppel, Jones, Lazet, Di Nisio & Lagro-Janssen, 2012). Nitrous oxide is a non-flammable, tasteless, odorless gas that is self-administered on demand by laboring women through a mouth piece or facemask (Collins, Starr, Bishop, Baysiner, 2012; Klomp et al., 2012). Inhaled nitrous oxide is typically administered as a 50% nitrous oxide / 50% oxygen combination. It can be administered at this concentration using a blender device (e.g., Nitronox®) or as a premixed gas (e.g., Entonox®). Entonox® is not currently available in the U.S., but appropriate types of blender equipment are available for hospital and out-of-hospital use.

Key questions

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

KQ1: What are the effects on mode of birth, use of neuraxial (e.g. epidural) analgesia and maternal satisfaction when nitrous oxide is used for labor analgesia?

KQ2: What are the maternal and fetal/neonatal harms of nitrous oxide used for labor pain?

Evidence review

Two systematic reviews (SR) (Klomp et al., 2012; Likis et al., 2012) identified in the core source search address the use of nitrous oxide for pain management during labor. Both SRs were of good methodological quality. The AHRQ SR (Likis, 2012; Likis, 2014) was selected as the index SR and is the primary evidence source for this coverage guidance because it is more comprehensive and matches the scope of the HERC's key questions better. In addition, the Cochrane SR (Klomp, 2012) did not add eligible studies or other information which were not included in the AHRQ SR. For further details on the methods of this evidence review please see Appendix B. The included study characteristics for the AHRQ SR are outlined below in Table 1.

Table 1. Overview of Index Systematic Review

Citation	Total Studies Included	Included Studies Specifically Addressing Coverage Guidance Scope
Likis et al (2012, 2014) [AHRQ SR]	59 studies (13 RCTs, 7 crossover RCTs, 4 non-randomized clinical trials, 14 prospective cohorts, 1 retrospective cohorts, 3 case series, 4 case-control studies, 11 cross sectional studies, and 2 trend studies)	<ul style="list-style-type: none">• 14 studies (5 RCTs; 8 prospective cohorts 1 case-series) for fetal/neonatal harms• 3 studies (2 prospective cohort studies, 1 cross-sectional study) for mode of delivery• 10 studies (7 RCTs; 2 prospective cohorts; 1 cross-sectional study) for maternal adverse effects• 2 studies (both cross-sectional studies) for use of neuraxial (e.g. epidural) anesthesia

Evidence from additional sources

No additional evidence sources were included in this review. A MEDLINE® (Ovid) search based on the search strategy of the AHRQ SR did not locate any additional eligible studies.

EVIDENCE SUMMARY

The AHRQ SR (Likis, 2012) included a total of 59 studies reported in 58 publications (13 RCTs, 7 crossover RCTs, 4 non-randomized clinical trials, 14 prospective cohorts, 1 retrospective cohorts, 3 case series, 4 case-control studies, 11 cross sectional studies, and 2 trend studies) to answer five key questions on the following issues: 1) effectiveness for pain (21 studies); 2) comparative effectiveness for women's satisfaction with their birth experience and pain management (9 studies); 3) effect on mode of birth (6 studies); 4) maternal and fetal/neonatal adverse effects (49 studies); and 5) health system factors influencing the use of nitrous oxide (no studies). Key Questions 2, 3 and 4 are directly applicable to this coverage guidance.

Most of the studies in the full AHRQ SR included comparator interventions that are not of interest for this guidance (comparators included other inhaled anesthetic gasses, most of which are not used in the U.S., alternative concentrations of N₂O; parenteral opioids and non-pharmacologic techniques not widely available or used in the U.S.). Many of the studies used different concentrations of N₂O compared to the 50% N₂O/50% oxygen mix that is used in most labor and delivery settings in countries such as the United Kingdom (U.K.) and which is the concentration used in U.S. settings that have adopted it for obstetric use. Most included studies did not report on populations or outcomes of interest for this guidance (e.g. pain scores, occupationally exposed workers). Some populations of interest (e.g. women in the third stage of labor requiring procedural analgesia such as for manual placental removal) were not explicitly included among the studies identified in the AHRQ SR. No study directly addressed or was designed to address whether availability or use of N₂O reduces the use of neuraxial (e.g. epidural) analgesia; we were only able to address this outcome descriptively. None of the included studies that did address the questions of interest for this evidence review were conducted in the U.S., although all were conducted in developed countries with modern maternity care systems. However, differences in health systems, provider training, hospital routines and patient expectations may limit the applicability of these studies to the U.S. context.

Although pain was not selected as a key outcome for this guidance, for background context, the AHRQ SR found that N₂O is less effective than epidural anesthesia for measures of pain in labor, but that the evidence was insufficient to determine the effectiveness compared with other, non-epidural pain management interventions. The studies are limited because of poor quality, use of varying outcome measures, and inconsistency. The review found no studies that met inclusion criteria and studied the systems factors related to using N₂O for management of labor pain, including provider preferences, availability, settings and resource utilization.

Critical Outcome: Fetal/neonatal adverse effects

The AHRQ SR (Likis, 2012) noted that while 49 studies reported on maternal, fetal, neonatal, or occupational harms associated with N2O use in labor, that 16 of these were conducted prior to 1980 when it was usual practice to combine N2O with other sedative, tranquilizing and anesthetic agents. Although N2O is transmitted via the placenta to the fetus, it is also quickly eliminated via maternal circulation and neonatal respiration. Twenty-nine studies included fetal or neonatal harms as outcomes. The SR found no significant differences between any comparison groups in Apgar scores at either one or five minutes after birth. Eight studies reported umbilical cord blood gasses. There was one study that compared infants of women using 50% N2O/50% oxygen to epidural anesthesia. It found that 7% of the N2O group had Apgar scores less than or equal to seven at one minute after birth compared to 6% of infants of women who used epidurals. At five minutes, the proportions with low Apgar scores were 1% and 4%, respectively (*p* values not reported). There was a statistically significant finding in one study of lower arterial cord blood gasses among infants of primiparous women who used N2O plus meperidine (a parenteral opioid) compared to those who used an epidural (pH 7.21 vs. pH 7.29, *p*<0.01). Use of meperidine alone has been associated with lower umbilical cord gasses and so it is not clear whether this finding can be attributed to N2O use or only to use of meperidine. The AHRQ SR was unable to analyze neonatal intensive care unit admission because of the varying definitions of intensive care across countries and lack of reporting of this outcome.

Only one study included in the AHRQ SR compared neonatal neurobehavioral outcomes among infants of women using N2O and who used other methods of labor pain management, including epidurals, opioids, TENS, and non-pharmacologic methods. This study reported no significant differences between groups in neonatal adaptive capacity scores (NACS).

Critical Outcome: Mode of birth

Six studies in the AHRQ review compared the mode of birth among women who used N2O to women who used other methods of pain relief and determined that there was insufficient evidence, primarily due to poor quality studies and inconsistent results. However, only three studies compared the intervention and comparator of interest for this guidance. One prospective cohort study from Ireland, published in 1987, enrolled primiparous women in an academic hospital. Twenty women used N2O and 50 women used epidural anesthesia. Other comparison groups in the study used TENS or parenteral opioids. Another prospective cohort study from Finland, published in 1994, included 210 women (27% primiparas) using N2O and 82 women (71% primiparas) using epidural anesthesia. This study also found higher rates of vaginal birth among women using N2O. No analysis of the results by parity was provided in the AHRQ SR. These two studies found the following proportions of women with vaginal, assisted vaginal (vacuum or forceps), Cesarean, or vaginal breech births as described in Table 2 below. No statistical testing of differences between pain management groups were reported in either study.

Table 2. Mode of Birth According to Pain Management Approach

Mode of Birth	Nitrous Oxide*	Epidural*
Vaginal	60%/95%	26%/80%
Assisted	35%/2%	62%/11%
Cesarean	0%/3%	6%/9%
Breech	5%/NR	6%/NR

NR: not reported

* The first percentage in each cell represents the Irish study and the second percentage is from the Finnish study.

One cross sectional study conducted in the U.K. and published in 1982 also reported the mode of birth. This U.K.-based study included women (51.4% primiparous) who had vaginal births and found that women who used N2O (n=128) were more likely to have a spontaneous vaginal birth and less likely to have an assisted vaginal birth compared with women who used epidural anesthesia (n=423) or women who used an epidural and N2O together (n=38). Proportions who had a vaginal birth for each of these three groups were 93.7%, 48.7%, and 60.5% and for assisted vaginal birth the proportions were 6.3%, 51.3%, and 39.5%.

Consistent with reported mode of birth outcomes, three of these studies (two prospective cohort studies and one cross sectional study) also reported shorter duration of labor for women in the N2O groups compared to the epidural groups. The reported duration of labor in the N2O groups ranged from a mean of 5.2 hours +/- 1.7 (standard deviation [S.D.]) to 6.7 +/- 3.0 hours. The reported range among women using epidural anesthesia was 7.7 +/- 2.4 hour to 10.8 +/- 4.9 hours.

Important Outcome: Maternal adverse effects

Most harms reported by studies included in the AHRQ SR were unpleasant side effects of N2O such as nausea, vomiting, dizziness and drowsiness. Some commonly reported adverse effect outcomes (e.g. nausea and oxygen desaturation) are reported often among women in labor regardless of pain management strategies used. Studies did not have adequate power to detect rare outcomes. Eight studies of women receiving N2O as the sole pain management agent report rates of nausea from 0% to 28%. Four of these studies also reported vomiting with a range of 0% to 14%. Four studies of women using N2O as the sole analgesia agent reported dizziness or lightheadedness, with rates ranging from 3% to 23%. Four studies reported drowsiness or sleepiness with sole use of N2O and proportions ranged from 0% to 67%.

Important Outcome: Maternal satisfaction

Nine studies in the AHRQ SR evaluated women's satisfaction with their birth experience or pain management, although most were of poor quality and reported varying outcome measures, making it difficult to synthesize results. However, the AHRQ authors concluded that there was low strength of evidence to support the equivalence or superiority of N2O relative to maternal satisfaction outcomes.

Among the three studies that specifically evaluated use of 50% N2O / 50% oxygen compared with epidural anesthesia, two studies (two prospective cohorts) evaluated women's satisfaction with labor pain management at various points in time between one hour and three days post-delivery. They both reported that women who used N2O were somewhat less satisfied with the adequacy of pain relief for N2O compared to epidural anesthesia. Satisfaction scores ranged from 60% to 90% for the N2O group and 98% to 100% for the epidural group in the prospective cohort study. Because N2O is not assumed or designed to achieve the same degree of pain relief as epidural anesthesia this is not considered by the AHRQ researchers to be as robust of an outcomes as is women's assessment of whether they would use the method again. One prospective cohort study conducted in Ireland found that 80% of women who used N2O would request the method again in a subsequent pregnancy compared with 88% of women who used an epidural. In a cross-sectional study performed in Sweden that evaluated this outcome, 69.9% of women who used N2O would request it in another pregnancy compared to 45.3% of women who used an epidural.

Important Outcome: Use of neuraxial analgesia in labor

The AHRQ SR did not report on this outcome. However, the two cross sectional studies (one from the U.K. and one from Sweden) that reported outcomes for groups of women choosing N2O and epidural anesthesia, respectively, do give some information on the methods that women choose when both choices are freely available. The U.K. based study, published in 1982, included only women who had a vaginal birth and approximately half were primiparous. Of 1000 women, about 13% used N2O, 42% used epidurals, and 4% used both methods. Other methods used in this study included parenteral opioids, pudendal or regional anesthetic blocks, no pharmacologic pain management, and combinations of these methods. The Swedish cross-sectional study, published in 1996, gathered data on women who had used N2O, epidural, local anesthesia, acupuncture, hydrotherapy, and breathing techniques as their primary pain management technique. About 79% of women used N2O and 34% used epidural (categories were not mutually exclusive and thus some women who started with N2O may have also used epidurals or other techniques).

OTHER DECISION FACTORS

Resource Allocation

The cost of N2O for labor is low (\$15 to \$100 per patient). The major cost is for the delivery equipment, which is borne by the facility or provider. The costs of the comparator intervention are relatively high (\$1,050 to \$2,400 per patient per epidural in the Portland metropolitan area). Use of N2O is associated with lower rates of assisted vaginal birth and cesarean delivery which would potentially result in significantly lower intrapartum costs. For some women who use both N2O and an epidural during the same labor, anesthesia costs of care could increase over use of an epidural alone. However, this combination may still result in higher vaginal birth rates and thus lower total costs of care. The literature review found that the length of labor was consistently shorter (about 2 to 4 hours shorter) among

women using N2O analgesia compared to women using epidural anesthesia such that increased use of N2O may also result in somewhat shorter length of stay on labor and delivery units.

Values and preferences

Some women and clinicians have a strong preference to avoid or delay neuraxial anesthesia and would potentially desire an intervention that may decrease their risk of assisted vaginal delivery or cesarean section. If N2O were available in Oregon facilities, many women would likely try it. Most women would not be concerned about potential harms because there do not appear to be adverse fetal/neonatal harms and women who experience adverse effects themselves can stop using N2O and their symptoms would resolve. Its quick onset would also be desired by women who are waiting for an epidural in labor and who would use it as a bridging technology. However, other women may strongly prefer neuraxial anesthesia (epidural) because of its greater effect in reducing labor pain, so the net assessment is that values and preferences would be highly variable.

Other considerations

There is currently no specific CPT code for N2O use in labor except for an anesthesia-specific code. Benefit plans may need to consider alternative payment methodologies and/or innovative mechanisms to encourage use by providers. Facilities and clinicians may have to invest in equipment and staff training to implement N2O for labor pain. Facilities may experience shorter length of stay on labor and delivery units with increased use of N2O that may result in higher bed availability and/or decreased staffing needs in some hospitals.

POLICY LANDSCAPE

Quality measures

No quality measures related to the use of nitrous oxide during labor were identified when searching the [National Quality Measures Clearinghouse](#).

Payer coverage policies

No public or private payer coverage policies¹ were identified for the use of nitrous oxide during labor.

Professional society guidelines

The National Institute for Health and Care Excellence (NICE) found there to be moderate evidence of benefit for the use of nitrous oxide during labor (NICE, 2014). The guideline notes that nitrous oxide can cause nausea and light-headedness for the mother. NICE did not find any evidence of harm to the baby. The use of 50:50 mixture oxygen and nitrous oxide is recommended to be available in all birth settings in the United Kingdom.

¹ Washington Medicaid, Aetna, Cigna, Regence Blue Cross Blue Shield, and Moda

The American College of Nurse-Midwives (ACNM) has a Position Statement that supports the increased availability and use of nitrous oxide analgesia (ACNM, 2011).

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Provide Health Services. (2015). Labor and delivery estimates. Retrieved July 29, 2015, from <http://oregon.providence.org/about-us/financial-services/common-estimates/>

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

APPENDIX A. GRADE INFORMED FRAMEWORK - ELEMENT

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

DESCRIPTIONS

Confidence in the quality of the evidence, across studies, about an outcome

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

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

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

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

Strong recommendation

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

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

Weak recommendation

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

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

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
Fetal/Neonatal Adverse Effects (Apgar scores, Cord gasses)¹							
14	5 RCTs; 8 Prospective cohorts; 1 Case-series	High	Consistent	Direct	Imprecise	None	Moderate confidence in estimate of effect ●●●○
Mode of Birth³							
3	2 Prospective cohort; 1 Cross-sectional	High	Consistent	Direct	Imprecise	Moderate magnitude of effect and some evidence of dose-response relationship	Low confidence in estimate of effect ●●○○
Maternal Adverse Effects (Nausea, Vomiting, Dizziness/Lightheadedness, Drowsiness/Sleepiness)²							
10	7 RCTs; 2 Prospective cohorts; 1 Cross-sectional	High	Consistent	Direct	Imprecise	None	Moderate confidence in estimate of effect ●●●○
Maternal Satisfaction³							
4	2 Prospective cohort; 2 Cross-sectional	High	Consistent	Direct	Imprecise	None	Low confidence in estimate of effect ●●○○

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
Use of Neuraxial Anesthesia³							
2	2 Cross-sectional	High	Consistent	Indirect	Imprecise	None	Very low confidence in estimate of effect (●○○○)

¹Studies from Tables 9, 10, 11 (AHRQ, 2012). Strength of evidence assessment based on AHRQ SR, Table 12 (AHRQ, 2012).

²Studies from Table 8 (AHRQ, 2012). Strength of evidence assessment based on AHRQ SR, Table 12 (AHRQ, 2012).

³Studies for benefit outcomes selected from AHRQ SR based on HERC review PICO only (neuraxial anesthesia comparator studies only) (AHRQ, 2012). Strength of evidence based on risk of bias assessments included for individual studies in AHRQ SR, Table 6 (AHRQ, 2012) and assessment of other GRADE elements by staff.

APPENDIX C. METHODS

Scope Statement

Populations

Pregnant women intending a vaginal birth in the first and second stages of labor and their fetus/neonate, women in the third stage of labor or immediate postpartum period

Population scoping notes: *Exclude women planning a Cesarean birth*

Interventions

Self-administered nitrous oxide used for labor analgesia or third stage/immediate postpartum management

Intervention exclusions: *Concentration of nitrous oxide blended with oxygen for analgesia other than 50%; non-self-administration of nitrous oxide*

Comparators

Neuraxial analgesia (e.g. epidural, combined spinal/epidural)

Outcomes

Critical: Mode of birth; Fetal/neonatal adverse effects (e.g. low Apgar score, low cord blood gasses)

Important: Maternal adverse effects (e.g. nausea/vomiting, dizziness, loss of consciousness); Use of neuraxial (e.g. epidural) analgesia; Maternal satisfaction

Considered but not selected for the GRADE table: Use of non-neuraxial analgesia

Key Questions

KQ1: What are the effects on mode of birth, use of neuraxial (e.g. epidural) analgesia and maternal satisfaction when nitrous oxide is used for labor analgesia?

KQ2: What are the maternal and fetal/neonatal harms of nitrous oxide used for labor pain?

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 “nitrous oxide,” and “labor pain management.” Searches of core sources were limited to citations published after 2004.

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

Based on this initial search, the AHRQ report (Likis, 2012) was selected as the index systematic review.

We also identified another good quality SR from the Cochrane Collaboration in the core source search. The Cochrane SR (Klomp, 2012) included four RCTs that were not included in the AHRQ SR. They were excluded from the AHRQ SR because they were not published in English. In total, five RCTs in the Cochrane SR, compared varying or unspecified concentrations of N2O to oxygen alone or no treatment. Only one of these RCTs evaluated the comparison, relevant to this coverage guidance, of 50% N2O/50% oxygen with epidural anesthesia. This RCT also included a no treatment control group. The Cochrane SR did not present outcomes for the comparison of N2O vs. epidural groups, but only the comparison of the N2O and no treatment groups. We were unable to incorporate the results of the N2O vs. epidural comparison to this evidence report due to this RCT being published in Chinese.

A MEDLINE® (Ovid) search was then conducted to identify systematic reviews, meta-analyses, and technology assessments published after the search dates of the AHRQ report (Likis, 2012). The search was limited to publications in English published after 2010 (the end search date for the AHRQ SR).

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

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

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, 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-9 Diagnosis Codes	
760.0-760.5,760.61-760.9,761.0-761.9,762.0-762.9,763.0-763.7,763.81-763.9,764.00-764.99,765.20-765.29,779.32,779.81-779.82,779.84,779.89,V30.00-V30.2,V31.00-V31.2,V32.00-V32.2,V33.00-V33.2,V34.00-V34.2,V35.00-V35.2,V36.00-V36.2,V37.00-V37.2,V39.00-V39.2	Birth of Infant
ICD-10 Diagnosis Codes	
P00.0-P00.7,P00.81-P00.9,P01.0-P01.9,P02.0-P02.1,P02.20-P02.9,P03.0-P03.6,P03.810-P03.9,P04.0-P04.3,P04.41-P04.9,P05.00,P05.10,P05.9,P29.0,P29.11-P29.2,P29.4,P29.81-P29.9,P36.0,P36.10-P36.9,P78.89,P92.01-P92.09,P94.1-P94.9,P96.0,P96.3-P96.5,P96.82-P96.89,Q27.0, Z38.00-Z38.8	Birth of Infant
CPT Codes	
01960	Anesthesia for vaginal delivery only
01961	Anesthesia for cesarean delivery only
01967	Neuraxial labor analgesia/anesthesia for planned vaginal delivery
01968	Anesthesia for cesarean delivery following neuraxial labor analgesia/anesthesia
01969	Anesthesia for cesarean hysterectomy following neuraxial labor analgesia/anesthesia
01996	Daily management of epidural, not to include the day that the catheter is placed

Note: Inclusion on this list does not guarantee coverage

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: NITROUS OXIDE USE FOR LABOR PAIN MANAGEMENT

Approved January 14, 2016

HERC Coverage Guidance

Nitrous oxide for labor pain is recommended for coverage (*weak recommendation*).

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

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.

GRADE-INFORMED FRAMEWORK

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

Coverage question: Should nitrous oxide (50% N2O) be recommended for coverage for labor pain management?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
Fetal/neonatal adverse effects <i>(Critical outcome)</i>	No significant differences in Apgar scores at 1 and 5 minutes, or umbilical cord gasses after birth when maternal N2O is compared to epidural anesthesia use. ●●●○ <i>(Moderate certainty, based on multiple RCTs and other studies with consistent findings)</i>	Use of N2O is likely to be cost-saving compared to epidural anesthesia. The cost of N2O is low. Use of N2O is associated with lower rates of assisted vaginal birth and cesarean delivery, and shorter length of stay on labor and delivery units.	High variability: Some women would want this additional option because of the reduced risk of caesarean section or assisted delivery. Concerns about harms would be mitigated because they could easily discontinue it and consider an epidural if adverse events occur or if analgesia is insufficient. Other	There is no specific CPT code for this service, other than an anesthesia code, so reimbursement to providers may require use of a non-specific code that may require manual review.
Mode of birth <i>(Critical outcome)</i>	Compared to women using epidural anesthesia, for those using N2O: 15 to 34 more women per 100 are likely to have an unassisted vaginal birth; 9 to 27 fewer women per 100 would experience assisted vaginal (forceps/vacuum) birth; and there would be about 6 fewer Cesarean births per 100 compared to those using epidural anesthesia for labor pain. ●○○○ <i>(Low certainty based on prospective cohort and cross sectional studies with consistent findings)</i>			

Coverage question: Should nitrous oxide (50% N2O) be recommended for coverage for labor pain management?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
Maternal adverse effects <i>(Important outcome)</i>	Women may experience unpleasant side effects when using N2O. (These data come from studies of women using N2O as the sole form of labor analgesia and are not compared to any other methods.) Nausea (0-28%), vomiting (0-14%), dizziness/lightheadedness (3-23%), and drowsiness/sleepiness (0-67%) were commonly reported side effects. Effects dissipated quickly when N2O use is stopped. ●●○○ (Moderate certainty based on multiple RCTs and other studies with consistent findings)		women may prefer epidural anesthesia because of its greater effect in reducing labor pain.	
Maternal satisfaction <i>(Important outcome)</i>	70 to 80% of women who used N2O said they would want to use it in a subsequent pregnancy compared to 45 to 88% of women who would request an epidural again. (These data come from studies where multiple labor pain management modalities are readily available and women using N2O or epidural were asked if they would want to use that method for a future birth.) ●●○○ (Low certainty based on prospective cohort and cross-sectional studies with consistent findings)			
Use of neuraxial (e.g., epidural) anesthesia <i>(Important outcome)</i>	When multiple pain management methods are available for women 13% to 79% will use N2O, compared to 34 to 42% who will select epidural anesthesia. There is no direct evidence on whether			

Coverage question: Should nitrous oxide (50% N2O) be recommended for coverage for labor pain management?				
Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource allocation	Values and Preferences	Other considerations
	availability or use of N2O changes the use of neuraxial anesthesia. ●○○○ (Very low certainty based on cross-sectional studies with consistent findings)			
Rationale: On balance, there are potential benefits to the use of N2O and no serious harms to its use. Costs are low and variable maternal preferences argue for increased availability of N2O for management of labor pain. Coverage is recommended because of the potential benefits of fewer cesarean and assisted deliveries, the lack of significant harms, maternal preferences, and low costs. The recommendation is a weak recommendation because there are few studies available for benefit outcomes, and the external validity of the data and its applicability in U.S. settings is limited. The confidence in the quality of evidence for most outcomes is low to moderate certainty.				
Recommendation: Nitrous oxide for labor pain is recommended for coverage (<i>weak recommendation</i>).				

Note: GRADE-informed framework elements are described in Appendix A. Appendix B provides a GRADE Evidence Profile.

Oregon Health Plan Prioritized List changes Indications for Proton Beam Therapy

The Health Evidence Review Commission approved the following changes to the Prioritized List of Health Services on January 14, 2016, based on the approved coverage guidance, “Indications for Proton Beam Therapy.” The changes will take effect on the Prioritized list of Health Services for the Oregon Health Plan on October 1, 2016.

HERC Decisions:

- 1) **Add proton beam therapy codes (77520, 77522, 77523,77525) to the following lines:**
 - a. 97 CHILDHOOD LEUKEMIAS
 - b. 133 GRANULOMATOSIS WITH POLYANGIITIS
 - c. 195 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
 - d. 205 CANCER OF BONES
 - e. 242 ACUTE PROMYELOCYTIC LEUKEMIA
 - f. 280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
 - g. 292 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX
 - h. 402 ACUTE MYELOID LEUKEMIA
 - i. 403 MYELOID DISORDERS
- 2) **Remove proton beam therapy codes** from Line 377 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS
- 3) **Add a new guideline note**

GUIDELINE NOTE XXX PROTON BEAM THERAPY FOR CANCER

Lines 97, 117, 130, 133, 195, 205, 242, 280, 292, 299, 377, 402, 403

Proton beam therapy is included on lines 117 CANCER OF EYE AND ORBIT, 130 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD and 299 CANCER OF BRAIN AND NERVOUS SYSTEM.

Proton beam therapy is included on lines 133, 205, and 292 only for: malignant skull base, paranasal sinus (including lethal midline granuloma), spinal, and juxtaspinal tumors .

Proton beam therapy is additionally included on lines 97, 195, 242, 280, 402, and 403 only for pediatric malignant tumors (incident cancer under age 21.)

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: PROTON BEAM THERAPY

Approved January 14, 2016

HERC Coverage Guidance

Proton beam therapy (PBT) is recommended for coverage for malignant ocular tumors (*strong recommendation*).

Proton beam therapy is recommended for coverage (*weak recommendation*) for:

- malignant brain, spinal, skull base, paranasal sinus, and juxtaspinal tumors
- pediatric malignant tumors (incident cancer under age 21)

Proton beam therapy is not recommended for coverage for cancer of the bone, breast, oropharynx, nasopharynx, esophagus, liver, lung, or prostate or for gynecologic or gastrointestinal cancers, lymphoma, sarcoma, thymoma, seminoma, arteriovenous malformation or ocular hemangiomas (*weak recommendation*).

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

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.

EVIDENCE SOURCES

Trusted sources

Washington State Health Care Authority Health Technology Assessment Program. (2014). Proton Beam Therapy. Olympia, WA: Health Technology Assessment Program. Retrieved January 22, 2015 from <http://www.hca.wa.gov/hta/Pages/proton.aspx>.

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

EVIDENCE OVERVIEW

Clinical background

Protons are positively-charged subatomic particles that have been in clinical use as a form of external beam radiotherapy for over 60 years. Compared to the photon X-ray energy used in conventional radiotherapy, proton beams have physical attributes that are potentially appealing. Specifically, protons deposit radiation energy at or around the target, at the end of the range of beam penetration, a phenomenon known as the Bragg peak. The goal of any external beam radiotherapy is to deliver sufficient radiation to the target tumor while mitigating the effects on adjacent normal tissue. This has been a challenge for conventional photon therapy due to the amount of radiation deposited both before and after the target is reached. While the amount of photon radiation at entry into the body is much higher than at exit, photon beams typically “scatter” to normal tissues after leaving the target. This so-called “exit” dose is absent for protons, as tissue beyond the point of peak energy deposition receives little to no radiation.

Initial use of proton beam therapy (PBT) focused on conditions where sparing very sensitive adjacent normal tissues was felt to be of utmost importance, such as cancers or noncancerous malformations of the brain stem, eye, or spinal cord. In addition, proton beam therapy was advocated for many pediatric tumors because even lower-dose irradiation of normal tissue in pediatric patients can result in pronounced acute and long-term toxicity. There are also long-standing concerns regarding radiation’s potential to cause secondary malignancy later in life, particularly in those receiving radiation at younger ages. Finally, radiation may produce more nuanced effects in children, such as neurocognitive impairment in pediatric patients treated with radiotherapy for brain cancers.

More recently, however, the use of PBT has been expanded in many settings to treat more common cancers such as those of the prostate, breast, liver, and lung. With the growth in potential patient numbers and reimbursement, the construction of proton centers has grown substantially. There are now 14 operating proton centers in the U.S., including one in Seattle, WA that came online in March 2013. Eleven additional centers are under construction or in the planning stages, and many more are proposed. The construction of cyclotrons at the heart of proton beam facilities is very expensive (\$150-\$200 million for a multiple gantry facility).

Indications

This appraisal focuses on the use of proton beam therapy (PBT) to treat patients with multiple types of cancer as well as those with selected noncancerous conditions. Within each condition type, two general populations were specified as of interest for this evaluation:

- Patients receiving PBT as primary treatment for their condition (i.e., curative intent)
- Patients receiving PBT for recurrent disease or for failure of initial therapy (i.e., salvage)

All forms of PBT were considered for this evaluation, including monotherapy, use of PBT as a “boost” mechanism to conventional radiation therapy, and combination therapy with other modalities such as

chemotherapy and surgery. All PBT studies that met entry criteria for this review were included, regardless of manufacturer, treatment protocol, location, or other such concerns.

Conditions included in the evidence review are as follows:

- Cancers
- Bone tumors
- Brain, spinal, and paraspinal tumors
- Breast cancer
- Esophageal cancer
- Gastrointestinal cancers
- Gynecologic cancers
- Head and neck cancers (including skull base tumors)
- Liver cancer
- Lung cancer
- Lymphomas
- Ocular tumors
- Pediatric cancers (e.g., medulloblastoma, retinoblastoma, Ewing's sarcoma)
- Prostate cancer
- Soft tissue sarcomas
- Seminoma
- Thymoma
- Noncancerous Conditions
- Arteriovenous malformations
- Hemangiomas
- Other benign tumors (e.g., acoustic neuromas, pituitary adenomas)

Evidence review

A summary of the net health benefit of PBT vs. alternative treatments and the strength of available evidence on net health benefit, as well as an evaluation of consistency of these findings with clinical guideline statements and public/private coverage policy, can be found in Table 1. The level of comparative evidence was extremely limited for certain conditions and entirely absent for others. We identified a total of six RCTs and 37 nonrandomized comparative studies across all 19 condition types. Importantly, five of the six RCTs involved different treatment protocols for PBT and had no other comparison groups; while these are included for completeness, primary attention was paid to studies (RCTs and otherwise) that compared PBT to an alternative form of treatment.

Most of the comparative studies identified also had major quality concerns. For example, nearly all non-randomized comparative studies were retrospective in nature, and many involved comparisons of a PBT cohort to a non-contemporaneous group receiving alternative therapy. Major differences in patient demographics and baseline clinical characteristics as well as duration of follow-up were often noted between groups. Of the 6 RCTs identified, 1, 4, and 1 were judged to be of good, fair, and poor quality respectively. Corresponding figures for non-randomized comparative studies were 1, 20, and 16.

As noted on Table 1, PBT was judged to have superior net health benefit for ocular tumors, and incremental net health benefit for adult brain/spinal tumors and pediatric cancers. PBT was comparable to alternative treatment options for patients with liver, lung, and prostate cancer as well as one noncancerous condition (hemangiomas). Importantly, however, the strength of evidence was low for all of these conditions. The evidence base for all other condition types was insufficient to determine net health benefit, including two of the four most prevalent cancers in the U.S.: breast and gastrointestinal (lung and prostate are the other two).

As with information on clinical effectiveness, data on potential harms of PBT come from RCTs, comparative cohort studies, and case series, although comparative harms data are still lacking for many condition types. Across all condition types, a total of 25 studies reported comparative information on treatment-related harms; differences in the types of harms relevant to each condition, as well as variability in harms classification even within conditions, precludes any attempt to summarily present harms data across all 19 condition categories.

Observational data on secondary malignancy with PBT are generally lacking. Two studies were identified with comparative information. One was a fair-quality matched retrospective cohort study comparing 1,116 patients in a linked Medicare-SEER database who received either PBT or photon radiation for a variety of cancers and were followed for a median of 6.4 years. On an unadjusted basis, the incidence rates of any secondary malignancy and malignancies occurring in the prior radiation field were numerically lower for PBT, but not statistically-significantly so. After adjustment for age, sex, primary tumor site, duration of follow-up, and year of diagnosis, PBT was associated with a risk of secondary malignancy approximately one-half that of photon therapy (HR=0.52; 95% CI: 0.32, 0.85; p=0.009). There are challenges with these findings, however. First and foremost, the lower rate of secondary malignancy with PBT appeared to be manifested almost entirely in the first five years after radiotherapy, a time period in which a second cancer event is not typically attributed to prior radiation (Bekelman, 2013). In addition, patients were accrued over a very long time period (1973-2001), only the very end of which included highly conformal photon techniques like IMRT.

The second study was a poor-quality retrospective cohort study comparing PBT to photon radiotherapy in 86 infants who were treated for retinoblastoma and followed for a median of 7 years (PBT) or 13 years (photon radiotherapy). Therapy was received at two different US centers (PBT at MGH and photon radiotherapy at Children's Hospital Boston). Kaplan-Meier analyses were conducted to control for differential follow-up but no adjustments were made for other differences between groups. Ten-year estimates of the cumulative incidence of secondary malignancy were numerically lower for PBT, but not statistically significantly so (5% vs. 14% for photon, p=0.12). However, when malignancies were restricted to those occurring in-field or thought to be radiation-induced, a significant difference in favor of PBT was observed (0% vs. 14%, p=0.015). In addition, significant differences in favor of PBT in both cumulative incidence and radiotherapy-related malignancy were observed for the subgroup of patients with hereditary disease.

Other harms are presented in detail for each condition type in the sections that follow.

No comparative studies were identified for curative therapy of: breast, esophageal, gastrointestinal, gynecologic, and pediatric cancers; lymphomas, sarcomas, seminomas, and thymomas; arteriovenous malformations.

No comparative studies were identified for salvage treatment of: brain/spinal/paraspinal, breast, esophageal, gastrointestinal, gynecologic, pediatric, and prostate cancers; lymphomas, sarcomas, seminomas, and thymomas; arteriovenous malformations and hemangiomas.

No comparative studies of harms identified for: gastrointestinal and gynecologic cancers; lymphomas, sarcomas, seminomas, and thymomas; arteriovenous malformations.

Cancers

Bone Cancer

Curative

A single poor-quality retrospective comparative cohort study evaluated PBT for primary and recurrent sacral chordomas in 27 patients. Among these patients 21 were treated with surgery and combination PBT /photon therapy (mean radiation dose: 72.8 Gray Equivalents [GyE]), in comparison to six patients who received PBT/photons alone (mean dose: 70.6 GyE). For patients with primary tumors, Kaplan-Meier estimates of local control, disease-free survival and overall survival exceeded 90% among those treated by surgery and radiation (n=14). Only two of the six patients with primary tumors received radiation alone, one of whom had local failure at four years, distant metastases at five years, and died at 5.5 years.

Salvage

In the same study of 27 patients with sacral chordomas who were treated with PBT/photon radiation alone or in combination with surgery, seven radiation/surgery patients and four radiation-only patients had recurrent disease. Among patients in the radiation/surgery group, four patients died of disease 4-10 years after treatment; the remainder was alive with disease at last follow-up. In the radiation-only group, two of four patients died of disease at 4-5 years of follow-up; the other two were alive with disease at last follow-up.

Harms

In the study described above, multiple descriptive harms were reported. Patients receiving radiation alone reported numerically lower rates of abnormal bowel or bladder function as well as difficulty ambulating in comparison to those receiving combination therapy, but rates were not statistically tested. PBT patients also reported higher rates of return to work, although this was also not tested statistically. Evidence is thus inadequate to compare the potential harms of PBT relative to other radiation modalities in patients with bone cancer.

Brain, Spinal, and Paraspinal Tumors

Curative

Two poor-quality retrospective comparative cohort studies investigated primary PBT for brain, spinal, and paraspinal tumors. One was an evaluation of PBT (mean dose: 54.6 GyE) vs. photon therapy (mean dose: 52.9 Gy) in 40 adults (mean age: 32 years; 65% male) who received surgical and radiation treatment of medulloblastoma at a single US cancer center. PBT patients were followed for a median of 2.2 years, while photon patients were followed for a median of nearly five years. No statistical differences between radiation modalities were seen in Kaplan-Meier assessment of either overall or progression-free survival at two years. A numeric difference was seen in the rate of local or regional failure (5% for PBT vs. 14% for photon), but this was not assessed statistically.

The second study involved 32 patients treated for intramedullary gliomas with either PBT (n=10) or IMRT (n=22). While explicit comparisons were made between groups, the PBT population was primarily pediatric (mean age: 14 years), while the IMRT population was adult (mean age: 44 years). Patients in both groups were followed for a median of 24 months; dose was >50 GyE or Gy in approximately 75% of patients. While the crude mortality rate was lower in the PBT group (20% vs. 32% for IMRT, not tested), in multivariate analyses controlling for age, tumor pathology, and treatment modality, PBT was associated with significantly increased mortality risk (Hazard Ratio [HR]: 40.0, p=0.02). The rate of brain metastasis was numerically higher in the PBT group (10% vs. 5% for IMRT), but this was not statistically tested. Rates of local or regional recurrence did not differ between groups.

Harms

In the first study described above, PBT was associated with statistically-significantly lower rates of weight loss (median % of baseline: -1.2% vs. 5.8% for photon, p=0.004) as well as requirements for medical management of esophagitis (5% vs. 57% respectively, p<0.001). PBT patients also experienced less RTOG grade 2 or greater nausea and vomiting (26% vs. 71%, p=0.004).

In the second study comparing primarily 10 pediatric patients (mean age: 14 years) receiving PBT for spinal cord gliomas to 22 adults receiving IMRT for the same condition (mean age: 44 years) (Kahn, 2011), no cases of long-term toxicity or myelopathy were reported in either group. Minor side-effect rates were reported for the overall cohort only. In summary, limited, low-quality evidence suggests that PBT is associated with reductions in acute radiation-related toxicity relative to photon radiation in patients with brain and spinal tumors.

Table 1: Summary table assessing strength of evidence, direction of benefit, and consistency with relevant guideline statements and coverage policy.

Condition	Incidence (per 100,000)	Net Health Benefit vs. Comparators	Type of Net Health Benefit	Strength of Evidence	Guideline Recommendations	Coverage Policies
Cancer						
Bone	1.3	Insufficient	---	+	M	M
Brain/spinal	9.6	Incremental	B: = H: ↓	+	U	U
Breast	97.7	Insufficient	---	o	NM	NR/NC
Esophageal	7.5	Insufficient	---	o	NM	NR/NC
GI	100.6	Insufficient	---	o	NM	NR/NC
Gynecologic	38.2	Insufficient	---	o	NM	NR/NC
Head/neck	17.2	Insufficient	---	+	NM	M
Liver	12.8	Comparable	B: = H: =	+	NM	M
Lung	95.0	Comparable	B: = H: =	+	M	M
Lymphomas	32.9	Insufficient	---	o	NR/NC	NR/NC
Ocular	1.2	Superior	B: ↑ H: ↓	++	U	U
Pediatric	9.1	Incremental	B: = H: ↓	+	U	U
Prostate	99.4	Comparable	B: = H: =	+	M	M
Sarcomas	4.8	Insufficient	---	o	NM	M
Seminoma	4.0	Insufficient	---	o	NM	NM
Thymoma	0.2	Insufficient	---	o	NM	NM
Noncancerous						
AVMs	1.0	Insufficient	---	o	NM	M
Hemangiomas	2.0	Comparable	B: = H: =	+	NM	NM
Other	2.0	Insufficient	---	o	NM	M

B: Benefits; H: Harms

Strength of Evidence: Low=+; Moderate=++; High=+++; No evidence=o

Legend: U = Universally recommended or covered; M=Mixed recommendations or coverage policies; NM=Not mentioned in guidelines or coverage policies; NR/NC=Not recommended or not covered

Esophageal Cancer

Harms

Two studies were identified that examined comparative harms in patients treated with PBT for esophageal cancer. One was a relatively large, fair-quality, retrospective comparative cohort study of 444 patients (median age: 61 years; 91% male) who were treated with chemotherapy and radiation (PBT, IMRT, or 3D-CRT) followed by surgical resection. Patients were followed for up to 60 days after hospital discharge. After adjustment for patient characteristics and clinical variables, 3D-CRT was associated with a significantly greater risk of postoperative pulmonary complications vs. PBT (Odds Ratio [OR]: 9.13, 95% CI: 1.83, 45.42). No significant differences were observed between PBT and IMRT, however. No differences in the rate of gastrointestinal complications were observed for any treatment comparison.

In addition, a fair-quality comparative study was identified that examined early impact on lung inflammation and irritation in 75 patients receiving PBT, IMRT, or 3D-CRT for esophageal cancer; patients were followed for up to 75 days following radiation. Nearly all outcome and toxicity measures were reported for the entire cohort only. However, the rate of pneumonitis was found to be significantly higher among PBT patients (33% vs. 15% for IMRT/3D-CRT, $p=0.04$). In summary, evidence is inadequate to compare the potential harms of PBT relative to other radiation modalities in patients with esophageal cancer, particularly in comparison to IMRT.

Head and Neck Cancers

Curative

There were two poor-quality retrospective comparative cohorts of primary PBT in head and neck cancer. One was an evaluation of 33 patients treated with either PBT alone or PBT+photon therapy to a target dose of 76 Gy for a variety of head and neck malignancies in Japan. Treatment groups differed substantially in terms of age, gender, and duration of follow-up (mean: 5.9 vs. 3.1 years). Numeric differences in favor of PBT+photon therapy were seen for local control, recurrence, and mortality, but these were not statistically tested, nor were multivariate adjustments made for differences between groups.

The other study was a very small ($n=6$) comparison of endoscopic resection followed by either PBT or IMRT as well as endoscopy alone in patients with malignant clival tumors. Limited description of the study suggests that PBT was used only in cases of residual disease, while it is unclear whether IMRT was also used in this manner or as an adjuvant modality. One of the IMRT patients died of causes unrelated to disease; no other deaths were reported.

Salvage

In the first study described above, four patients were identified as having recurrent disease, three of whom received PBT alone. Two of the three PBT-only patients were alive with local tumor control at last follow-up (5 and 17 years respectively); one patient had their cancer recur three months after PBT and died in month 7 of follow-up. The one PBT+photon patient died at 2.5 years of follow-up, but was described as having local tumor control.

Harms

In the first study describe above, rates of tongue ulceration, osteonecrosis, and esophageal stenosis differed somewhat between treatment groups, but were not statistically tested. Overall toxicity rates were estimated to be 22.8% at both three and five years, but were not stratified by treatment modality.

In a separate, fair-quality study comparing rates of vision loss from radiation-induced optic neuropathy in 75 patients treated with PBT or carbon-ion therapy for head and neck or skull base tumors, unadjusted rates of vision loss were similar between modalities (8% and 6% for PBT and carbon-ion respectively, not statistically tested). In multivariate analyses controlling for demographic and clinical characteristics, treatment modality had no effect on rates of vision loss ($p=0.42$). Another comparison of PBT and carbon-ion therapy in 59 patients with head and neck or skull base tumors was of poor quality (due to no control for differences between patient groups) and focused on the incidence of radiation-induced brain changes. The incidence of CTCAE brain injury of any grade was significantly ($p=0.002$) lower in the PBT group. MRI-based assessment of brain changes showed a lower rate in the PBT group (17% vs. 64% for carbon-ion), although this was not tested statistically. In summary, evidence is inadequate to compare the potential harms of PBT relative to other radiation modalities in patients with head and neck cancer.

Liver Cancer

Curative

Two fair-quality prospective comparative cohort studies provided evidence of the clinical effectiveness of primary use of PBT in liver cancer. One was an evaluation of 35 patients with unresectable hepatocellular carcinoma (HCC) who were treated with PBT (mean dose: 76.5 GyE) either alone or in combination with chemotherapy and were followed for up to 4 years. While statistical testing was not performed, rates of local tumor control and the proportion of patients experiencing reductions in tumor volume were nearly identical between groups.

The other study was also prospective but compared PBT to another heavy-ion modality not in circulation in the U.S. (carbon ion). In this study, a fair-quality comparison of 350 patients with HCC who received PBT (53-84 GyE) or carbon-ion (53-76 GyE) therapy and were followed for a median of 2.5 years, no statistically-significant differences were observed in 5-year Kaplan-Meier estimates of local control, no biological evidence of disease, or overall survival between treated groups.

Salvage

Two studies were identified with information on recurrent disease. One was a poor-quality comparison of PBT to conventional photon radiation in eight patients with recurrent HCC after hepatectomy. Five patients were treated with PBT (68.8-84.5 GyE), and three with photons (60-70 Gy). Seven of eight patients died of liver failure or lung metastasis a median of 1.5 years after radiation; the one patient alive at the end of follow-up was a photon patient. The rate of local tumor control was 78%, and did not differ between treatment groups.

The other study was a previously-described prospective comparison of PBT to carbon-ion therapy in 350 patients with primary or recurrent HCC. No subgroup analyses were performed, but prior treatment history for HCC was found not to have a statistically-significant impact on local tumor control ($p=0.73$). Prior treatment was not examined as a risk factor for overall survival, however.

Harms

Two comparative studies were identified with comparative information on radiation-related harms. In a previously-described study of eight patients with recurrent HCC after hepatectomy, there were no instances of bone marrow depression or gastrointestinal complications in either group. Serum aspartate aminotransferase (AST) levels increased in the three photon patients and 4/5 PBT patients, although this was not tested statistically.

In the other study, a previously-described comparison of PBT to carbon-ion therapy in 350 patients with primary or recurrent HCC, rates of toxicities as graded by the Common Terminology Criteria for Adverse Events (CTCAE) framework were comparable between groups, including dermatitis, GI ulcer, pneumonitis, and rib fracture. The rate of grade 3 or higher toxicities was similar between groups (3% vs. 4% for PBT and carbon-ion respectively), although this was not statistically tested.

In summary, limited, low-quality evidence suggests that PBT is associated with comparable rates of toxicity to other radiation modalities in patients with liver cancer.

Lung Cancer

Curative

Three fair-quality comparative cohort studies examined the clinical effectiveness of PBT in lung cancer. Two studies retrospectively compared outcomes with PBT to those with IMRT or older three-dimensional conformal radiotherapy (3D-CRT) at a US cancer center. One study involved 250 patients with non-small-cell lung cancer (NSCLC) who were treated with 66 Gy of photons or 74 GyE of protons and followed for up to one year to assess a key measure of lung function known as diffusing capacity of lung for carbon monoxide (DLCO). While this measure did not differ between PBT and IMRT at 5-8 months after treatment, DLCO declined significantly more in the 3D-CRT group as compared to PBT after adjustment for pretreatment characteristics and other lung function measures ($p=0.009$).

A second study focused on survival in 202 patients with locally-advanced, unresectable NSCLC who were followed for a median of 1.5 years and treated 74 GyE of PBT or 63 Gy of either IMRT or 3D-CRT. Actuarial estimates of median overall survival were 24.4, 17.6, and 17.7 months for PBT, IMRT, and 3D-CRT respectively, although these differences were not statistically significant ($p=0.1061$).

A third study was a prospectively-measured cohort but, as with the study of liver cancer mentioned above, compared PBT to carbon ion therapy, evaluating 111 Japanese NSCLC patients over a median of 3.5 years. No statistically-significant differences between groups were observed in three-year actuarial estimates of local control, progression-free survival, or overall survival.

Salvage

In the second study described above, 22% of the study sample was identified as having a prior malignancy of any type. The effects of prior malignancy on overall survival were not reported, however.

Harms

A total of three comparative studies assessed harms in patients with lung cancer. One was a study of severe radiation-induced esophagitis (within six months of treatment) among 652 patients treated for NSCLC with PBT, IMRT, or 3D-CRT at a US cancer center. Rates of grade 3 or higher esophagitis were 6%, 8%, and 28% for PBT, 3D-CRT, and IMRT respectively ($p<.05$ for PBT and 3D-CRT vs. IMRT).

In the previously-described noncontemporaneous case series comparison of patients with locally-advanced, unresectable NSCLC who were treated with PBT, IMRT, or 3D-CRT, hematologic toxicity rates did not differ by radiation modality. Significant differences in favor of PBT were seen in rates of grade 3 or higher esophagitis (5%, 39%, and 18% for PBT, IMRT, and 3D-CRT respectively, $p<0.001$) as well as pneumonitis (2%, 6%, and 30%, $p<0.001$), while rates of grade 3 or higher dermatitis were significantly greater in the PBT group (24% vs. 17% and 7% for IMRT and 3D-CRT, $p<0.001$).

Finally, in a previously-described comparison of PBT to carbon-ion therapy in 111 patients in Japan, rates of pneumonitis, dermatitis, and rib fracture did not differ statistically between radiation modalities across all toxicity grades. In summary, moderate evidence suggests that rates of treatment-related toxicities with PBT are comparable to those seen with other radiation modalities in patients with lung cancer.

Ocular Tumors

Curative

In comparison to other cancer types, the evidence base for ocular tumors was relatively substantial. A total of seven comparative studies were identified of the clinical benefits of primary PBT in such cancers—a single RCT, four retrospective cohort studies, a comparison of a recent case series to the treatment groups from the RCT, and a comparison of noncontemporaneous case series. The RCT compared PBT alone to a combination of PBT and transpupillary thermotherapy (TTT) in 151 patients treated for uveal melanoma and followed for a median of 3 years. Combination therapy was associated with a statistically-significantly ($p=0.02$) reduced likelihood of secondary enucleation; no other outcomes differed significantly between groups. In a separate, poor-quality comparison of these findings to a separate series of patients undergoing PBT with endoresection of the scar, rates of secondary enucleation did not differ between groups, but rates of neovascular glaucoma were significantly lower in the PBT+endoresection group vs. the groups from the RCT (7% vs. 58% and 49% for PBT alone and PBT+TTT respectively, $p<0.0001$). Of note, however, median follow-up was less than two years in the PBT+endoresection series vs. 9 years in the RCT.

Three of the cohort studies were all fair-quality and involved comparisons to surgical enucleation in patients with uveal melanoma at single centers. PBT was associated with statistically-significant improvements in overall survival rates relative to enucleation at 2-5 years in two of these studies. Rates of metastasis-related and all cancer-related death were statistically-significantly lower among PBT patients through two years of follow-up in one study ($n=1,051$), but were nonsignificant at later timepoints. The 5-year metastasis-free survival rate in a second study ($n=67$) was 50% higher among PBT patients in a Cox regression model controlling for baseline characteristics (59.0% vs. 39.4% for enucleation, $p=0.02$). In the third study, Kaplan-Meier curves for all-cause mortality, melanoma-related mortality and metastasis-free survival did not statistically differ for 132 patients treated with PBT and enucleation. Metastasis-free survival also did not differ in Cox regression adjusting for age, sex, and tumor thickness.

Another fair-quality study assessed the impact of PBT + chemotherapy vs. PBT alone in 88 patients with uveal melanoma who were followed for 5-8 years. Five-year overall survival rates did not statistically differ between groups on either an unadjusted or Cox regression-adjusted basis.

Finally, a poor-quality comparison of noncontemporaneous case series evaluated treatment with PBT + laser photocoagulation or PBT alone in 56 patients with choroidal melanoma. At one year, there were no differences in visual acuity between groups.

Salvage

A single comparative study examined PBT in recurrent ocular cancer. In this fair-quality, comparative cohort study, a total of 73 patients with uveal melanoma had recurrence of disease following an initial course of PBT at a US hospital. Patients (mean age: 58 years) were treated with either a second course of PBT (70 GyE) in five fractions or surgical enucleation and followed for 5-7 years. The likelihood of overall survival at five years was significantly ($p=0.04$) longer in the PBT group (63% vs. 36% for enucleation), as was the probability of being free of metastasis at this timepoint (66% vs. 31% respectively, $p=0.028$). Findings were similar after Cox proportional hazards regression adjusting for tumor volume and year of retreatment as well as patient age. The likelihood of local tumor recurrence at five years was 31% in the PBT group. No local recurrences were found in the enucleation group, which is not surprising given the nature of the treatment.

Harms

Two comparative studies assessed the harms of PBT for ocular cancers. In the previously-described RCT comparing PBT with thermotherapy to PBT alone in 151 patients with uveal melanoma, no statistically-significant differences were observed between groups in rates of cataracts, maculopathy, papillopathy, glaucoma, or intraocular pressure. The combination therapy group had a significantly lower rate of secondary enucleation ($p=0.02$), although actual figures were not reported.

In a previously-described comparison of PBT to enucleation in 132 patients treated for unilateral choroidal tumors, rates of eye loss in the PBT arm were assessed and estimated to be 26% at five years of follow-up. In summary, limited, low-quality evidence suggests comparable rates of harm for PBT relative to treatment alternatives in patients with ocular tumors.

Pediatric Cancers

Harms

PBT's theoretical potential to lower radiation-induced toxicity in children serves as the comparative evidence base. Comparative studies are lacking, most likely due to a lack of clinical equipoise.

Other than the study of secondary malignancy described above, no comparative studies of the potential harms of PBT in patients with pediatric cancers were identified.

Prostate Cancer

Curative

The largest evidence base available was for prostate cancer (10 studies). However, only 6 of these studies reported clinical outcomes *and* compared PBT to alternative treatments. These included an RCT, a prospective comparative cohort, and four comparisons of noncontemporaneous case series.

The included RCT was a fair-quality comparison of 202 patients with advanced (stages T3-T4) prostate cancer who were randomized to receive either photon therapy with a proton boost (total dose: 75.2 GyE) or photons alone (67.2 Gy) and were followed for a median of five years. Kaplan-Meier estimates of local tumor control, disease-specific survival, and overall survival were similar at both 5- and 8-year

timepoints among the entire intent-to-treat population as well as those completing the trial (n=189). However, in patients with poorly-differentiated tumors (Gleason grades 4 or 5), local control at 8 years was significantly better in patients receiving PBT+photons (85% vs. 40% for photons alone, p=0.0014).

The prospective cohort study was a fair-quality comparison of patient-reported health-related QoL at multiple timepoints among 185 men (mean age: 69 years) with localized prostate cancer who were treated with PBT, PBT+photons, photons alone, surgery, or watchful waiting. Overall QoL, general health status, and treatment-related symptom scales were employed. No differences in overall QoL or general health status were observed at 18 months of follow-up, although men treated with PBT monotherapy reported better physical function in comparison to surgery (p=0.01) or photon radiation (p=0.02), and better emotional functioning in relation to photon radiation (p<0.001). Men receiving PBT+photons also reported significantly fewer urinary symptoms at 18 months in comparison to watchful waiting (p<0.01).

Outcomes were also assessed in three comparisons of noncontemporaneous case series. One was a fair-quality evaluation of high-dose PBT+photons (79.2 GyE) in 141 patients enrolled in a clinical trial who were matched on clinical and demographic criteria to 141 patients treated with brachytherapy. Patients were followed for a median of eight years. Eight-year actuarial estimates of overall survival, freedom from metastasis, and biochemical failure did not statistically differ between groups. The proportion of patients achieving a nadir PSA level of ≤ 0.5 ng/mL as of their final measurement was significantly higher in the brachytherapy group (92% vs. 74% for PBT, p=0.0003).

Two additional studies were deemed to be of poor quality due to a lack of control for confounding between study populations. One was a comparison of a cohort of 206 brachytherapy patients compared with the same PBT+photon group described above. The difference in the percentage of patients achieving nadir PSA after a median of 5.4 years of follow-up was similar to that reported in the study above (91% vs. 59%), although statistical results were not reported. Five-year estimates of disease-free survival (using biochemical failure definitions) did not statistically differ between groups. The other study involved comparisons of bowel- and urinary-related QoL in three distinct cohorts receiving PBT (n=95; 74-82 GyE), IMRT (n=153; 76-79 Gy), or 3D-CRT (n=123; 66-79 Gy). Statistical changes were assessed within (but not between) each cohort immediately following treatment as well as at 12 and 24 months of follow-up, and were also assessed for whether the change was considered “clinically meaningful” (>0.5 SD of baseline values). Some differences in QoL decrements were seen at earlier timepoints. However, at 24 months, all groups experienced statistically and clinically significant decrements in bowel QoL, and none of the groups had significant declines in urinary QoL.

A fourth, poor-quality comparison of case series involved an evaluation of patient-reported outcomes on the Expanded Prostate Cancer Index Composite (EPIC) questionnaire among a cohort of 1,243 patients receiving PBT for prostate cancer and a group of 204 patients receiving IMRT from a previous multicenter study. Statistically-significant differences between treatment groups were observed for many baseline characteristics, only some of which were adjusted for in multivariate analyses. No differences were observed in summary scores for bowel, urinary, and sexual QoL at two years, although more IMRT patients reported specific bowel frequency (10% vs. 4% for PBT, p=0.05) and urgency (15% vs. 7%, p=0.02) problems at two years.

Harms

Four comparative studies examined the harms associated with PBT and alternative treatments in patients with prostate cancer. The previously-described RCT of PBT+photon therapy vs. photons alone examined rates of rectal bleeding, urethral stricture, hematuria, incontinence, and loss of full potency; no patients in either arm had grade 3 or higher toxicity during radiation therapy. Actuarial estimates of rectal bleeding at eight years were significantly higher in the PBT+photon arm (32% vs. 12% for photons alone, $p=0.002$), although this was primarily grade 2 or lower toxicity. Rates of urethral stricture, hematuria, incontinence, and loss of potency did not differ between groups.

Three additional studies involved retrospective comparisons using available databases. The most recent was a matched comparison of 314 PBT and 628 IMRT patients treated for early-stage prostate cancer using the linked Chronic Condition Warehouse-Medicare database with a focus on complications occurring within 12 months of treatment. At six months, rates of genitourinary toxicity were significantly lower in the PBT arm (5.9% vs. 9.5%, $p=0.03$). This difference was not apparent after 12 months of follow-up, however (18.8% vs. 17.5%, $p=0.66$). Rates of gastrointestinal and other (e.g., infection, nerve damage) complications did not statistically differ at either timepoint.

Another recent study compared matched cohorts of men with prostate cancer in the linked Medicare-SEER database who were treated with PBT or IMRT (684 patients in each arm) and followed for a median of four years. IMRT patients had a statistically-significantly lower rate of gastrointestinal morbidity (12.2 vs. 17.8 per 100 person-years, $p<0.05$). No other statistical differences were noted in genitourinary morbidity, erectile dysfunction, hip fracture, or use of additional cancer therapy.

Finally, there was an analysis of nearly 30,000 men in the Medicare-SEER database who were treated with PBT, IMRT, 3D-CRT, brachytherapy, or conservative management (observation alone) and evaluated for gastrointestinal toxicity. All forms of radiation had higher rates of GI morbidity than conservative management. In pairwise comparisons using Cox proportional hazards regression, PBT was associated with higher rates of GI morbidity than conservative management (HR: 13.7; 95% CI: 9.1, 20.8), 3D-CRT (HR: 2.1; 95% CI: 1.5, 3.1), and IMRT (HR: 3.3; 95% CI: 2.1, 5.2).

In summary, moderate evidence suggests that rates of major harms are comparable between PBT and photon radiation treatments, particularly IMRT.

Noncancerous Conditions

Ocular Hemangiomas

Curative

A single poor-quality retrospective study evaluated PBT's clinical effectiveness in 44 patients with diffuse or circumscribed choroidal hemangiomas who were treated with either PBT (20-23 GyE) or photon therapy (16-20 Gy) and followed for an average of 2.5 years. Unadjusted outcomes were reported for the entire cohort only; reduction in tumor thickness, resolution of retinal detachment, and stabilization of visual acuity were observed in >90% of the overall sample. In Kaplan-Meier analysis of outcomes adjusting for differential follow-up between treatment groups, therapeutic modality had no statistically-significant effects on stabilization of visual acuity ($p=0.43$).

Harms

A single, previously-described retrospective comparative cohort study assessed outcomes in patients with circumscribed or diffuse hemangiomas treated with PBT or photon radiation. Small differences in unadjusted rates of optic nerve/disc atrophy, lacrimation (formation of tears) and ocular pressure as well as effects on the retina, lens, and iris were observed between groups, but most side effects were grade 1 or 2. The rate of retinopathy was substantially higher in PBT patients (40% vs. 16% for photons). However, in Cox proportional hazards regression adjusting for between-group differences, no effect of radiation modality on outcomes was observed, including retinopathy (p=0.12).

Other Benign Tumors

Curative

Two comparative studies of PBT's clinical effectiveness in other benign tumors were both of poor quality. One was a retrospective cohort of consisting of 20 patients with giant-cell bone tumors who were treated with PBT+photon therapy (mean: 59 GyE) or photons alone (mean: 52 Gy) and followed for median of 9 years. Patients could also have received partial tumor resection. Of note, the PBT population consisted entirely of young adults (mean age: 23 years), while the photon-only population was much older (mean: 46 years); no attempt was made to control for differences between treatment groups. Rates of disease progression, progression-free survival, and distant metastases were numerically similar between groups, although these rates were not statistically tested.

The other study was a small cohort study comparing PBT alone, photon therapy alone, or PBT + photons in 25 patients with optic nerve sheath meningioma. On an overall basis, visual acuity improved in most patients. Rates did not numerically differ between treatment groups, although these were not tested statistically.

Salvage

In the first study described above, five of 20 were identified as having recurrent disease. Two of the five were treated with PBT+photon therapy, one of whom had progression of disease at eight months but no further progression after retreatment at five years of follow-up. The other patient was free of local progression and metastases as of 9 years of follow-up. In the three photon patients, one had local progression at 12 months but no further progression as of year 19 of follow-up, one patient was free of progression and metastases as of five years of follow-up, and one patient had unknown status.

Harms

The previously-described study comparing PBT, PBT+photon, and photon therapy alone in 25 patients treated for optic nerve sheath meningiomas showed numerically lower rates of acute orbital pain and headache for both PBT groups compared to photon therapy, and numerically higher rates of late asymptomatic retinopathy. None of these comparisons were tested statistically, however. Evidence is limited and inadequate to compare the potential harms of PBT relative to other radiation modalities in patients with other benign tumors.

Cost & Cost-Effectiveness

Limited data are available about costs of PBT in most types of cancer. One study of breast cancer patients in the US examined reimbursement for treatment with 3D-conformal partial breast irradiation using protons or photons vs. traditional whole breast irradiation. Payments included those of treatment

planning and delivery as well as patient time and transport. Total per-patient costs were substantially higher for PBT vs. photon partial irradiation (\$13,200 vs. \$5,300) but only modestly increased relative to traditional whole breast irradiation (\$10,600), as the latter incurred higher professional service fees and involved a greater amount of patient time. Two additional studies from the same group assessed the cost-effectiveness of PBT vs. photon radiation among women with left-sided breast cancer in Sweden. In the first of these, photon radiation was assumed to increase the risk of ischemic and other cardiovascular disease as well as pneumonitis relative to PBT; clinical effectiveness was assumed to be identical. Reductions in adverse events led to a gain in quality-adjusted life years (QALYs) equivalent to approximately one month (12.35 vs. 12.25 for photon). Costs of PBT were nearly triple those of photon therapy, however (\$11,124 vs. \$4,950), leading to an incremental cost-effectiveness ratio (ICER) of \$65,875 per QALY gained. The other study used essentially the same model but focused attention only on women at high risk of cardiac disease (43% higher than general population). In this instance, a much lower ICER was observed (\$33,913 per QALY gained).

One study evaluated the economic impact of PBT in lung cancers among patients in the Netherlands. A Markov model compared PBT to carbon-ion therapy, stereotactic radiation therapy, and conventional radiation in patients with stage 1 non-small-cell lung cancer (NSCLC) over a 5-year time horizon. Effects of therapy included both overall and disease-related mortality as well as adverse events such as pneumonitis and esophagitis. For inoperable NSCLC, PBT was found to be both more expensive and less effective than either carbon-ion or stereotactic radiation and was therefore not included in subsequent analyses focusing on inoperable disease. While not reported in the paper, PBT's derived cost-effectiveness relative to conventional radiation (based on approximately \$5,000 in additional costs and 0.35 additional QALYs) was approximately \$18,800 per QALY gained.

Three decision analyses were available that focused on pediatric cancers, all of which focused on a lifetime time horizon in children with medulloblastoma who were treated at 5 years of age. In a US-based model that incorporated costs and patient preference (utility) values of treatment and management of adverse events such as growth hormone deficiency, cardiovascular disease, hypothyroidism, and secondary malignancy, PBT was found to generate lower lifetime costs (\$80,000 vs. \$112,000 per patient for conventional radiation) and a greater number of QALYs (17.37 vs. 13.91). Reduced risks for PBT were estimated based on data from dosimetric and modeling studies. Sensitivity analyses on the risk of certain adverse events changed the magnitude of PBT's cost-effectiveness, but it remained less costly and more effective in all scenarios.

Pediatric medulloblastoma was assessed in two modeling studies. As with the analysis above, PBT was assumed to reduce both mortality and nonfatal adverse events relative to conventional photon therapy. On a per-patient basis, PBT was assumed to reduce lifetime costs by approximately \$24,000 per patient and increase quality-adjusted life expectancy by nearly nine months (12.8 vs. 12.1 QALYs). On a population basis, 25 medulloblastoma patients treated by PBT would have lifetime costs reduced by \$600,000 and generate an additional 17.1 QALYs relative to conventional photon radiation.

Finally, four studies were identified that examined costs and cost-effectiveness of PBT for prostate cancer. An analysis of the 2008-2009 Chronic Condition Warehouse examined treatment costs for matched Medicare beneficiaries with prostate cancer who received PBT or IMRT. Median Medicare reimbursements were \$32,428 and \$18,575 for PBT and IMRT respectively (not statistically tested).

A relatively recent Markov decision analysis estimated the lifetime costs and effectiveness of PBT, IMRT, and stereotactic body radiation therapy (SBRT) for localized prostate cancer. Clinical effectiveness and impact on mortality were assumed to be equivalent across all three groups. SBRT was found to have the lowest treatment costs and shortest time in treatment of the three modalities, and produced slightly more QALYs (8.11 vs. 8.05 and 8.06 for IMRT and PBT respectively) based on an expected rate of sexual dysfunction approximately half that of IMRT or PBT. SBRT was cost-saving or cost-effective vs. PBT in 94% of probabilistic simulations.

An earlier decision analysis estimated the potential cost-effectiveness of a hypothetically-escalated PBT dose (91.8 GyE) vs. 81 Gy delivered with IMRT over a 15-year time horizon. The model focused on mortality and disease progression alone (i.e., toxicities were assumed to be similar between groups), and assumed a 10% reduction in disease progression from PBT's higher dose. This translated into QALY increases of 0.42 and 0.46 years in 70- and 60-year-old men with intermediate-risk disease respectively. Costs of PBT were \$25,000-\$27,000 higher in these men. ICERs for PBT vs. IMRT were \$63,578 and \$55,726 per QALY for 70- and 60-year-old men respectively.

Finally, the model also evaluated costs and outcomes for a hypothetical cohort of 300 65 year-old men with prostate cancer. PBT was assumed to result in a 20% reduction in cancer recurrence relative to conventional radiation as well as lower rates of urinary and gastrointestinal toxicities. PBT was estimated to be approximately \$8,000 more expensive than conventional radiation over a lifetime but result in a QALY gain of nearly 4 months (0.297). The resulting cost-effectiveness ratio was \$26,481 per QALY gained.

EVIDENCE SUMMARY

Proton beam therapy (PBT) has been used for clinical purposes for over 50 years and has been delivered to tens of thousands of patients with a variety of cancers and noncancerous conditions. Despite this, evidence of PBT's comparative clinical effectiveness and comparative value is lacking for nearly all conditions under study in this review. As mentioned previously, it is unlikely that significant comparative study will be forthcoming for childhood cancers despite uncertainty over long-term outcomes, as the potential benefits of PBT over alternative forms of radiation appear to be generally accepted in the clinical and payer communities. In addition, patient recruitment for potential studies may be untenable in very rare conditions (e.g., thymoma, arteriovenous malformations). In other areas, however, including common cancers such as breast and prostate, the poor evidence base and residual uncertainty around the effects of PBT is highly problematic.

The net health benefit of PBT relative to alternative treatments is rated "Superior" (moderate-large net health benefit) in ocular tumors and "Incremental" (small net health benefit) in adult brain/spinal and pediatric cancers. The net health benefit is judged "Comparable" (equivalent net health benefit) in several other cancers, including liver, lung, and prostate cancer, as well as ocular hemangiomas. It should be noted, however, that judgments of comparability were made based on a limited evidence base that provides relatively low certainty that PBT is roughly equivalent to alternative therapies. While further study may reduce uncertainty and clarify differences between treatments, it is currently the case that PBT is far more expensive than its major alternatives, and evidence of its short or long-term relative cost-effectiveness is lacking for many of these conditions. It should also be noted that evidence was

examined for 11 cancers and noncancerous conditions not listed above, and it was determined that there was insufficient evidence to obtain even a basic understanding of PBT's comparative clinical effectiveness and comparative value.

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 four 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. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for ocular tumors (excluding hemangiomas)	Superior benefit, fewer harms	Moderate	Moderate; expensive, but lowered projected costs due to greater benefit and fewer harms	Low variability (preference for PBT)	Recommended for coverage (<i>strong recommendation</i>)	Moderate quality evidence demonstrates PBT is superior to other therapies with fewer harms, although at a greater cost, and many patients would choose this.
PBT for adult malignant brain/spinal tumors	Comparable benefit but fewer harms.	Very Low**	Moderate; expensive, but lowered projected costs due to fewer harms	Low variability (preference for PBT)	Recommended for coverage (<i>weak recommendation</i>)	There is very low quality evidence of incremental benefit compared to alternatives, but also with higher costs. People would likely choose what is thought to have fewer harms and greater benefit.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for skull base, paranasal sinus, and juxtaspinal tumors	Comparable benefit but fewer harms.	Very Low**	Moderate, expensive, but lowered projected costs due to fewer harms	Low (preference for PBT)	Recommended for coverage (<i>weak recommendation</i>)	The subcommittee heard expert testimony that skull-base tumors were one of the first uses of proton beam therapy in the 1960s and that reduction in harms to surrounding structures while delivering adequate dosimetry to tumor tissue is the primary consideration in treatment planning. Based on comparable benefit and fewer harms, allowing for higher costs but patient preference, weak recommendation for coverage.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for malignant pediatric tumors	Comparable benefit but fewer harms.	Very Low**	Moderate, expensive, but lowered projected costs due to fewer harms	Moderate (significant concerns regarding radiation therapy, given variety of tumors may have options for alternative therapies)	Recommended for coverage (<i>weak recommendation</i>)	Very low quality evidence suggests comparable benefit, and fewer harms, with a potential health impact over decades. There is a strong theoretical benefit for reducing secondary tumors although there is not good evidence to support this. Cost-effectiveness analyses suggest long term cost savings with PBT for pediatric tumors. There is a lack of clinical equipoise and therefore future studies on this are unlikely.
PBT for liver cancer	Comparable benefit, comparable harms	Low	High	Moderate	Do not recommend (<i>weak recommendation</i>)	There is low quality evidence that PBT has comparable benefits and harms to alternatives, but is more expensive,

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for lung cancer	Comparable benefit, comparable harms	Low	High	Moderate	Do not recommend (<i>weak recommendation</i>)	Low quality evidence of similar effectiveness, similar risk, and more cost.
PBT for prostate cancer	Comparable benefit, comparable harms	Low	High	Moderate	Do not recommend (<i>weak recommendation</i>)	There is low quality evidence of similar effectiveness, similar risk, and more cost. There may be improved local control in poorly differentiated prostate cancer (Glisan 4-5) but no demonstrated impact on survival.
PBT for ocular hemangiomas	Comparable benefit, comparable harms	Very Low	High	Moderate to high, due to uncertainty of benefit	Do not recommend (<i>weak recommendation</i>)	Very low quality evidence exists, but it is suggesting comparable benefit. Given that there are alternatives available with similar risk and less expensive, recommendation against coverage.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for bone, breast, oropharyngeal, nasopharyngeal, esophageal, GI, gynecologic, lymphomas, sarcomas, seminomas, thymomas, AVMs, and other noncancerous conditions	Unknown	Bone: Low All others: No evidence	High	Moderate (many would not choose PBT due to cost, need to travel, uncertain benefit)	Do not recommend (weak recommendation)	, Unknown benefit and unknown risk compared to alternative, and increased cost.

*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee, except as specified.

** The Quality of Evidence rating was assigned by the HERC Subcommittee.

Note: GRADE framework elements are described in Appendix A

POLICY LANDSCAPE

Quality measures

No quality measures were identified when searching the National Quality Measures Clearinghouse.

Professional society guidelines

Guidelines on the use of proton beam therapy are available from the National Comprehensive Cancer Network (NCCN, 2013-2014), American Society for Radiation Oncology (ASTRO, 2013), American College of Radiology (ACR, 2011-2013), American Cancer Society (ACS), and the Alberta Health Services in Canada (2013).

Bone Cancer

NCCN guidelines state that for unresectable high- and low-grade chondrosarcomas of the skull base and axial skeleton, PBT may be indicated to allow for high-dose treatment. Alberta guidelines recommend PBT for sarcomas, including chordoma and chondrosarcoma. According to the ACR, PBT-based treatment plans are considered inappropriate (rated 1-2) in spinal and non-spinal bone metastases.

Brain, Spinal, and Paraspinal Tumors

Alberta guidelines recommend PBT as an option for CNS lesions including craniopharyngioma, germ cell tumors and low-grade gliomas.

Head and Neck Cancers

For ethmoid and maxillary sinus tumors, NCCN considers PBT an investigative therapeutic technique only. Alberta guidelines state that treatment with PBT for adults with acoustic neuromas, and paranasal sinus and nasal cavity tumors is recommended.

Lung Cancer

NCCN considers PBT appropriate for non-small-cell lung cancer. ACR recommends against use of PBT for NSCLC patients with poor performance status or requirements for palliative treatment, while Alberta guidelines do not recommend PBT for NSCLC.

Lymphomas

NCCN states that PBT may be appropriate for patients with Hodgkin and Non-Hodgkin lymphoma as well as soft tissue sarcomas; however, long-term studies are necessary to confirm benefits and harms. Alberta guidelines do recommend PBT for lymphomas only in patients less than 30 years of age.

Ocular Tumors

NCCN guidelines for treatment options in ocular tumors are under development. Alberta guidelines recommend PBT for ocular melanoma.

Pediatric Tumors

Guidelines from Alberta recommend consideration of PBT for pediatric tumors including ependymomas, rhabdomyosarcoma, Ewing's sarcoma, pineal tumors, and patients requiring craniospinal irradiation.

Prostate Cancer

NCCN and Alberta guidelines do not recommend PBT for use in prostate cancer, as superior or equivalent effects have not been demonstrated in comparison to conventional external-beam therapy. In a position statement, ASTRO concluded that the evidence supporting the use of PBT in prostate cancer continues to develop and define its role among current alternate treatment modalities. ASTRO strongly supports the provision of coverage with evidence development to evaluate the comparative effectiveness of PBT relative to other options including IMRT and brachytherapy. The ACR Appropriateness Criteria® consider PBT for treatment planning in T1 and T2 prostate cancer to be appropriate but with lower ratings than for IMRT (6-7 versus 8-9, based on a 1-9 scale).

Non-cancerous conditions

Alberta Health Services guidelines recommend PBT for benign conditions such as AVMs and meningiomas.

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

APPENDIX A. GRADE INFORMED FRAMEWORK – ELEMENT DESCRIPTIONS

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

Strong recommendation

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

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

Weak recommendation

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

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

Quality or strength of evidence rating across studies for the treatment/outcome¹

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

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

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

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

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

APPENDIX B. APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
170.0-170.9	Malignant neoplasm of bone and articular cartilage
171.0-171.9	Malignant neoplasm of connective and other soft tissue
189.0	Malignant neoplasm of kidney, except pelvis
190.0	Malignant neoplasm eyeball, except conjunctive, cornea, retina, choroids
190.5	Malignant neoplasm of retina
190.6	Malignant neoplasm of eye, choroid
191.0-191.9	Malignant neoplasm of brain
192.1-192.3	Malignant neoplasm of cerebral meninges, spinal cord, spinal meninges
194.0	Malignant neoplasm of adrenal gland
194.3	Malignant neoplasm of pituitary gland and craniopharyngeal duct
194.4	Malignant neoplasm of pineal gland
198.3	Secondary malignant neoplasm, brain and spinal cord
209.29	Malignant carcinoid tumors of other sites
225.0-225.9	Benign neoplasm of brain and other parts of nervous system
227.3	Benign neoplasm of pituitary gland
234.8	Carcinoma in situ of other specified sites (pituitary)
237.0	Neoplasm of uncertain behavior of pituitary gland
239.7	Neoplasm of unspecified nature, endocrine gland (pituitary)
437.3	Cerebral aneurysm, non-ruptured
437.8-437.9	Other and unspecified cerebrovascular disease
747.81	Anomalies of the cerebrovascular system (AVM)
185	Malignant neoplasm of prostate
198.82	Secondary malignant neoplasm, genital organs
233.4	Carcinoma in situ, prostate
ICD-10 Diagnosis Codes	
C40.00-C41.9	Malignant neoplasm of bone and articular cartilage
C47.0-C47.9	Malignant neoplasm of peripheral nerves and autonomic nerves
C49.0-C49.9	Malignant neoplasm of other connective and soft tissue
C64.1-C64.9	Malignant neoplasm of kidney, except renal pelvis
C69.20-C69.22	Malignant neoplasm of retina
C69.30-C69.32	Malignant neoplasm of choroid
C69.40-C69.42	Malignant neoplasm of ciliary body
C70.0-C70.9	Malignant neoplasm of meninges
C71.0-C71.9	Malignant neoplasm of brain
C72.0-C72.9	Malignant neoplasm of spinal cord, cranial nerves and other parts of central nervous system
C74.00-C74.92	Malignant neoplasm of adrenal gland
C75.1-C75.3	Malignant neoplasm of pituitary gland, craniopharyngeal duct, pineal gland
C7A.8	Other malignant neuroendocrine tumors
C79.31	Secondary malignant neoplasm of brain
C79.40-C79.49	Secondary malignant neoplasm of other and unspecified parts of nervous system
D09.3	Carcinoma in situ of thyroid and other endocrine glands [pituitary]

D32.0-D32.9	Benign neoplasm of meninges
D33.0-D33.9	Benign neoplasm of brain and other parts of central nervous system
D35.2	Benign neoplasm of pituitary gland
D44.3-D44.4	Neoplasm of uncertain behavior of pituitary gland, craniopharyngeal duct
D49.7	Neoplasm of unspecified behavior of endocrine glands and other parts of nervous system [pituitary]
I67.1	Cerebral aneurysm, nonruptured
I67.89-I67.9	Other and unspecified cerebrovascular disease
Q28.2	Arteriovenous malformation of cerebral vessels
C61	Malignant neoplasm of prostate
C79.82	Secondary malignant neoplasm of genital organs
D07.5	Carcinoma in situ of prostate
ICD-10 Procedure Codes	
D0004ZZ	Beam radiation of brain using heavy particles (protons, ions)
D0014ZZ	Beam radiation of brain stem using heavy particles (protons, ions)
D0064ZZ	Beam radiation of spinal cord using heavy particles (protons, ions)
D0074ZZ	Beam radiation of peripheral nerve using heavy particles (protons, ions)
D8004ZZ	Beam radiation of eye using heavy particles (protons, ions)
DP004ZZ- DPOC4ZZ	Beam radiation of bone using heavy particles (protons, ions) [by site; includes codes DP004ZZ, DP024ZZ, DP034ZZ, DP044ZZ, DP054ZZ, DP064ZZ, DP074ZZ, DP084ZZ, DP094ZZ, DP0B4ZZ, DPOC4ZZ]
DT004ZZ	Beam radiation of kidney using heavy particles (protons, ions)
DW014ZZ	Beam radiation of head and neck using heavy particles (protons, ions)
DW024ZZ	Beam radiation of chest using heavy particles (protons, ions)
DW034ZZ	Beam radiation of abdomen using heavy particles (protons, ions)
DW064ZZ	Beam radiation of pelvic region using heavy particles (protons, ions)
CPT Codes	
32701	Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (proton or particle beam), entire course of treatment
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
77421	Stereoscopic X-ray guidance for localized of target volume for the delivery of radiation therapy
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)
77435	Stereotactic body radiation therapy, treatment management, per treatment course, 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex
HCPCS Level II Codes	
S8030	Scleral application of tantalum ring(s) for localization of lesions for proton beam therapy

Note: Inclusion on this list does not guarantee coverage

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: PROTON BEAM THERAPY

Approved January 14, 2016

HERC Coverage Guidance

Proton beam therapy (PBT) is recommended for coverage for malignant ocular tumors (*strong recommendation*).

Proton beam therapy is recommended for coverage (*weak recommendation*) for:

- malignant brain, spinal, skull base, paranasal sinus, and juxtaspinal tumors
- pediatric malignant tumors (incident cancer under age 21)

Proton beam therapy is not recommended for coverage for cancer of the bone, breast, oropharynx, nasopharynx, esophagus, liver, lung, or prostate or for gynecologic or gastrointestinal cancers, lymphoma, sarcoma, thymoma, seminoma, arteriovenous malformation or ocular hemangiomas (*weak recommendation*).

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

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.

EVIDENCE SOURCES

Trusted sources

Washington State Health Care Authority Health Technology Assessment Program. (2014). Proton Beam Therapy. Olympia, WA: Health Technology Assessment Program. Retrieved January 22, 2015 from <http://www.hca.wa.gov/hta/Pages/proton.aspx>.

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 four 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. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for ocular tumors (excluding hemangiomas)	Superior benefit, fewer harms	Moderate	Moderate; expensive, but lowered projected costs due to greater benefit and fewer harms	Low variability (preference for PBT)	Recommended for coverage (<i>strong recommendation</i>)	Moderate quality evidence demonstrates PBT is superior to other therapies with fewer harms, although at a greater cost, and many patients would choose this.
PBT for adult malignant brain/spinal tumors	Comparable benefit but fewer harms.	Very Low**	Moderate; expensive, but lowered projected costs due to fewer harms	Low variability (preference for PBT)	Recommended for coverage (<i>weak recommendation</i>)	There is very low quality evidence of incremental benefit compared to alternatives, but also with higher costs. People would likely choose what is thought to have fewer harms and greater benefit.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for skull base, paranasal sinus, and juxtaspinal tumors	Comparable benefit but fewer harms.	Very Low**	Moderate, expensive, but lowered projected costs due to fewer harms	Low (preference for PBT)	Recommended for coverage (<i>weak recommendation</i>)	The subcommittee heard expert testimony that skull-base tumors were one of the first uses of proton beam therapy in the 1960s and that reduction in harms to surrounding structures while delivering adequate dosimetry to tumor tissue is the primary consideration in treatment planning. Based on comparable benefit and fewer harms, allowing for higher costs but patient preference, weak recommendation for coverage.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for malignant pediatric tumors	Comparable benefit but fewer harms.	Very Low**	Moderate, expensive, but lowered projected costs due to fewer harms	Moderate (significant concerns regarding radiation therapy, given variety of tumors may have options for alternative therapies)	Recommended for coverage (<i>weak recommendation</i>)	Very low quality evidence suggests comparable benefit, and fewer harms, with a potential health impact over decades. There is a strong theoretical benefit for reducing secondary tumors although there is not good evidence to support this. Cost-effectiveness analyses suggest long term cost savings with PBT for pediatric tumors. There is a lack of clinical equipoise and therefore future studies on this are unlikely.
PBT for liver cancer	Comparable benefit, comparable harms	Low	High	Moderate	Do not recommend (<i>weak recommendation</i>)	There is low quality evidence that PBT has comparable benefits and harms to alternatives, but is more expensive,

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for lung cancer	Comparable benefit, comparable harms	Low	High	Moderate	Do not recommend (<i>weak recommendation</i>)	Low quality evidence of similar effectiveness, similar risk, and more cost.
PBT for prostate cancer	Comparable benefit, comparable harms	Low	High	Moderate	Do not recommend (<i>weak recommendation</i>)	There is low quality evidence of similar effectiveness, similar risk, and more cost. There may be improved local control in poorly differentiated prostate cancer (Glisan 4-5) but no demonstrated impact on survival.
PBT for ocular hemangiomas	Comparable benefit, comparable harms	Very Low	High	Moderate to high, due to uncertainty of benefit	Do not recommend (<i>weak recommendation</i>)	Very low quality evidence exists, but it is suggesting comparable benefit. Given that there are alternatives available with similar risk and less expensive, recommendation against coverage.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendati on	Rationale
PBT for bone, breast, oropharyngeal, nasopharyngeal, esophageal, GI, gynecologic, lymphomas, sarcomas, seminomas, thymomas, AVMs, and other noncancerous conditions	Unknown	Bone: Low All others: No evidence	High	Moderate (many would not choose PBT due to cost, need to travel, uncertain benefit)	Do not recommend (weak recommendation)	, Unknown benefit and unknown risk compared to alternative, and increased cost.

*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee, except as specified.

** The Quality of Evidence rating was assigned by the HERC Subcommittee.

Note: GRADE framework elements are described in Appendix A

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

DIGITAL BREAST TOMOSYNTHESIS FOR BREAST CANCER SCREENING

Population description	<p>Women between the ages of 40 and 74 years referred for breast cancer screening</p> <p><i>Population scoping notes: Exclude women with a personal history of breast cancer or ductal carcinoma in situ; BRCA mutations</i></p>
Intervention(s)	<p>Digital breast tomosynthesis (3-D mammography) or digital breast tomosynthesis in conjunction with standard 2-D mammography with or without standard digital mammography</p> <p><i>Intervention exclusions: None</i></p>
Comparator(s)	<p>Standard 2-D mammography with or without computer-aided diagnosis, no screening, MRI for breast cancer screening</p>
Outcome(s) (up to five)	<p>Critical: Breast cancer morbidity and mortality, quality of life</p> <p>Important: Cancer detection rate (invasive), recall rate for false positive tests including additional invasive and non-invasive testing</p> <p><i>Considered but not selected for GRADE Table: All-cause mortality, radiation exposure</i></p>
Key questions	<ol style="list-style-type: none"> 1. What is the effectiveness of digital breast tomosynthesis as a primary screening modality in women referred for breast cancer screening? 2. Does the effectiveness of digital breast tomosynthesis as a primary screening modality vary by the following characteristics: <ol style="list-style-type: none"> a. Age b. Breast density c. Baseline risk (as ascertained by risk assessment tools) d. Screening interval 3. In a screening population, how do the operating characteristics of digital breast tomosynthesis compare to those of standard 2-D mammography?
Contextual questions	<p>None</p>

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

DIGITAL BREAST TOMOSYNTHESIS FOR BREAST CANCER SCREENING

CHANGE LOG

Date	Change	Rationale
1/26/2016	Changed interventions to Digital breast tomosynthesis (3-D mammography) with or without standard digital mammography. Reworded for brevity and clarity but chose not to limit scope at this time.	Public comment suggested removing DBT alone from interventions.

DRAFT

Date received: 1/15/2016 at 4:26 pm
Associate Professor of Radiology
Teaching hospital

To whom it may concern,

With respect to the "Interventions" section, it should be noted that in the US, Digital Breast Tomosynthesis is only approved to be used with both the 2D and 3D information. Accordingly, the vast majority of scientific publications compare combined 2D/3D imaging with 2D imaging alone. As a radiologist who reads digital breast tomosynthesis exams on a daily basis I want to be very clear that I, and my colleagues throughout Oregon and the United States, read BOTH the 2D image set and the 3D image set side-by-side on patients. Our workstations acquire the 2D image sets to be used for comparing priors (2D compared to 2D) as well as the 3D image sets to scan through each slice of the breast on that same patient to find cancer the 2D mammography alone misses, or rule out suspicious lesions, masses and calcifications so the patient does not need to be recalled unnecessarily as a false-positive for additional testing.

I am attaching a PDF of publications released only during 2015, but please be aware the body of evidence going as far back as 2011 supports my comments above on a consistent basis with regard to study design comparing 2D/3D to 2D imaging alone (over 100 studies). At a later date I would like the opportunity to share the most significant of those with the HERC.

Date received: 1/16/2016 at 11:39 am
Radiologist, specializing in women's imaging
Radiology clinic

Regarding the Outcomes section of the scope statement, I strongly disagree that “morbidity and mortality, quality of life” are “critical outcomes” when evaluating an improved mammography technique such as DBT. The link between the early detection of invasive cancer with mammography and reduced breast cancer mortality is already very well established. Thus, when evaluating the potential benefits of a new mammography technology, it is sufficient to evaluate the ability of this new technology to detect invasive cancers. A long term study evaluating breast cancer mortality rates with DBT is not necessary to understand the potential benefits compared to traditional mammography. Furthermore, with a large body of published data showing that DBT finds more cancers than traditional mammography, it is unlikely a randomized controlled trial comparing the mortality rates of DBT and traditional mammography will ever be conducted because it would be impractical and potentially unethical to randomly assign women to receive a lifetime of screening with traditional mammography.

The National Institute of Health articulates this position very clearly in its publication “Fundamental Concepts for Health Technology Assessments”:

“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.”

It is well documented in studies with over 50,000 patients that standard 2D mammography finds cancer. It is even better documented in studies with over 200,000 patients that DBT finds more cancer. Even if DBT found the same numbers of cancer as standard 2D mammography, there is not a need to evaluate “morbidity and mortality, quality of life”, because this has already been proven out. If this were not so, then standard 2D mammography would not be available to your members or inclusive as a preventive service under USPSTF. The proposed Critical outcomes are unreasonable and unnecessary endpoints, and not a worthwhile investment of the HERC’s time. It is my opinion these should be removed from the Scope Statement.

As an alternative I would like to suggest that the most critical outcomes are cancer detection rate, invasive cancer detection rate, recall rate, PPV for recalls and PPV for biopsies. These outcomes are listed as Important, but should instead be listed as Critical because it is these outcomes that drive morbidity, mortality and quality of life. It is these five endpoints that will ultimately determine (and improve) morbidity, mortality and quality of life. Therefore, these five should be the Critical outcomes the HERC spends its time focused on and assessing.

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

Fecal Microbiota Transplantation for Clostridium difficile Infection

Population description	Adults and children with Clostridium difficile infection (CDI) <i>Population scoping notes: None</i>
Intervention(s)	Fecal microbiota transplantation (FMT) by any route <i>Intervention exclusions: None</i>
Comparator(s)	Oral or intravenous metronidazole, oral or rectal vancomycin, oral rifaximin, oral fidaxomicin, bile acid sequestrants, combinations of these treatments, probiotics
Outcome(s) (up to five)	Critical: Mortality, CDI-related morbidity (including hospitalizations), symptom resolution without recurrence Important: Iatrogenic infections, harms from intervention (e.g., colon perforation, antibiotic side effects) <i>Considered but not selected for GRADE Table: None</i>
Key questions	<ol style="list-style-type: none"> 1. What is the comparative effectiveness of FMT for patients with CDI? 2. Does the effectiveness, harm, or patient acceptance of FMT for CDI vary by: <ol style="list-style-type: none"> a. Initial vs recurrent vs refractory infection b. Previous treatment regimen c. Severity of infection d. Route of administration e. Donor characteristics
Contextual questions	None

CHANGE LOG

Date	Change	Rationale
m/d/yyyy		

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

GENETIC TESTING TO GUIDE USE OF ANTI-DEPRESSANT MEDICATIONS

Population description	<p>Adults or children with major depressive disorder who are initiating or changing anti-depressant medications</p> <p><i>Population scoping notes: None</i></p>
Intervention(s)	<p>Genetic testing to inform the selection of anti-depressant medications</p> <p><i>Intervention exclusions: None</i></p>
Comparator(s)	<p>Usual care</p>
Outcome(s) (up to five)	<p>Critical: Depression remission, functional improvement, quality of life</p> <p>Important: Timing to remission, depression improvement</p> <p><i>Considered but not selected for GRADE Table: Total health care costs</i></p>
Key questions	<ol style="list-style-type: none"> 1. Are genetic tests to guide selection of anti-depressant medications analytically valid? 2. Are genetic tests to guide selection of anti-depressant medications clinically valid? <ol style="list-style-type: none"> a. Do these tests predict the likelihood of responding to anti-depressant medications? b. Do these tests predict the likelihood of discontinuation of anti-depressant medications? 3. Are genetic tests to guide selection of anti-depressant medications clinically useful? <ol style="list-style-type: none"> a. Do these tests change the treatments selected by physicians and patients? 4. Do these tests improve depression or quality of life outcomes for patients? 5. Does the clinical utility of these tests vary by: <ol style="list-style-type: none"> a. Whether the depression is an initial or recurrent episode b. Chronicity c. Severity of depression 6. <u>Does the use of genetic testing to guide use of anti-depressant medication reduce total health care costs?</u>

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

GENETIC TESTING TO GUIDE USE OF ANTI-DEPRESSANT MEDICATIONS

CHANGE LOG

Date	Change	Rationale
1/26/2016	Added Key Question 6 on impact on total health care costs.	In response to public comment.

DRAFT

Comments received: 1/22/2016
From: National Account Manager Government Accounts
Organization: Pharmacogenetics laboratory

Comments pertaining to the Scope Statement for HERC Coverage Guidance

“Genetic Testing to Guide Use of Anti-Depressant Medications”

Population Description:

The GeneSight test is intended to aid in the selection of anti-depressant medications for patients with major depressive disorder who have failed at least one medication and a change in medication is being considered. We are not intended for a treatment naive patient population.

Intervention:

Intervention is appropriate

Comparator:

Treatment as Usual

Outcomes

Critical: Depression response (defined as a 50% decrease in baseline HAMD-17 score), Depression remission (defined as HAMD-17 score of < 7), quality of life

Important: Timing to response, timing to remission, depression improvement, reduction in polypharmacy

If we can add a question, I would suggest:

Are genetic tests able to reduce total health care costs?

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

INTERVENTIONS TO REDUCE THE HARMS OF TOBACCO DURING PREGNANCY

Population description	Women during pregnancy and the postpartum period <i>Population scoping notes: Includes all forms of tobacco, including e-cigarettes</i>
Intervention(s)	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 <i>Intervention exclusions: None</i>
Comparator(s)	No care, usual care, other studied interventions
Outcome(s) (up to five)	Critical: Pregnancy complications, low birth weight, perinatal/infant death Important: Abstinence from tobacco during pregnancy, long-term tobacco abstinence <i>Considered but not selected for GRADE Table: Maternal exposure to secondhand smoke, health benefits to mothers.</i>
Key questions	<ol style="list-style-type: none"> 1. What interventions are most effective and most cost-effective to: <ol style="list-style-type: none"> a. Reduce tobacco-related perinatal/infant morbidity and mortality? b. Reduce tobacco use prevalence in pregnant women? c. Sustain tobacco abstinence after delivery among women who quit tobacco use during pregnancy? 2. Does effectiveness vary by socioeconomic factors such as race, ethnicity, income and educational attainment? 3. What models of care would allow these interventions to be implemented most effectively and cost-effectively?

CHANGE LOG

Date	Change	Rationale
m/d/yyyy		

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

GASTROINTESTINAL MOTILITY TESTS

Population description	<p>Adults and children with suspected gastrointestinal motility disorders (e.g., gastroparesis, colonic pseudo-obstruction, slow-transit constipation)</p> <p><i>Population scoping notes: None</i></p>
Intervention(s)	<p>Radiographic and capsule-based gastrointestinal motility tests:</p> <ul style="list-style-type: none"> • Gastric emptying scintigraphy • Radiopaque marker testing • Barium small bowel follow through • Colonic scintigraphy • Whole gut scintigraphy • Wireless motility capsule • Isotope breath tests <p><i>Intervention exclusions: None</i></p>
Comparator(s)	<p>No testing, other listed interventions, usual care (diagnosis based on clinical criteria/assessment tools) diagnosis based on clinical criteria/assessment tools, empiric therapy</p>
Outcome(s) (up to five)	<p>Critical: Patient-reported symptoms, quality of life, morbidity (including hospitalization)</p> <p>Important: Change in management, harms of intervention</p> <p><i>Considered but not selected for GRADE Table: Need for additional testing, diagnostic accuracy (will be reported as contextual information), need for further testing</i></p>
Key questions	<ol style="list-style-type: none"> 1. What is the comparative effectiveness of gastrointestinal motility tests for patients with suspected motility disorders? 2. What is the diagnostic accuracy of gastrointestinal motility tests in patients with suspected motility disorders? 3. What are the harms of gastrointestinal motility tests for patients with suspected motility disorders?
Contextual questions	<p>1. What is the diagnostic accuracy of the interventions?</p>

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

GASTROINTESTINAL MOTILITY TESTS

CHANGE LOG

Date	Change	Rationale
1/28/2016	Added diagnostic accuracy as a contextual question	Based on decision above not to include this as an outcome.

DRAFT

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

TIMING OF LONG-ACTING REVERSIBLE CONTRACEPTIVE PLACEMENT

Population description	Women in the post-partum or post-abortal period who desire contraception <i>Population scoping notes: None</i>
Intervention(s)	Offering immediate post-partum or post-abortal placement of a long-acting reversible contraceptive (LARC) <i>Intervention exclusions: None</i>
Comparator(s)	Usual care: offering immediate non-LARC forms of contraception, scheduling delayed LARC placement, delaying discussion of options until 6 weeks post-partum or post-abortion
Outcome(s) (up to five)	Critical: Pregnancies, abortions Important: Presence of LARC at one year, need for alternate/replacement contraception, procedural harms <i>Considered but not selected for GRADE Table: Patient satisfaction, device expulsion, discontinuation of contraception for any reason other than desire to conceive</i>
Key questions	<ol style="list-style-type: none">1. What is the comparative effectiveness of offering immediate post-partum or post-abortal placement of a long-acting reversible contraceptive?2. What are the harms of immediate post-partum or post-abortal placement of a long-acting reversible contraceptive?

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

PERCUTANEOUS INTERVENTIONS FOR LOW BACK PAIN

Population description	Adults with acute, subacute , or chronic low back pain with or without radiculopathy <i>Population scoping notes: None</i>
Intervention(s)	Epidural, facet joint, or sacroiliac corticosteroid injections <i>Intervention exclusions: None</i>
Comparator(s)	Other injection therapies (e.g., local anesthetics, hyaluronic acid, or saline), physical therapy, home exercise programs, medications (e.g., oral corticosteroids, opioids, nonsteroidal anti-inflammatory drugs), complementary and alternative therapies (e.g., acupuncture, yoga, chiropractic therapy), soft tissue injections, ablative interventions, no treatment, surgery
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: Immediate-, short- and long-term pain, immediate-term function.</i>
Key questions	<ol style="list-style-type: none"> 1. What is the comparative effectiveness of corticosteroid injection therapies for low back pain? 2. Does the effectiveness of corticosteroid injection therapies for low back pain vary based on: <ol style="list-style-type: none"> a. Duration of back pain Acute vs chronic back pain b. Etiology of back or radicular pain (e.g., stenosis, radicular pain, disc herniation) c. Choice of corticosteroid, dose, or frequency d. Anatomic approach e. Use of imaging guidance f. Previous back surgery g. Response to previous diagnostic injections h. Response to previous injection therapies 3. What are the harms of corticosteroid injection therapies for low back pain?

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

PERCUTANEOUS INTERVENTIONS FOR LOW BACK PAIN

Contextual questions	<ol style="list-style-type: none">1. Does the use of these therapies influence subsequent utilization of health care resources (e.g., chiropractic, opioids, acupuncture, physical therapy)?2. Does the effectiveness of these interventions depend on prior treatments the patient has received?
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CHANGE LOG

Date	Change	Rationale
1/26/2015	<ol style="list-style-type: none">1. Added subacute to population, and qualified that pain could be with or without radiculopathy2. Added surgery to comparators3. Changed Key Question 2:<ol style="list-style-type: none">a. duration of back pain rather than whether the pain was acute or chronicb. Changed "Etiology of back pain (e.g. stenosis, radicular pain)" to "Etiology of back or radicular pain (e.g. stenosis, disc herniation)"c. Added "response to previous diagnostic injections"	Based on public comment

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

SACRAL NERVE STIMULATION FOR NON-OBSTRUCTIVE URINARY RETENTION

Population description	Adults and children with non-obstructive urinary retention <i>Population scoping notes: None</i>
Intervention(s)	Sacral nerve stimulation <i>Intervention exclusions: None</i>
Comparator(s)	Intermittent self-catheterization, in-dwelling urinary catheters, urethral dilatation
Outcome(s) (up to five)	Critical: Quality of life, development of chronic kidney disease, avoidance of surgical urinary diversion Important: Urinary tract infections, harms <i>Considered but not selected for GRADE Table: Ability to void spontaneously, post-void residuals, reduced need for catheterization, improved urodynamic measures, procedural harms</i>
Key questions	<ol style="list-style-type: none">1. What is the comparative effectiveness of sacral nerve stimulation for the treatment of non-obstructive urinary retention?2. Does the comparative effectiveness of sacral nerve stimulation vary by:<ol style="list-style-type: none">a. Etiology of non-obstructive urinary retentionb. Anatomic location (sacral nerve root) of electrodec. Observed effectiveness in the evaluation stage of a 2-stage techniqued. Duration of symptom prior to implantation3. What are the comparative harms of sacral nerve stimulation?

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

SACRAL NERVE STIMULATION FOR NON-OBSTRUCTIVE URINARY RETENTION

CHANGE LOG

Date	Change	Rationale
m/d/yyyy		

DRAFT

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

SACRAL NERVE STIMULATION FOR NON-OBSTRUCTIVE URINARY RETENTION

For internal use only:

Experts (appointed or informally consulted)	
Data needs	
How was topic discovered	
Reports available from core sources	

DRAFT

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

NONINVASIVE TESTING FOR LIVER FIBROSIS IN CHRONIC HEPATITIS C INFECTION

Population description	<p>Adults and children with chronic hepatitis C infection</p> <p><i>Population scoping notes: None</i></p>
Intervention(s)	<p>Non-invasive tests of liver fibrosis (e.g., acoustic radiation force impulse imaging, transient elastography, magnetic resonance elastography, biochemical tests with predictive algorithms)</p> <p><i>Intervention exclusions: None</i></p>
Comparator(s)	<p>Liver biopsy, other interventions listed above</p>
Outcome(s) (up to five)	<p>Critical: Change in treatment plan (especially decision to begin antiviral therapy), quality of life, need for liver biopsy</p> <p>Important: Testing-related adverse events</p> <p><i>Considered but not selected for GRADE Table: None</i></p>
Key questions	<ol style="list-style-type: none"> 1. What is the comparative effectiveness of noninvasive tests for the diagnosis and management of hepatic fibrosis in patients with chronic hepatitis C? 2. Does the comparative effectiveness of non-invasive tests of liver fibrosis in patients with chronic hepatitis C vary based on: <ol style="list-style-type: none"> a. Duration of infection b. Fibrosis score c. Body habitus d. Operator/interpreter training or experience e. Co-existence of other etiologies of liver disease (e.g., non-alcoholic steatohepatitis) 3. What are the comparative diagnostic operating characteristics of tests of liver fibrosis? 4. What is the evidence for the timing of the initial testing for fibrosis and interval for subsequent reassessment of fibrosis.

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

NONINVASIVE TESTING FOR LIVER FIBROSIS IN CHRONIC HEPATITIS C INFECTION

CHANGE LOG

Date	Change	Rationale
m/d/yyyy		

DRAFT

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

NONINVASIVE TESTING FOR LIVER FIBROSIS IN CHRONIC HEPATITIS C INFECTION

For internal use only:

Experts (appointed or informally consulted)	
Data needs	
How was topic discovered	
Reports available from core sources	

DRAFT

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

ULTRASOUND-ENHANCED CATHETER-DIRECTED THROMBOLYSIS FOR PULMONARY EMBOLISM

Population description	Adults or children with pulmonary embolism (PE) <i>Population scoping notes: None</i>
Intervention(s)	Ultrasound-enhanced catheter-directed thrombolysis <i>Intervention exclusions: None</i>
Comparator(s)	Catheter-directed thrombolysis, systemic thrombolysis, mechanical thrombectomy, pharmacomechanical thrombectomy, anticoagulation (heparin, low-molecular weight heparin, novel oral anticoagulants, warfarin)
Outcome(s) (up to five)	Critical: Mortality, major bleeding Important: Pulmonary hypertension, recurrent PE, hospitalization/length of stay <i>Considered but not selected for GRADE Table: Total dose of thrombolytics, resolution of thrombus, vessel patency, time to recanalization, thrombus load, recurrent DVT</i>
Key questions	<ol style="list-style-type: none">1. What is the comparative effectiveness of ultrasound-enhanced catheter-directed thrombolysis for PE?2. Does the comparative effectiveness of ultrasound-enhanced catheter-directed thrombolysis for PE vary by:<ol style="list-style-type: none">a. Extent of thrombosis (i.e., massive, sub-massive, non-obstructive)b. Severity (PESI score)c. Previous treatmentsd. Presence of pulmonary embolism3. What are the harms of ultrasound-enhanced catheter-directed thrombolysis for PE?

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

ULTRASOUND-ENHANCED CATHETER-DIRECTED THROMBOLYSIS FOR PULMONARY EMBOLISM

CHANGE LOG

Date	Change	Rationale
m/d/yyyy		

DRAFT

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

ULTRASOUND-ENHANCED CATHETER-DIRECTED THROMBOLYSIS FOR PULMONARY EMBOLISM

For internal use only:

Experts (appointed or informally consulted)	
Data needs	
How was topic discovered	
Reports available from core sources	

DRAFT

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

ULTRASOUND-ENHANCED CATHETER-DIRECTED THROMBOLYSIS FOR PULMONARY EMBOLISM

Population description	Adults or children with pulmonary embolism (PE) <i>Population scoping notes: None</i>
Intervention(s)	Ultrasound-enhanced catheter-directed thrombolysis <i>Intervention exclusions: None</i>
Comparator(s)	Catheter-directed thrombolysis, systemic thrombolysis, mechanical thrombectomy, pharmacomechanical thrombectomy, anticoagulation (heparin, low-molecular weight heparin, novel oral anticoagulants, warfarin)
Outcome(s) (up to five)	Critical: Mortality, major bleeding Important: Pulmonary hypertension, recurrent PE, hospitalization/length of stay <i>Considered but not selected for GRADE Table: Total dose of thrombolytics, resolution of thrombus, vessel patency, time to recanalization, thrombus load, recurrent DVT</i>
Key questions	<ol style="list-style-type: none">1. What is the comparative effectiveness of ultrasound-enhanced catheter-directed thrombolysis for PE?2. Does the comparative effectiveness of ultrasound-enhanced catheter-directed thrombolysis for PE vary by:<ol style="list-style-type: none">a. Extent of thrombosis (i.e., massive, sub-massive, non-obstructive)b. Severity (PESI score)c. Previous treatmentsd. Presence of pulmonary embolism3. What are the harms of ultrasound-enhanced catheter-directed thrombolysis for PE?

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

ULTRASOUND-ENHANCED CATHETER-DIRECTED THROMBOLYSIS FOR PULMONARY EMBOLISM

CHANGE LOG

Date	Change	Rationale
m/d/yyyy		

DRAFT

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

ULTRASOUND-ENHANCED CATHETER-DIRECTED THROMBOLYSIS FOR PULMONARY EMBOLISM

For internal use only:

Experts (appointed or informally consulted)	
Data needs	
How was topic discovered	
Reports available from core sources	

DRAFT

Continuous Glucose Monitoring in Diabetes Mellitus – 2015 Rescanning Summary

Subcommittee: Health Technology Assessment Subcommittee (HERC approved May 2013)

HTAS Recommendation: Develop a new coverage guidance to update this topic.

Bottom Line: Despite publication of several RCTs since the 2013 coverage guidance, the body of evidence on continuous glucose monitoring (CGM) remains mixed. The use of real-time continuous glucose monitoring (RT-CGM) in adults with T1DM appears to be the best supported in the literature and there is some suggestion that the effects of RT-CGM may be amplified in those patients using an insulin pump. The evidence for CGM in children and adolescents or adults with T2DM is mixed. There is low certainty and conflicting evidence on the use of CGM in pregnant patients, though recent NICE guidance provides for its use in certain circumstances. It should be noted that the primary effectiveness outcome reported in these trials is change in HbA1c. Additionally, while the effect of CGM on HbA1c in the meta-analyses may be statistically significant, the magnitude of the effect appears to be small (invariably <0.5%, a commonly accepted threshold for clinical significance).

Coverage Recommendation (Box Language)

Continuous blood glucose monitoring with real-time or retrospective continuous glucose monitoring systems should only be covered for Type 1 diabetes mellitus patients for whom insulin pump management is being considered, initiated, or utilized and who also have one of the following:

- HbA1c levels greater than 8.0% despite compliance with therapy, or
- A history of recurrent hypoglycemia.

Real-time and retrospective continuous glucose monitoring systems should not be covered for Type 2 diabetes mellitus patients.

Scope Statement

Population description	Children, adolescents, and adults with type 1 or type 2 diabetes mellitus (DM) on insulin therapy, including pregnant women <i>Population scoping notes: None</i>
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Intervention(s)	Continuous blood glucose monitoring (CBGM), either retrospective or real time <i>Intervention exclusions: None</i>
Comparator(s)	Self-monitoring blood glucose (SMBG) and/or routine HbA1c monitoring
Outcome(s) (up to five)	Critical: Severe morbidity (e.g. microvascular and macrovascular complications), severe hypoglycemia ¹ Important: Quality-of-life, change in HbA1c, ketoacidosis <i>Considered but not selected for GRADE table: Myocardial infarction, cerebrovascular accident, amputations, neuropathy, retinopathy, nephropathy (We chose to generalize these into severe morbidity to simplify consideration), diabetes-related hospitalizations, and emergency department visits.</i>
Key questions	<ol style="list-style-type: none"> 1. What is the evidence of effectiveness of CGM in improving outcomes in people with diabetes? 2. What are the indications for retrospective and for real time CGM? 3. Is there evidence of differential effectiveness of CGM based on: <ol style="list-style-type: none"> a. Type 1 vs Type 2 DM? b. Insulin pump vs multiple daily insulin injections (MDII)? c. Frequency and duration of CGM? d. Persistently poor glycemic control

Original Evidence Sources

Langendam, M., Luijf, Y. M., Hooft, L., DeVries, J. H., Mudde, A. H., Scholten, R. J. P. M. (2012). Continuous glucose monitoring systems for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*, Issue 1. Art. No.: CD008101. DOI: 10.1002/14651858.CD008101.pub2. Retrieved from <http://summaries.cochrane.org/CD008101/continuous-glucose-monitoring-systems-for-type-1-diabetes-mellitus>.

¹ "An event requiring assistance of another person to actively administer carbohydrate, glucagons, or other resuscitative actions." (ADA Workgroup on Hypoglycemia, 2005)

Golden, S. H., Brown, T., Yeh, H. C., Maruthur, N., Ranasinghe, P., ... Bass, E. B. (2012). Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness. Comparative Effectiveness Review No. 57. (Prepared by Johns Hopkins University Evidence-based Practice Center under Contract No. 290-2007-10061-I.) AHRQ Publication No. 12-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Scanning Results

1. Blumer, I., Hadar, E., Hadden, D. R., Jovanovic, L., Mestman, J. H., ... Yogeve, Y. (2013). Diabetes and pregnancy: an Endocrine Society clinical practice guideline. *Journal of Clinical Endocrinology and Metabolism*, 98(11), 4227-49.

Citation 1 is a clinical practice guideline on diabetes and pregnancy from the Endocrine Society. The guideline suggests that CGM be used in pregnancy “in women with overt or gestational diabetes when self-monitored blood glucose levels (or, in the case of the woman with overt diabetes, HbA1C values) are not sufficient to assess glycemic control...” This is a weak recommendation based on low certainty evidence. (NB: The Endocrine Society has adopted GRADE methodology for their CPGs).

2. Floyd, B., Chandra, P., Hall, S., Phillips, C., Alema-Mensah, E., Strayhorn, G., ... Umpierrez, G. E. (2012). Comparative analysis of the efficacy of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes mellitus. *Journal of Diabetes Science and Technology*, 6(5), 1094-1102.

Citation 2 is a systematic review of RCTs comparing CGM with SMBG in patients with T1DM. The pooled effect appears to be a reduction in A1c of 0.3% favoring CGM (effects were similar for both real-time and retrospective CGM). There was no difference in hypoglycemic events. It should be noted that the search dates for this review (1966 to Nov 2009) are subsumed by both the Cochrane and AHRQ reviews that served as the basis of the 2013 coverage guidance.

3. Hayes, Inc. (2015). *Continuous glucose monitoring systems*. Lansdale, PA: Hayes, Inc.

Citation 3 is a Hayes HTA and systematic review published in August 2015. It includes 23 RCTs and 1 randomized cross-over trial published between 2003 and early 2015. The overall conclusion is that “CGM is reasonably safe but there is conflicting evidence concerning efficacy that is difficult to interpret.” They offer a B rating for CGM in adults with T1DM who do not achieve target glycemic control with SMBG; a C rating for use of CGM in adults with T2DM; a C rating for CGM in children and adolescents with T1DM who do not achieve target glycemic control with SMBG; a D2 rating for use of CGM in children and adolescents with T2DM; and a

D2 rating for use of CGM in women with pre-gestational or gestational diabetes (B=Some proven benefit, C=Potential but unproven benefit, D2=Insufficient evidence).

4. Moy, F. M., Ray, A., & Buckley, B. S. (2014). Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. *Cochrane Database of Systematic Reviews*, Issue 4. Retrieve from <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009613.pub2/epdf>

Citation 4 is a Cochrane review of techniques for monitoring blood glucose during pregnancy for women with pre-gestational diabetes (type 1 or 2). The systematic review identified 9 RCTs comparing CGM and SMBG. The authors conclude that there is no evidence that one glucose monitoring technique is superior to another in this population and that the overall evidence base is weak.

5. Neu, A., Beyer, P., Burger-Busing, J., Danne, T., Etspuler, J., Heidtmann, B., ... Holterhus P. M., German Diabetes Association. (2014). Diagnosis, therapy and control of diabetes mellitus in children and adolescents. *Experimental & Clinical Endocrinology & Diabetes*, 122(7), 425-34.

Citation 5 is not currently available through the OHSU library. I have requested a manuscript through ResearchGate.

6. NICE. (2015). *Diabetes in pregnancy: Management of diabetes and its complications from preconception to the postnatal period*. London: NICE. Retrieved from <http://www.nice.org.uk/guidance/ng3/resources/diabetes-in-pregnancy-management-of-diabetes-and-its-complications-from-preconception-to-the-postnatal-period-51038446021>

Citation 6 is a NICE guideline on the management of diabetes in pregnancy. The guideline states that CGM should not be routinely offered to pregnant women with diabetes, but that it may be considered in pregnant women “who have problematic severe hypoglycemia, unstable blood glucose levels, or to gain information about variability in blood glucose levels.” CGM should only be offered by a team “with expertise in its use.”

7. Poolsup, N., Suksomboon, N., & Kyaw, A. M. (2013). Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. *Diabetology and Metabolic Syndrome*, 5, 39.

Citation 7 is a systematic review and meta-analysis of 14 RCTs comparing CGM with SMBG for children with T1DM (10 trials) or adults with T2DM (4 trials). Overall, there was no significant difference between CGM and SMBG in children with T1DM (mean A1c difference of -0.13%), though the subset of trials comparing RT-CGM to SMBG showed a small benefit in favor of CGM (mean A1c difference of -0.18%). In the trials of adults with T2DM, CGM was slightly better than SMBG with a mean A1c difference of -0.31%.

8. Rewers, M. J., Pillay, K., de Beaufort, C., Craig, M. E., Hanas, R., Acerini, C. L., Maahs, D. M., International Society for Pediatric and Adolescent Diabetes. (2014). *Pediatric Diabetes*, 15(Suppl20), 102-114.

Citation 8 is a clinical practice guideline on assessing and monitoring glycemic control in children and adolescents published by the International Society for Pediatric and Adolescent Diabetes. It states that “CGM devices are becoming available that may particularly benefit those with hypoglycemic unawareness, as the devices will alarm when glucose is below a specified range or with rapid rate of fall of glucose.”

9. Szypowska, A., Ramotowska, A., Dzygalo, K., & Golicki, D. (2012). Beneficial effect of real-time continuous glucose monitoring system on glycemic control in type 1 diabetic patients: systematic review and meta-analysis of randomized trials. *European Journal of Endocrinology*, 166(4), 567-574.

Citation 9 is a systematic review and meta-analysis of 7 RCTs comparing RT-CGM with SMBG in patients with T1DM. The authors conclude that use of RT-CGM results in better glycemic control (mean A1c difference -0.25%). Use of RT-CGM did not appear to result in increased major hypoglycemic events. The authors note that further studies are needed in children.

10. Voormolen, D. N., DeVries, J. H., Evers, I.M., Mol, B. W., & Franx, A. (2013). The efficacy and effectiveness of continuous glucose monitoring during pregnancy: a systematic review. *Obstetrical & Gynecological Survey*, 68(11), 753-63.

Citation 10 is a systematic review of CGM in pregnancy. The authors note that the current evidence is limited to 2 RCTs with conflicting results and that evidence on cost-effectiveness is lacking.

Appendix A. Methods

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 “continuous glucose” and “glucose monitor.” Searches of core sources were limited to citations published after 2011.

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.
- 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® (Ovid) search was conducted to identify systematic reviews, meta-analyses, and technology assessments published after the search dates of original evidence sources. The search was limited to publications in English published after 2010.

Searches for clinical practice guidelines were limited to those published since 2012. 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
- 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 assessment, or clinical practice guidelines.

Topic:

3D Mammography/Digital Breast Tomosynthesis for Screening Mammography						
Scoring:	Score 0	Score 1	Score 2	Score 3	Scoring	Notes
Disease Burden (morbidity/mortality)	Inconsequential	Minor	Moderate	Major	3	
Prevalence/Population affected	Minimal	Low	Moderate	Highly prevalent	3	
Uncertain Efficacy/Harm	No controversy	Low uncertainty	Moderate	High uncertainty	3	
Variation/ Controversy	Standard Of Care in Oregon aligns w/evidence; low abuse	Little controversy/abuse/variation	Some controversy/abuse/variation	SOC differs from evidence, or frequently abused	3	
Magnitude of economic impact of intervention (population level, includes downstream costs)	No impact	Low impact	Moderate impact	High impact	2	
Potential of intervention to improve health outcomes	No impact	Minimal impact	Moderate impact	High impact	2	
Public/Professional Interest	Not in the public eye; general public would have little understanding of the issue.	Some members of the public would be interested in/aware of this topic	Frequent media coverage	Hot button issue with significant public controversy	3	
Potential of interventions to reduce health disparities	None or unknown	Low impact	Moderate impact	High impact	1	
Meaningful Coverage Guidance	No "theory of change" for how CG would increase alignment of practice/evidence	Minor change possible through promotion/precert/metrics	Moderate change possible through promotion/precert/metrics	Lever (denials, precerts, bundling, metrics) available to purchasers to align care with recommendation	3	
Totals					60	0

Scoping notes:

Topic:

Fecal Microbiota Transplants for C. difficile						
Scoring:	Score 0	Score 1	Score 2	Score 3	Scoring	Notes
Disease Burden (morbidity/mortality)	Inconsequential	Minor	Moderate	Major	2	
Prevalence/Population affected	Minimal	Low	Moderate	Highly prevalent	1	
Uncertain Efficacy/Harm	No controversy	Low uncertainty	Moderate	High uncertainty	3	
Variation/ Controversy	Standard Of Care in Oregon aligns w/evidence; low abuse	Little controversy/abuse/variation	Some controversy/abuse/variation	SOC differs from evidence, or frequently abused	3	
Magnitude of economic impact of intervention (population level, includes downstream costs)	No impact	Low impact	Moderate impact	High impact	1	
Potential of intervention to improve health outcomes	No impact	Minimal impact	Moderate impact	High impact	2	
Public/Professional Interest	Not in the public eye; general public would have little understanding of the issue.	Some members of the public would be interested in/aware of this topic	Frequent media coverage	Hot button issue with significant public controversy	3	
Potential of interventions to reduce health disparities	None or unknown	Low impact	Moderate impact	High impact	0	
Meaningful Coverage Guidance	No "theory of change" for how CG would increase alignment of practice/evidence	Minor change possible through promotion/precert/metrics	Moderate change possible through promotion/precert/metrics	Lever (denials, precerts, bundling, metrics) available to purchasers to align care with recommendation	3	
Totals					45	0

Scoping notes:

Topic:

Genetic Tests for Selection of Antidepressant Therapy						
Scoring:	Score 0	Score 1	Score 2	Score 3	Scoring	Notes
Disease Burden (morbidity/mortality)	Inconsequential	Minor	Moderate	Major	3	
Prevalence/Population affected	Minimal	Low	Moderate	Highly prevalent	3	
Uncertain Efficacy/Harm	No controversy	Low uncertainty	Moderate	High uncertainty	3	
Variation/ Controversy	Standard Of Care in Oregon aligns w/evidence; low abuse	Little controversy/abuse/variation	Some controversy/abuse/variation	SOC differs from evidence, or frequently abused	1	
Magnitude of economic impact of intervention (population level, includes downstream costs)	No impact	Low impact	Moderate impact	High impact	2	
Potential of intervention to improve health outcomes	No impact	Minimal impact	Moderate impact	High impact	2	
Public/Professional Interest	Not in the public eye; general public would have little understanding of the issue.	Some members of the public would be interested in/aware of this topic	Frequent media coverage	Hot button issue with significant public controversy	1	
Potential of interventions to reduce health disparities	None or unknown	Low impact	Moderate impact	High impact	0	
Meaningful Coverage Guidance	No "theory of change" for how CG would increase alignment of practice/evidence	Minor change possible through promotion/precert/metrics	Moderate change possible through promotion/precert/metrics	Lever (denials, precerts, bundling, metrics) available to purchasers to align care with recommendation	3	
Totals					45	0

Scoping notes:

Topic:

Interventions to Reduce the Harms of Tobacco During Pregnancy						
Scoring:	Score 0	Score 1	Score 2	Score 3	Scoring	Notes
Disease Burden (morbidity/mortality)	Inconsequential	Minor	Moderate	Major	3	
Prevalence/Population affected	Minimal	Low	Moderate	Highly prevalent	2	
Uncertain Efficacy/Harm	No controversy	Low uncertainty	Moderate	High uncertainty	3	
Variation/ Controversy	Standard Of Care in Oregon aligns w/evidence; low abuse	Little controversy/abuse/variation	Some controversy/abuse/variation	SOC differs from evidence, or frequently abused	3	Multisector interventions underutilized, variation in clinical interventions
Magnitude of economic impact of intervention (population level, includes downstream costs)	No impact	Low impact	Moderate impact	High impact	3	
Potential of intervention to improve health outcomes	No impact	Minimal impact	Moderate impact	High impact	3	
Public/Professional Interest	Not in the public eye; general public would have little understanding of the issue.	Some members of the public would be interested in/aware of this topic	Frequent media coverage	Hot button issue with significant public controversy	3	
Potential of interventions to reduce health disparities	None or unknown	Low impact	Moderate impact	High impact	3	
Meaningful Coverage Guidance	No "theory of change" for how CG would increase alignment of practice/evidence	Minor change possible through promotion/precert/metrics	Moderate change possible through promotion/precert/metrics	Lever (denials, precerts, bundling, metrics) available to purchasers to align care with recommendation	2	
Totals					46	0

Scoping notes:

Topic:

Intestinal motility tests						
Scoring:	Score 0	Score 1	Score 2	Score 3	Scoring	Notes
Disease Burden (morbidity/mortality)	Inconsequential	Minor	Moderate	Major	2	
Prevalence/Population affected	Minimal	Low	Moderate	Highly prevalent	1	
Uncertain Efficacy/Harm	No controversy	Low uncertainty	Moderate	High uncertainty	2	Uncertain utility not efficacy/harm
Variation/ Controversy	Standard Of Care in Oregon aligns w/evidence; low abuse	Little controversy/abuse/variation	Some controversy/abuse/variation	SOC differs from evidence, or frequently abused	2	
Magnitude of economic impact of intervention (population level, includes downstream costs)	No impact	Low impact	Moderate impact	High impact	1	
Potential of intervention to improve health outcomes	No impact	Minimal impact	Moderate impact	High impact	1	
Public/Professional Interest	Not in the public eye; general public would have little understanding of the issue.	Some members of the public would be interested in/aware of this topic	Frequent media coverage	Hot button issue with significant public controversy	0	
Potential of interventions to reduce health disparities	None or unknown	Low impact	Moderate impact	High impact	0	
Meaningful Coverage Guidance	No "theory of change" for how CG would increase alignment of practice/evidence	Minor change possible through promotion/precert/metrics	Moderate change possible through promotion/precert/metrics	Levers (denials, precerts, bundling, metrics) available to purchasers to align care with recommendation	3	
Totals					27	0

Scoping notes:

Topic:

Long-acting reversible contraceptives						
Scoring:	Score 0	Score 1	Score 2	Score 3	Scoring	Notes
Disease Burden (morbidity/mortality)	Inconsequential	Minor	Moderate	Major	3	
Prevalence/Population affected	Minimal	Low	Moderate	Highly prevalent	3	
Uncertain Efficacy/Harm	No controversy	Low uncertainty	Moderate	High uncertainty	2	
Variation/ Controversy	Standard Of Care in Oregon aligns w/evidence; low abuse	Little controversy/abuse/variation	Some controversy/abuse/variation	SOC differs from evidence, or frequently abused	3	Due to reimbursement issues and high expulsion rate
Magnitude of economic impact of intervention (population level, includes downstream costs)	No impact	Low impact	Moderate impact	High impact	3	
Potential of intervention to improve health outcomes	No impact	Minimal impact	Moderate impact	High impact	3	
Public/Professional Interest	Not in the public eye; general public would have little understanding of the issue.	Some members of the public would be interested in/aware of this topic	Frequent media coverage	Hot button issue with significant public controversy	2	
Potential of interventions to reduce health disparities	None or unknown	Low impact	Moderate impact	High impact	3	
Meaningful Coverage Guidance	No "theory of change" for how CG would increase alignment of practice/evidence	Minor change possible through promotion/precert/metrics	Moderate change possible through promotion/precert/metrics	Levers (denials, precerts, bundling, metrics) available to purchasers to align care with recommendation	3	
Totals					66	0

Scoping notes:

Topic:

Pain Management Injection Therapies for Back Pain						
Scoring:	Score 0	Score 1	Score 2	Score 3	Scoring	Notes
Disease Burden (morbidity/mortality)	Inconsequential	Minor	Moderate	Major	1	
Prevalence/Population affected	Minimal	Low	Moderate	Highly prevalent	3	
Uncertain Efficacy/Harm	No controversy	Low uncertainty	Moderate	High uncertainty	3	
Variation/ Controversy	Standard Of Care in Oregon aligns w/evidence; low abuse	Little controversy/abuse/variation	Some controversy/abuse/variation	SOC differs from evidence, or frequently abused	3	
Magnitude of economic impact of intervention (population level, includes downstream costs)	No impact	Low impact	Moderate impact	High impact	2	1000 per year with imaging before and during
Potential of intervention to improve health outcomes	No impact	Minimal impact	Moderate impact	High impact	1	
Public/Professional Interest	Not in the public eye; general public would have little understanding of the issue.	Some members of the public would be interested in/aware of this topic	Frequent media coverage	Hot button issue with significant public controversy	1	
Potential of interventions to reduce health disparities	None or unknown	Low impact	Moderate impact	High impact	1	
Meaningful Coverage Guidance	No "theory of change" for how CG would increase alignment of practice/evidence	Minor change possible through promotion/precert/metrics	Moderate change possible through promotion/precert/metrics	Levers (denials, precerts, bundling, metrics) available to purchasers to align care with recommendation	3	
Totals					45	0

Scoping notes:

Topic:

Treatments for Recurrent Acute Otitis Media						
Scoring:	Score 0	Score 1	Score 2	Score 3	Scoring	Notes
Disease Burden (morbidity/mortality)	Inconsequential	Minor	Moderate	Major	2	
Prevalence/Population affected	Minimal	Low	Moderate	Highly prevalent	1	
Uncertain Efficacy/Harm	No controversy	Low uncertainty	Moderate	High uncertainty	2	
Variation/ Controversy	Standard Of Care in Oregon aligns w/evidence; low abuse	Little controversy/abuse/variation	Some controversy/abuse/variation	SOC differs from evidence, or frequently abused	2	
Magnitude of economic impact of intervention (population level, includes downstream costs)	No impact	Low impact	Moderate impact	High impact	2	
Potential of intervention to improve health outcomes	No impact	Minimal impact	Moderate impact	High impact	2	
Public/Professional Interest	Not in the public eye; general public would have little understanding of the issue.	Some members of the public would be interested in/aware of this topic	Frequent media coverage	Hot button issue with significant public controversy	1	
Potential of interventions to reduce health disparities	None or unknown	Low impact	Moderate impact	High impact	2	
Meaningful Coverage Guidance	No "theory of change" for how CG would increase alignment of practice/evidence	Minor change possible through promotion/precert/metrics	Moderate change possible through promotion/precert/metrics	Lever (denials, precerts, bundling, metrics) available to purchasers to align care with recommendation	3	
Totals					42	0

Scoping notes:

**Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on January 14, 2016**

For specific coding recommendations and guideline wording, please see the text of the 1-14-2016 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective with the next set of interim modifications, no later than 10/1/16, unless otherwise indicated)

- Move the diagnosis code for Barrett’s esophagus without dysplasia from an uncovered line to a covered line with a guideline change allowing long term proton pump inhibitor therapy
- Move the diagnosis codes for Barrett’s esophagus with dysplasia from an uncovered line to the covered esophageal cancer line, a line title was changed to reflect this inclusion
- Move the eosinophilic esophagitis diagnosis code from one covered line to another
- Move several conditions of the mouth with no treatment from a covered line to an uncovered line
- Add procedure codes for acupuncture and chiropractic/osteopathic manipulation to the scoliosis line *(implemented along with delayed changes related to conditions of the back and spine)*
- Move the procedure code for placement of artificial discs from the scoliosis line to the covered back surgery line
- Delete the procedure codes for epidural steroid injections from the back conditions line and add to the Services Recommended For Non-Coverage Table
- Delete the procedure codes for maintenance of intrathecal pumps from the back condition lines
- Add procedure codes for proton beam therapy to nine lines for pediatric malignancies and remove from one benign tumor line
- Various straightforward coding changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- A guideline on smoking cessation prior to elective surgical procedures was discussed in detail and staff was directed to complete more research and bring the topic back in March

RECOMMENDED GUIDELINE CHANGES (effective with the next set of interim modifications, no later than 10/1/16, unless otherwise indicated)

- Edit the wording of the guideline regarding disease of the lips to clarify the included ICD-10 codes
- Edit the surgical back guideline to remove the requirement for 6 months of conservative therapy prior to a patient being eligible for surgery on the uncovered back surgery line; add epidural steroid injections to the list of uncovered procedures *(implemented along with delayed changes related to conditions of the back and spine)*
- Edit the guideline for advanced imaging for low back conditions to specify that repeat imaging is only covered for significant changes in a patient’s condition, and to return to

the old definition of radiculopathy as neurologic changes rather than just radiating pain
(implemented along with delayed changes related to conditions of the back and spine)

- The epidural steroid injection guideline and the intrathecal pump maintenance guideline were deleted
- Add a new guideline on proton beam therapy
- Add a new guideline on nitrous oxide for labor pain management

DRAFT

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
January 14, 2016
9:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; David Pollack, MD; Susan Williams, MD (via phone until 10:30, then in person); Mark Gibson; Irene Crosswell, RPh; Holly Jo Hodges, MD; Gary Allen, DMD (at 9:30 AM)

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, Adam Obley, MD, MPH, and Craig Mosbaek (OHSU Center for Evidence-based Policy); Erica Pettigrew, MD, JD (OHSU); Nancy Noe (Johnson & Johnson); Reb Huggins (Oregon Affiliate, American College of Nurse Midwives).

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

The meeting was called to order at 9:10 am and roll was called. Minutes from the November 12, 2015 VbBS meeting were reviewed and approved.

Coffman reported that Vern Saboe, DC will be joining VbBS as the complementary and alternative medicine representative. Kevin Olson, MD will be joining the HERC as well as maintaining his role as VbBS chair. Coffman also reported that there is not yet an implementation date for the back line changes.

Smits reported on several issues:

- 1) Staff will be changing the ICD-10 codes in all guidelines to remove terminal “x’s” which are there to indicate that all further digit “children” codes are included. These entries will be changed to simply have the ICD-10 code terminated at the digit that includes all children codes. Staff will be eliminating ICD-9 codes from guidelines, and will be eliminating ICD-10 codes from guidelines unless they are absolutely necessary. These changes will not be routinely brought to VbBS for approval.
- 2) The 2018 biennial review is starting. Smits requested suggestions for topics. Topics proposed to date include obesity (subject of a new taskforce), merging the two low birth weight lines into a single prematurity line, and review of coverage for uncomplicated inguinal hernia. A provider has also requested review of treatment of allergic rhinitis, but staff feels that this topic was recently reviewed and will only do a scan to see if

significant new evidence has been found. Gibson suggested reviewing shorter course radiation therapy for breast cancer in situ. Pollack suggested reviewing personalized medicine/gene tests for targeted drug therapy. Staff reported that many of these types of tests are going to be reviewed through the coverage guidance process, and therefore this topic does not need to be part of the biennial review.

- 3) The publication of errata continues, and the most recent errata was summarized in the packet.
- 4) The statewide back pain guidelines will be retired with HERC approval. The coverage guidances resulting from these guidelines will continued to be maintained and updated.
- 5) Staff has identified that diaphragmatic hernia with obstruction or gangrene diagnosis codes have been separated from their treatment CPT codes. Staff will move the ICD-10 diagnosis codes for these conditions to the upper GERD line where the CPT codes reside as an errata, and bring back the issue for more definitive discussion in March. The subcommittee agreed with this plan.

➤ **Topic: Straightforward/Consent Agenda**

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

Recommended Actions:

- 1) Add 50948 (Laparoscopy, surgical; ureteroneocystostomy without cystoscopy and ureteral stent placement) to line 184 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER
- 2) Add 47535 (Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy), and all associated radiological supervision and interpretation) to line 320 CANCER OF LIVER
- 3) Add 47534-47536 (Placement/conversion/ exchange of biliary drainage catheter, percutaneous) to line 84 INJURY TO INTERNAL ORGANS
- 4) Add 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft) to line 205 CANCER OF BONES
- 5) Modify guideline note 65 as shown in Appendix A
- 6) Delete guideline note 16 as shown in Appendix C

**MOTION: To approve the recommendations stated in the consent agenda. CARRIES 6-0.
(Absent: Allen)**

➤ **Topic: Barrett's esophagus**

Discussion: Smits reviewed the summary document. Two separate options for code and guideline changes were reviewed. The subcommittee agree with the changes in "option A" as they felt that Barrett's with dysplasia should have a higher priority for treatment than GERD.

Recommended Actions:

- 1) Add K20.0 (Eosinophilic esophagitis) to line 383 ESOPHAGEAL STRICTURE; ACHALASIA and remove from lines 385 ESOPHAGITIS; ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS and 516 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA
- 2) Affirm addition of K22.70 (Barrett's esophagus) to line 385 ESOPHAGITIS; ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS (done as an errata) and remove from line 516 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA
- 3) Affirm addition of K22.711 (Barrett's esophagus with high grade dysplasia) to line 319 CANCER OF ESOPHAGUS (done as an errata) and remove from line 516 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA
- 4) Affirm addition of K22.710 (Barrett's esophagus with low grade dysplasia) and K22.719 (Barrett's esophagus with unspecified dysplasia) to line 319 CANCER OF ESOPHAGUS (done as an errata) and remove from line 516 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA
- 5) Change the title of line 319 CANCER OF ESOPHAGUS; [BARRETT'S ESOPHAGUS WITH DYSPLASIA](#)
- 6) Modify GN 144 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented as "option A." CARRIES 7-0.

➤ **Topic: Other diseases of the lips and oral mucosa**

Discussion: Smits reviewed the summary document. Gary Allen, DMD agreed with the dental changes. There was no other discussion.

Recommended Actions:

- 1) Affirm the change in line title for line 168 ~~LEUKOPLAKIA AND~~ CARCINOMA IN SITU OF UPPER AIRWAY, INCLUDING ORAL CAVITY (done as an errata)
- 2) Add K13.2 (Minimal keratinized residual ridge mucosa) to line 579 STOMATITIS AND OTHER DISEASES OF ORAL SOFT and remove from line 623 BENIGN LESIONS OF TONGUE
- 3) Add K13.23 (Excessive keratinized residual ridge mucosa) to line 579 STOMATITIS AND OTHER DISEASES OF ORAL SOFT and remove from line 168 ~~LEUKOPLAKIA AND~~ CARCINOMA IN SITU OF UPPER AIRWAY, INCLUDING ORAL CAVITY

- 4) Add K13.24 (Leukokeratosis nicotina palati) to line 579 STOMATITIS AND OTHER DISEASES OF ORAL SOFT and remove from line 168 ~~LEUKOPLAKIA AND~~ CARCINOMA IN SITU OF UPPER AIRWAY, INCLUDING ORAL CAVITY
- 5) Modify GN113 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 7-0.

➤ **Topic: Straightforward back line items**

Discussion: Smits reviewed the summary document. There was no discussion of these items. Note that these changes will be implemented along with the currently delayed changes related to treatments of conditions of the back and spine.

Recommended Actions:

- 1) Add M96.5 (Postradiation scoliosis) to line 366 SCOLIOSIS and remove from lines 407 CONDITIONS OF THE BACK AND SPINE and 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS.
- 2) Add Q06.0 (Amyelia), Q06.1 (Hypoplasia and dysplasia of spinal cord), Q06.3 (Other congenital cauda equina malformations) and Q06.8 (Other specified congenital malformations of spinal cord) to line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
- 3) Add Q67.5 (Congenital deformity of spine) and Q76.3 (Congenital scoliosis due to congenital bony malformation) to line 366 SCOLIOSIS and delete from the applicable lines in the set of lines including 407 CONDITIONS OF THE BACK AND SPINE and 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS and 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
- 4) Add S23.101, S23.111, S23.121, S23.123, S23.131, S23.133, S23.141, S23.143, S23.151, S23.153, S23.161, S23.163, S23.171 (Dislocation of thoracic vertebra), and S33.101, S33.111, S33.121, S33.131, S33.141 (Dislocation of lumbar vertebra) to line 482 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY and remove from any of the following lines on which they appear: 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS and/or 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
- 5) Remove M46.1 (Sacroiliitis, not elsewhere classified) from line 532.
- 6) Add S33.8XXA (Sprain of other parts of lumbar spine and pelvis, initial encounter) to line 407 CONDITIONS OF THE BACK AND SPINE and remove from line 611 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR

- 7) Remove M42.1 (Adult osteochondrosis of spine) and M42.9 (Spinal osteochondrosis, unspecified) from line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS and add to line 407
- 8) Remove M43.3 (Recurrent atlantoaxial dislocation with myelopathy), M43.4 (Other recurrent atlantoaxial dislocation), M43.5x2 (Other recurrent vertebral dislocation, cervical region) and M43.5x3 (Other recurrent vertebral dislocation, cervicothoracic region) from any of the following lines on which they currently appear: line 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS, and/or line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS. Add these codes to line 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
- 9) Remove M43.5X3, M43.5x4, M43.5X5, M43.5X6, M43.5X7, M43.5X8, M43.5X9, (Other recurrent vertebral dislocation, non cervical) from lines 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS, and line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS. Add these codes to line 482 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY
- 10) Remove M45 (Ankylosing spondylitis) from line 50 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES
- 11) Add M45.9 (Ankylosing spondylitis of unspecified sites in spine) to line 407 CONDITIONS OF THE BACK AND SPINE
- 12) Remove M46.0 (Spinal enthesopathy) from line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
- 13) Remove M46.2x (Osteomyelitis of vertebra) from line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS. This condition is on the osteomyelitis line with appropriate surgeries.
- 14) Remove M46.3 (Infection of intervertebral disc (pyogenic)) from line 259 CHRONIC OSTEOMYELITIS and line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS and add to line 51 DEEP ABSCESES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
- 15) Remove M46.5 (Other infective spondylopathies) from line 50 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES and add to line 407 CONDITIONS OF THE BACK AND SPINE
- 16) Remove M46.80 (Other specified inflammatory spondylopathies, site unspecified) and M46.90 (Unspecified inflammatory spondylopathy, site unspecified) from line 50 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES and add to line 407 CONDITIONS OF THE BACK AND SPINE
- 17) Remove M46.81-M46.89 (Other specified inflammatory spondylopathies) and M46.91-M46.99 (Unspecified inflammatory spondylopathy) from line 50

- 18) Remove M48.8X (Other specified spondylopathies) from line 467 OSTEOARTHRITIS AND ALLIED DISORDERS and add to line 407 CONDITIONS OF THE BACK AND SPINE
- 19) Remove M53.2X9 (Spinal instabilities, site unspecified) from line 663 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY and add to line 407 CONDITIONS OF THE BACK AND SPINE
- 20) Remove M99.80 (Other biomechanical lesions of head region) from line 261 DEFORMITIES OF HEAD and line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS and add to line 543 TENSION HEADACHES
- 21) Remove M99.81-M99.85 (Other biomechanical lesions of spine) from line 663 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY and add to line 407 CONDITIONS OF THE BACK AND SPINE
- 22) Remove M99.86-M99.89 (Other biomechanical lesions of extremity or trunk) from line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
- 23) Add Q06.2 (Diastematomyelia) and Q06.9 (Congenital malformation of spinal cord, unspecified) to line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
- 24) Remove S13.0XXA (Traumatic rupture of cervical intervertebral disc, initial encounter) from line 520 and add to line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS.
- 25) Add S34.3XXA (Injury of cauda equina, initial encounter) to line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
- 26) Add Z47.82 (Encounter for orthopedic aftercare following scoliosis surgery) to line 366 SCOLIOSIS and remove from lines 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS and 407 CONDITIONS OF THE BACK AND SPINE
- 27) Add acupuncture and chiropractic CPT codes (97810-97814, 98925- 98929, 98940-98942) to line 366 SCOLIOSIS

MOTION: To recommend the code changes as presented. CARRIES 7-0.

➤ **Topic: Artificial discs**

Discussion: Smits reviewed the summary document. The question was raised about whether artificial discs should be an included procedure on the upper back surgical line, as the conditions on this line are all urgent indications for surgery and the artificial disc guideline requires 6 months of conservative care. Livingston noted that artificial discs have equivalent efficacy as fusion, and as fusion is on this line, she felt that artificial discs should be included as an option which might avoid fusion. This led to a discussion about whether spinal fusion should be included on the upper surgical back line. Smits noted that the surgical back guideline does have some restrictions for fusion. The decision was to approve the recommended changes as presented. These changes will be implemented with the other changes to the treatment of conditions of the back and spine once their delay is lifted.

Recommended Actions:

- 1) Add CPT 22586-22865 (placement, revision and removal of total disc arthroplasty (artificial disc), anterior approach, cervical and lumbar) to line 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
- 2) Remove CPT 22586-22865 from line 366 SCOLIOSIS

MOTION: To recommend the code changes as presented. CARRIES 7-0.

➤ **Topic: Surgical back guideline revisions**

Discussion: Smits reviewed the summary document. The concern was raised that not requiring conservative care prior to surgery on the lower priority back surgical line would be an issue if the funding line dropped below this line number. A member also pointed out that the current back surgery guideline may actually prevent surgery on the lower line as the patient must have neurologic deficits to qualify for surgery and it is doubtful that any diagnoses on the lower line would meet these guideline note requirements.

The decision was to delete the problematic phrase from the guideline note without adding any alternative wording. This change will be implemented with the other changes to the treatment of conditions of the back and spine once their delay is lifted.

Recommended Actions:

- 1) Modify GN 37 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 7-0.

➤ **Topic: Advanced imaging for low back conditions guidelines**

Discussion: Smits reviewed the summary document. Williams raised concerns about the fact that much of the evidence included in this summary was reviewed at VbBS previously, with different conclusions. Gingerich answered that the evidence reviewed previously included the coverage guidance for percutaneous interventions for low back pain, which included two Chou reviews, but not the AHRQ report, and likely not the Cochrane review. Smits answered that the AHRQ report was presented to the VbBS during the previous discussion, but that the only substantive discussion of the report centered on the definition of radiculopathy used in that review. Livingston noted that the coverage guidance on which the decision to include epidural steroid injections (ESIs) was based upon will be revised shortly, using the AHRQ report and its negative findings.

Pollack then shared his personal, very positive experience with ESI. He was concerned about not allowing OHP patients access to such a possibly beneficial therapy. He felt that

ESI is essential to get immediate pain relief, and get patients into PT or other active therapy. He was concerned that not covering ESI would increase opioid use.

Olson and Gibson responded that VbBS decisions need to focus on the population studies rather than personal anecdote. Williams raised a concern that the larger population studies have conflicting results and that VbBS should not pick and choose what evidence to consider. Smits noted that most studies found poor evidence of effectiveness for the general population. Livingston pointed out that the AHRQ report noted that there were few patients included with acute or subacute symptoms in the studies reviewed, and therefore the AHRQ report may not reflect the population response for patients with acute/subacute pain.

Hodges noted that ESI could be covered as an exception, but that she could not recall a request for an exception for ESI from a patient with acute, incapacitating back pain. Her exceptions normally involve patients with chronic back pain.

Pollack requested that when the coverage guidance goes back through re-review, that HTAS or EGBS attempt to identify what subpopulations could benefit from ESI. Staff replied that this was part of the re-review process.

Note: As the placement of epidural steroid injections were prioritized on the list based on the coverage guidance prior to the biennial review resulting in the “package” of changes to related to the treatment of conditions of the back and spine that are currently delayed, changes involving the placement of ESI will occur at the time of the next set of interim modifications to the list. The changes to the diagnostic guideline on advanced imaging of the back were a part of the “package” of back changes, and therefore will only go into effect once the implementation of those changes is lifted.

Recommended Actions:

- 1) Remove CPT 64483 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level) and 64484 (each additional level) from line 407 CONDITIONS OF THE BACK AND SPINE
- 2) Modify GN37 as shown in Appendix A
- 3) Remove 64484 (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, additional levels) from line 159 HERPES ZOSTER; HERPES SIMPLEX AND WITH NEUROLOGICAL AND OPHTHALMOLOGICAL COMPLICATIONS
- 4) Place 64483 and 64484 ((Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral) on the Services Recommended for Non-Coverage table
- 5) Delete guideline note 105 EPIDURAL STEROID INJECTIONS FOR LOW BACK PAIN as shown in Appendix C

- 6) Modify DIAGNOSTIC GUIDELINE D4, ADVANCED IMAGING FOR LOW BACK PAIN as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0. (Abstained: Pollack and Williams)

➤ **Topic: Intrathecal pump guideline deletion**

Discussion: Smits reviewed the evidence summary. Gibson was concerned that adding the maintenance codes for these pumps to the complications line would allow use of an intervention that the Commission has previously determined was not effective. Hodges agreed, noting that OHP does not generally pay for complications directly related to uncovered procedures. Hodges felt that OHP should pay for pump removal for back pain indications, but not maintenance. Wentz noted that it was relatively common to have patients have pumps placed for back pain prior to coming on an OHP plan, and they need maintenance. It was noted that maintenance of these pumps could be covered as an exception if it was placed for a non-pairing condition if the patient was doing well. It was also noted that intrathecal pumps are not benign, but rather have some rather serious complications including CNS infections. The decision was to remove the pump maintenance codes from the back condition lines and delete the guideline note that applied to these lines. The subcommittee voted to not place the maintenance CPT codes or the maintenance ICD-10 Z code on the complications line. This leave coverage for maintenance only for indications on the dysfunction or cancer lines. A patient may appeal for continued coverage through the exception process. This change will be implemented with the other changes to the treatment of conditions of the back and spine once their delay is lifted.

Recommended Actions:

- 1) Delete GN72 as shown in Appendix C
- 2) Remove 62367 (Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill), 62368 (with reprogramming), 62369 (with reprogramming and refill), and 62370 (with reprogramming and refill (requiring skill of a physician or other qualified health care professional)) from lines 351* CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS, 366* SCOLIOSIS, and 532* CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS, and 607 DISORDERS OF SOFT TISSUE
 - a. *implementation of these lines is delayed

MOTION: To recommend the code and guideline note changes as amended. CARRIES 7-0.

➤ **Topic: Tobacco cessation and elective surgical procedures**

Discussion:

Livingston presented an update on feedback from the QHOC Medical Directors. There was a debate about whether cessation support or requiring cessation was the most appropriate requirement. There was general agreement that implementing cessation support would be difficult, and most members favored moving forward with requiring cessation.

There was a proposal to have cessation counseling be offered in the first year, and then a smoking requirement in the second year of implementation, but this was felt to be too confusing to providers. A proposal to leave certain types of surgeries out was made (e.g. dental). King shared that there is an updated MED report that looks at procedures in detail. Livingston said she would bring this back to the group.

Additionally, there were concerns raised about the acceptability of other nicotine replacement strategies and appropriate testing of smoking abstinence, what the definition of elective entails, the possibility of a severe comorbid psychiatric disorder interfering with cessation, and which specific surgeries might be included or excluded. Members asked HERC staff to return with further details that would assist with implementation.

Recommended Actions:

- 1) Staff to perform further review and return with additional information and modifications to the proposed guideline note

➤ **Topic: Coverage Guidance—Proton beam therapy**

Discussion:

Obley reviewed the evidence. Livingston reviewed the Coverage Guidance box language and the proposed application to the Prioritized List. Staff recommended some additional amendments for clarification purposes in the guideline note.

Questions were raised about the availability of proton beam therapy (PBT) in Oregon. It was clarified that there is no proton beam therapy centers in Oregon. OHP would have to cover travel, lodging, and transportation expenses, as well as an attendant. There was clarification about the duration of treatment with protons. Dr. Rengan clarified that PBT intensity and duration is similar to other radiation regimens and may need daily radiation for several weeks. There are trials underway to examine more intense treatments of shorter duration.

Dr. Rengan addressed a question about how to decide which gliomas need proton beam therapy compared to x-ray radiation therapy. He explained that low-grade glioma patients with excellent prognosis would benefit from protons as opposed to those with high-grade gliomas in which prevention of secondary malignancies may be less relevant.

Dr. Rengan wanted to clarify the intent to cover benign brain and spinal cord tumors. It was clarified that those lines for which there is no additional guideline note language (eye Value-

tumor, benign brain and malignant brain tumor lines) there are no specific restrictions and PBT is to be covered for these conditions. For all other listed tumors, PBT is only covered for malignancy. Members asked for the condition descriptions of the lines with no restrictions be added for clarity.

Recommended Actions:

- 1) Add proton beam therapy codes (77520, 77522, 77523,77525) to the following lines:
 - a. 97 CHILDHOOD LEUKEMIAS
 - b. 133 GRANULOMATOSIS WITH POLYANGIITIS
 - c. 195 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
 - d. 205 CANCER OF BONES
 - e. 242 ACUTE PROMYELOCYTIC LEUKEMIA
 - f. 280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
 - g. 292 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX
 - h. 402 ACUTE MYELOID LEUKEMIA
 - i. 403 MYELOID DISORDERS
- 2) Remove proton beam therapy codes from Line 377 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS
- 3) Add a new guideline note as show in Appendix B

MOTION: To approve the recommended changes to the Prioritized List based on the draft Indications for Proton Beam Therapy Coverage Guidance scheduled for review by HERC immediately following the VbBS meeting. CARRIES 7-0.

➤ **Topic: Coverage Guidance—Nitrous oxide for labor pain management**

Discussion:

Dr. Valerie King reviewed the evidence and coverage guidance process. Livingston reviewed the box language and application to the Prioritized List.

There was discussion about the challenge implementation will present with no specific code for nitrous oxide, the costs associated with this service, women’s preferences when compared to an epidural, and about the safety of nitrous oxide in out-of-hospital birth settings. No changes were proposed.

Recommended Actions:

- 1) Advise HSD to consider reimbursement options for the use of nitrous oxide
- 2) Adopt a new guideline note indicating inclusion of nitrous oxide for labor pain on Line 1 as shown in Appendix B

MOTION: To approve the recommended changes to the Prioritized List based on the draft Nitrous Oxide for Labor Pain Coverage Guidance scheduled for review by HERC immediately following the VbBS meeting. CARRIES 7-0.

➤ **Public Comment:**

No additional public comment was received.

➤ **Issues for next meeting:**

- 2018 Biennial review
 - Merging the two low birth weight lines
- Inguinal hernias
- Intracranial stenting and angioplasty
- Pectus excavatum and pectus caravatum
- Diaphragmatic hernias
- Retractable testicles
- Remote imaging for screening and management of retinopathy of prematurity
- Tobacco cessation and elective surgery
- Hyperbaric oxygen
- Rehabilitation guideline for mental health disorders
- Bariatric surgery coverage guidance
- Electronic tumor treatment fields
- Gender dysphoria
- Acupuncture for smoking cessation
- Nasal steroids for obstructive sleep apnea

➤ **Next meeting:**

March 10, 2016 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

➤ **Adjournment:**

The meeting adjourned at 1:10 PM.

Appendix A Revised Guideline Notes

DIAGNOSTIC GUIDELINE D4, ADVANCED IMAGING FOR LOW BACK PAIN

In patients with non-specific low back pain and no “red flag” conditions [see Table D4], imaging is not a covered service; otherwise work up is covered as shown in the table.

Repeat imaging is only covered when there is a substantial clinical change (e.g. progressive neurological deficit) or new clinical indication for imaging (i.e. development of a new red flag condition). Repeat imaging for acute exacerbations of chronic radiculopathic pain is not covered.

Electromyography (CPT 96002-4) is not covered for non-specific low back pain.

**Table D4
Low Back Pain - Potentially Serious Conditions (“Red Flags”) and Recommendations for Initial Diagnostic Work-up**

Possible cause	Key features on history or physical examination	Imaging ¹	Additional studies ²
Cancer	<ul style="list-style-type: none"> History of cancer with new onset of LBP 	MRI	ESR
	<ul style="list-style-type: none"> Unexplained weight loss Failure to improve after 1 month Age >50 years Symptoms such as painless neurologic deficit, night pain or pain increased in supine position 	Lumbosacral plain radiography	
	<ul style="list-style-type: none"> Multiple risk factors for cancer present 	Plain radiography or MRI	
Spinal column infection	<ul style="list-style-type: none"> Fever Intravenous drug use Recent infection 	MRI	ESR and/or CRP
Cauda equina syndrome	<ul style="list-style-type: none"> Urinary retention Motor deficits at multiple levels Fecal incontinence Saddle anesthesia 	MRI	None
Vertebral compression fracture	<ul style="list-style-type: none"> History of osteoporosis Use of corticosteroids Older age 	Lumbosacral plain radiography	None
Ankylosing spondylitis	<ul style="list-style-type: none"> Morning stiffness Improvement with exercise Alternating buttock pain Awakening due to back pain during the second part of the night Younger age 	Anterior-posterior pelvis plain radiography	ESR and/or CRP, HLA-B27
Nerve compression/ disorders (e.g. herniated disc with radiculopathy)	<ul style="list-style-type: none"> Back pain with leg pain in an L4, L5, or S1 nerve root distribution present < 1 month Positive straight-leg-raise test or crossed straight-leg-raise test 	None	None
	<ul style="list-style-type: none"> Radiculopathic signs³ present >1 month Severe/progressive neurologic deficits (such as foot drop), progressive motor weakness 	MRI ³	Consider EMG/NCV
Spinal stenosis	<ul style="list-style-type: none"> Radiating leg pain Older age Pain usually relieved with sitting (Pseudoclaudication a weak predictor) 	None	None
	<ul style="list-style-type: none"> Spinal stenosis symptoms present >1 month 	MRI ³	Consider EMG/NCV

Appendix A Revised Guideline Notes

¹ Level of evidence for diagnostic evaluation is variable

² Radiculopathic signs are defined for the purposes of this guideline as ~~pain, weakness, or sensory deficits, in a nerve root distribution~~ the presence of any 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

³ Only if patient is a potential candidate for surgery ~~or, if indicated, lumbar epidural steroid injection (see guideline note 105)~~

~~⁴ Only if patient is a potential candidate for surgery~~

Red Flag: Red flags are findings from the history and physical examination that may be associated with a higher risk of serious disorders. CRP = C-reactive protein; EMG = electromyography; ESR = erythrocyte sedimentation rate; MRI = magnetic resonance imaging; NCV = nerve conduction velocity.

Extracted and modified from Chou R, Qaseem A, Snow V, et al: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007; 147:478-491.

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

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

Spondylolithesis (ICD-9 738.4, 756.11-756.12 / ICD-10 M43.1*, Q76.2) is included on line 351 only when it results in spinal stenosis with signs and symptoms of neurogenic claudication. Otherwise, these diagnoses are included on line 532.

Appendix A Revised Guideline Notes

Surgical correction of spinal stenosis (ICD-9 ~~721.1~~, 723.0, 724.0x / ICD-10 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.

Only decompression surgery is covered for spinal stenosis; spinal fusion procedures are not covered for this diagnosis. Otherwise, these diagnoses are included on line 532.

~~For conditions on line 532, surgical interventions may only be considered after the patient has completed at least 6 months of conservative treatment, provided according to Guideline Note 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.~~

The following interventions are not covered due to lack of evidence of effectiveness for back pain, with or without radiculopathy:

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

GUIDELINE NOTE 65, TELEPHONE AND EMAIL CONSULTATIONS

Included on all lines with evaluation & management (E&M) codes

Telephone and email consultations ([CPT 98966-98969](#)) must meet the following criteria:

- 1) Patient must have a pre-existing relationship with the provider as demonstrated by at least one prior office visit within the past 12 months.
- 2) E-visits must be provided by a physician or licensed provider within their scope of practice.
- 3) Documentation should model SOAP charting; must include patient history, provider assessment, and treatment plan; follow up instructions; be adequate so that the information provided supports the assessment and plan; must be retained in the patient's medical record and be retrievable.
- 4) Telephone and email consultations must involve permanent storage (electronic or hard copy) of the encounter.

Appendix A Revised Guideline Notes

- 5) Telephone and email consultations must meet HIPAA standards for privacy.
- 6) There needs to be a patient-clinician agreement of informed consent for E-visits by email. This should be discussed with and signed by the patient and documented in the medical record.

Examples of reimbursable telephone and email consultations include but are not limited to:

- 1) Extended counseling when person-to-person contact would involve an unwise delay.
- 2) Treatment of relapses that require significant investment of provider time and judgment.
- 3) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone and email consultations include but are not limited to:

- 1) Prescription renewal.
- 2) Scheduling a test.
- 3) Scheduling an appointment.
- 4) Reporting normal test results.
- 5) Requesting a referral.
- 6) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
- 7) Brief discussion to confirm stability of chronic problem and continuity of present management.

GUIDELINE NOTE 113, DISEASES OF LIPS

Lines 210,585

ICD-10-CM code K13.0 (Diseases of lips) is included on Line 210 only for treatment of abscess or cellulitis of the lips. All other ~~subdiagnoses~~ diagnoses coded using K13.0 ~~under this code~~ are included on Line 585.

GUIDELINE NOTE 144, PROTON PUMP INHIBITOR THERAPY FOR GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Lines 385,516

Short term treatment (up to 8 weeks) of GERD without Barrett's (ICD-10 K20.8, K20.9, K21.0, K21.9) with proton pump inhibitor therapy is included on Line 385. Long term treatment is included on Line 516.

Long term proton pump inhibitor therapy is included on line 385 for Barrett's esophagus (ICD-10 K22.70).

Appendix B New Guideline Notes

GUIDELINE NOTE XXX, PROTON BEAM THERAPY FOR CANCER

Lines 97, 117, 130, 133, 195, 205, 242, 280, 292, 299, 377, 402, 403

Proton beam therapy is included on lines 117 CANCER OF EYE AND ORBIT, 130 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD and 299 CANCER OF BRAIN AND NERVOUS SYSTEM.

Proton beam therapy is included on lines 133, 205, and 292 only for: malignant skull base, paranasal sinus (including lethal midline granuloma), spinal, and juxtaspinal tumors .

Proton beam therapy is additionally included on lines 97, 195, 242, 280, 402, and 403 only for pediatric malignant tumors (incident cancer under age 21.)

GUIDELINE NOTE XXX, NITROUS OXIDE FOR LABOR PAIN

Line 1

Nitrous oxide for labor pain is included on this line.

Appendix C Deleted Guideline Notes

GUIDELINE NOTE 16, CYSTIC FIBROSIS CARRIER SCREENING

Lines 1, 625

~~Cystic fibrosis carrier testing is covered for 1) non-pregnant adults if indicated in the genetic testing algorithm or 2) pregnant women.~~

GUIDELINE NOTE 72, ELECTRONIC ANALYSIS OF INTRATHECAL PUMPS

Lines 351, 366, 532, 612

~~Electronic analysis of intrathecal pumps, with or without programming (CPT codes 62367-62370), is included on these lines only for pumps implanted prior to April 1, 2009.~~

GUIDELINE NOTE 105, EPIDURAL STEROID INJECTIONS FOR LOW BACK PAIN

Line 407

~~Epidural lumbar steroid injections (CPT 62311, 64483, 64484) are included on this line for patients with persistent radiculopathy due to herniated lumbar disc, where radiculopathy is defined as lower extremity pain in a nerve root distribution, with or without weakness or sensory deficits.~~

~~One epidural steroid injection is included on this line; a second epidural steroid injection may be provided after 3-6 months only if objective evidence of 3 months of sustained pain relief was provided by the first injection. It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. Epidural lumbar steroid injections are not included on this line for spinal stenosis or for patients with low back pain without radiculopathy. Epidural steroid injections are only included on this line when the patient is also participating in an active therapy such as physical therapy or home exercise therapy.~~

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

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February 2016

Emilee Coulter-Thompson, MSW &
Safina Koreishi, MD, MPH



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POLICY AND ANALYTICS
Transformation Center



Now accepting applications!
Oregon Clinical Innovation Fellows
2016-2017

The Oregon Council of Clinical Innovators is **now accepting applications for our third cohort of Clinical Innovation Fellows**. This is an opportunity to build the capacity of health care leadership within our state, support the success of coordinated care organizations (CCOs) and spread the coordinated care model. Funding for this program is generously provided by the Centers for Medicare and Medicaid Innovation (CMMI) State Innovation Model grant.

This year-long learning experience focuses on fellows' local innovation projects that align with Oregon's health system transformation priorities; leadership; quality improvement; and project implementation and dissemination science.

We are looking for health care professionals (physicians, nurses, pharmacists, physical therapists, behaviorists, social workers, dentists, etc.) who have the following:

- An existing innovation project that aligns with their CCO's (or commercial payer's) health system transformation priorities and [Oregon's coordinated care model](#)
- At least five years of professional experience with demonstrated leadership attributes
- Commitment from their CCO (or commercial payer) leadership and sponsoring organization for their project
- Commitment to addressing health equity
- Diversity with respect to Oregon geography, clinical discipline and cultural identity

Benefits to fellows include:

- Four in-person learning seminars and monthly interactive webinars
- Presentations by dynamic national and local experts
- Mentorship and peer support for innovation projects
- Travel reimbursement

Benefits to sponsoring organizations include:

- Enhanced innovation leadership capacity
- Focused project management time that supports a local improvement priority
- Dissemination of innovation skills and links to projects across the state

To apply: Review the call for applications for eligibility details and complete the application form at transformationcenter.org/cci/ by **April 15, 2016**.

If you have questions, please contact Laura Kreger at laura.e.kreger@state.or.us or 971-673-3386

Statewide PIP on Opioid Safety

How CCOs can develop and implement successful programs for non-opioid therapies



Agenda

1. Panel discussion of key questions followed by question and answers
2. Small group discussion



Session Objectives

Participants will gain a better understanding of:

1. How to decide which alternative therapies to support
2. Ways to work with providers to develop and use alternative therapies
3. Options for funding services



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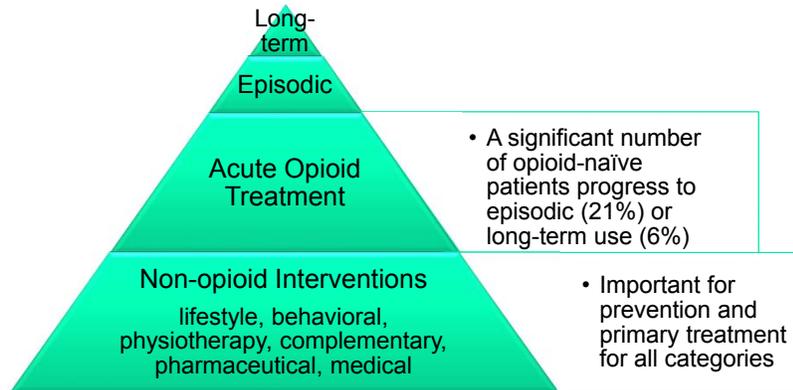
Panelists

- Columbia Pacific CCO
 - Dr. Safina Koreishi, Medical Director
- AllCare CCO
 - Dr. Mark Bradshaw, Behavioral Health Medical Director
 - Dr. Amy Burns, PharmD, Director of Population Health Management
- Health Share of Oregon CCO
 - Graham Bouldin, QM Manager, Health Share of Oregon
 - Dr. Linda Cruz, Clinic Medical Director, Providence Medical Group
 - Dr. Mark Whitaker, Senior Medical Director, Providence Health Plan



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Opioid Treatment Categories



Mayo Clin Proc. July 2015;90(7)850–856. <http://dx.doi.org/10.1016/j.mayocp.2015.04.012>

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Key Questions

1. How did your CCO decide which alternative, non-opioid therapies to offer to members?
2. How did your CCO work with providers to develop and use alternative, non-opioid therapies?
3. How is your CCO paying for alternative, non-opioid therapies and services?



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Small Group Discussion

Choose a table of your choice:

Table #1: Discuss decision process for identifying alternative, non-opioid therapies to offer members.

- Focus: therapies for members receiving chronic opioid therapy

Table #2: Discuss decision process for identifying alternative, non-opioid therapies.

- Focus: therapies for members who are opioid-naïve



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Small Group Discussion, cont.

Table #3: Discuss best practices for working with providers to develop and use alternative, non-opioid therapies.

- Focus: therapies for members receiving chronic opioid therapy

Table #4: Discuss best practices for working with providers to develop and use alternative, non-opioid therapies.

- Focus: therapies for members who are opioid-naïve



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Small Group Discussion, cont.

Table #5: Discuss possible payment structures for alternative, non-opioid therapies and services.

- Focus: therapies for members receiving chronic opioid therapy

Table #6: Discuss possible payment structures for alternative, non-opioid therapies and services.

- Focus: therapies for members who are opioid-naïve



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Small Group Discussion, cont.

Table #7: Discuss CCO process for evaluating and measuring program success of alternative, non-opioid therapies and services.

- Focus: therapies for members receiving chronic opioid therapy

Table #8: Discuss CCO progress for evaluating and measuring program success of alternative, non-opioid therapies.

- Focus: therapies for members who are opioid-naïve



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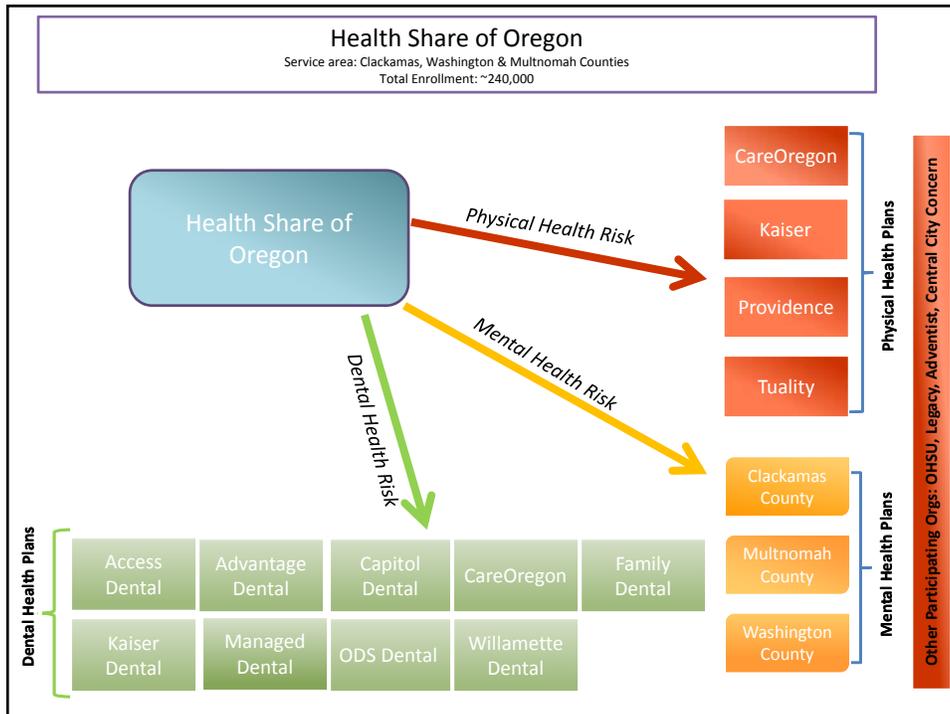
Summary

Thank you to our panelists and
participants!

For additional information, contact:
PIPTeam@acumentra.org



Health Share of Oregon: Providence Medical Group & Providence Health Plan Opiates Approach



System Context

- Health Share has more than 30 clinic *systems* with 1,000+ assigned members, hundreds of individual clinic locations
- Different clinic cultures, resources, business models, patient mix and demographics
- **Collective Impact is critical to complex system change**
 - Common Agenda
 - Shared Measurement Systems
 - Mutually Reinforcing Activities
 - Continuous Communication
 - Backbone Support Organization



System Context

- Tri-County Prescription Opioid Safety Coalition: Coordinating Committee & work groups re: Chronic Pain Management, Public Awareness, Treatment and Recovery, Provider Education, Prescribing Guidelines, Monitoring, Naloxone & Safe Disposal and Storage



Today's Presentation

Providence Medical Group (PMG) & Providence Health Plan (PHP)

PHP:

- Health Share's second largest physical health plan system
- Currently assigned about 37,000 Medicaid members across three counties

PMG:

- Health Share of Oregon's third largest provider system
- Currently assigned about 28,000 Medicaid members



How did your CCO decide which alternative, non opioid therapies to offer to members?

Training in pain neurophysiology:

- Medical home and rehab

Pain education classes and videos developed before enforcement of opiate guidelines

- ↓ threat value, ↓ pain

Moving towards integrated care using services within our system and supported by the CCO through:

- Rehab Department
 - Basic pain protocol of 4 physical therapy visits (available since Fall 2015)
 - Pain education
 - Physiological quieting
 - Pacing and graded exposure
 - Focus on function
- Integrated Behavioral Health developing pain protocol aligned with rehab
- Persistent Pain Case Reviews in our ambulatory clinics that started in 2014.

How did your CCO work with providers to develop the use of alternative, non opiate therapies?

Cost shift:

- Recognition of the concept of a shift in cost and willingness to cover rehab and pain education with the expectation that this would reduce ED utilization

Pain education training

- Provided education around neurophysiology of pain, and rehab offerings to all 38 clinics

Physician Champion/Multidisciplinary case review

- Used a physician champion in the clinic and extended PCMH team to set up multidisciplinary case reviews

Integrated behaviorists

- Address motivation and beginning to develop pain protocol

Rehab availability (4 sessions)

Pain Education for patients

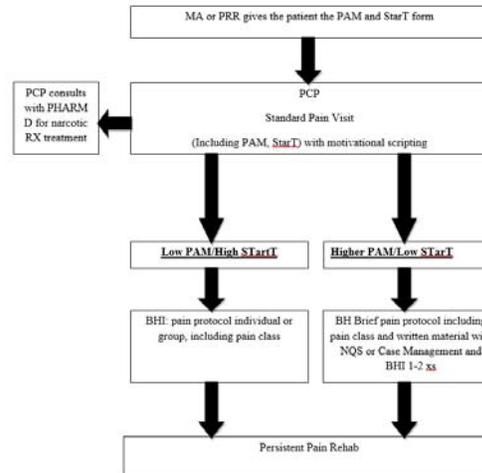
- Videos, PHP covering pain education classes at no charge for PHP OHP

Pharmacy

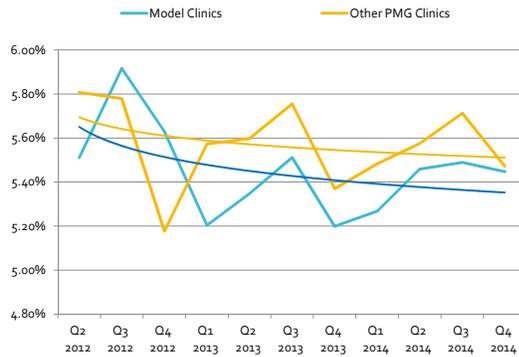
- monitored patients over 120 MED and CMD's reviewed the care plan with individual providers to ensure a patient centered approach to care

Implemented prior to enforcement of the limit on opiate prescribing

Using Behavioral Health and Rehab



ED Utilization by Quarter (Trended) in relation to use of pain tools



ED usage for those clinics with both higher class attendance and use of case review (Blue) have an ED reduction of almost 2% year over year, while those without both higher class attendance and use of case review (Orange) show a trend of less than 1%. Trend shows a 2.3 times reduction of ED utilization for those with higher attendance for pain education.

Model Clinics = Optimizing Pain Education Tools (Case Review and Patient Classes)
Other PMG Clinics = Not using both case reviews and higher pain class attendance

Providers

How is your CCO paying for alternative, non-opioid therapies and services?

- Providence Rehab
 - Up to 4 PT visits for chronic pain without a prior auth
 - Persistent Pain Program class
- Progressive Rehab Associates
 - CARF-accredited Outpatient Interdisciplinary Pain Program

How is your CCO paying for alternative, non-opioid therapies and services?

Community Programs

- Care Management can pay for classes or programs through Flexible Services Fund
 - MS, RA, and Fibromyalgia support groups
 - Acupuncture and Massage Therapy schools
 - Yoga classes
 - Warm water pool classes

How is your CCO paying for alternative, non-opioid therapies and services?

Assistance with ADLs

- Meals on Wheels
- Store to Door
- Portland on the Cheap



CCO Performance Improvement Projects

	Reducing Preventable Re-Hospitalizations		Population Health							Care Teams				Integration	Appropriate Care/ Appropriate Setting							Perinatal/ Maternity Care					PCPCH	CCO Subtotal	
	Reduce Re-hospitalization	High utilizers	Developmental Screening	CVD: Identify and screen	ECU	Colorectal Cancer Screening	Best practices in prescribing opiates for chronic pain	Decrease Opioid / Benzo use	Tobacco Cessation	ER utilization	MH First Aid Training	Chronic conditions/SPMI	Best Practices for chronic pain	Statewide PIP: Reduction of Opioid use	COPD: Dx, Tx and Reduction	Foster Care Medical Home	MH Services for children	Adolescent Well Child Visits	ACEs	Depression Screening	AD or POLST	Early Prenatal care	Maternity Case Management	Pregnancy / Oral Health Visit	Pregnant women / addiction and/or MH	Post partum visit	Maternal Medical Home		Increase PCPCH enrollment
AllCare													P								P							F	4
Cascade Health Alliance														P	P							P						F	4
Columbia Pacific			A					P				A	P					F			P								4
Eastern Oregon			A										P			F	P					P							4
FamilyCare						P					P		P				P										A	4	
Health Share	A		A		F				A				P		P											P			4
Intercommunity Health	P			A					P				P										P	A					4
Jackson Care Connect		P					A						P				P				P								4
PS Columbia Gorge			P										P				P						P		A				4
PS Central Oregon			P										P				P						P		A				4
Primary Health of Josephine		P								F			P													P			4
Trillium	P												P						P		F								4
Umpqua									P				P											P			F	4	
Western Oregon	P							P					P														F	4	
Willamette Valley								P	P				P														F	4	
Yamhill Community Care													P				P									A	P	3	
Subtotal	3	2	2	0	1	1	0	1	2	3	1	1	0	16	1	1	6	1	1	1	4	1	3	3	0	1	6		
TOTAL	5		7							5				16	11							12					6	62	

P: Performance Improvement Project (PIP), F: focus area, A: archived project in last 12 mo
 As of: 4Q2015 reports rcvd 1/31/2016
 Categories as defined by OHA1115 waiver