Oregon Health Authority

Quality and Health Outcomes Committee
AGENDA

MEETING INFORMATION
Meeting Date: January 14, 2019
Location: HSB Room 137 A-D, 500 Summer Street, NE, Salem, OR
Parking: Map Phone: 503-378-5090 x0
Call in information: Toll free dial-in: 888-278-0296 Participant Code: 310477
Webinar: https://attendee.gotowebinar.com/rt/4303958396461018881
All meeting materials are posted on the QHOC website.

Clinical Director Workgroup 10:30 a.m. – 12:30 p.m.			
Time	**Topic**	**Owner**	**Materials (page #)**
10:30 a.m.	**Welcome / Announcements**	Andy Luther	-SUD Waiver memo (2-4) -Public Health Update (4-7) -November Meeting Notes (8-12)
10:40 a.m.	**P&T Update**	Roger Citron	
10:50 a.m.	**HEP C policy update**	Trevor Douglass Dana Hargunani	-Hep C memo (13-18)
11:05 a.m.	**Effective Contraceptive Use**	Maria Rodgriuez	-Presentation slides (19-23)
11:30 a.m.	**Tobacco Cessation Media Campaign**	Sarah Wylie	-Presentation slides (24-29) -Overview Handout (30-33)
11:45 a.m.	**HERC update**	Cat Livingston Ariel Smits	-Presentation slides (34-36) -HERC Materials (37-116)
12:30 p.m.	**LUNCH**		
Quality and Performance Improvement Session 1:00 p.m. – 3:00 p.m.			
1:00 p.m.	**Welcome / Announcements**	Carla Munns Lisa Bui	-TQS TA Flyer (117)
1:15 p.m.	**2019 Statewide PIP Measure Specifications**	Lisa Bui	-Draft Measure Specification (118)
1:30 p.m.	**Complaints and Grievance** • **Process** • **Reporting**	Ann Brown	-Presentation slides (119-126)
2:15 p.m.	**Other Business**	Allison Tonge	-Presentation slides (127-129)
2:45 p.m.	**Items from the Floor**	All	

Upcoming February Topics:

- Back Pain study

HEALTH SYSTEMS DIVISION
Medicaid Policy

Kate Brown, Governor

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Date: January 3, 2019

To: Oregon Health Plan and Addiction Services Stakeholders

From: Dana Hittle, Interim Deputy Medicaid Director

Subject: Substance Use Disorder (SUD) 1115 Demonstration: A new opportunity to expand SUD services and supports in Oregon's Medicaid delivery system

The Oregon Health Authority (OHA) is pleased to announce that Oregon is applying to the Centers for Medicare & Medicaid Services (CMS) for a new five-year Medicaid 1115 Demonstration waiver to help build a full continuum of care for Medicaid members with substance use disorders (SUD).

- CMS recognizes that 42 CFR §435.1009, the payment exclusion for services provided in an Institute for Mental Disease (IMD) presents challenges to funding effective SUD treatment.
- Most of Oregon's SUD residential treatment facilities fall under this payment exclusion.
- Oregon's SUD 1115 Demonstration waiver application will ask CMS to waive this exclusion and allow federal match for SUD treatment of Medicaid members in an IMD, for estimated General Fund cost savings of $30 million per demonstration year (July 1, 2019 through June 30, 2024).

Under this demonstration, Oregon will support the following primary goals:

- Improve adherence to SUD treatment plans
- Reduce overdose and overdose deaths due to opioids
- Reduce utilization of ED and inpatient hospital setting for SUD treatment
- Reduce readmissions to the same or higher level of care for SUD treatment
- Improve access to care for SUD at all levels (outreach, initiation, treatment and recovery)
- Expand Medication Assisted Treatment services and supports for opioid use disorders

OHA is collecting feedback on the draft waiver application according to the following timeline:

- **January 2019:** Begin tribal consultation process, and public notice to coordinated care organizations, providers and fee-for-service stakeholders; submit draft application to CMS
- **February 2019:** Public notice continues
- **March 2019:** Tribal consultation process ends; revise draft application based on public comment; submit final application to CMS

How Oregon's SUD 1115 Demonstration will affect CCOs:

If approved, Oregon's SUD 1115 Demonstration will advance and expand the current SUD benefit package covered by CCOs, beginning July 1, 2019. OHA will work on a 24-month implementation plan upon CMS approval. Proposed requirements for CCOs include, but are not limited to:

- Statewide SUD-specific Performance Improvement Projects
- Demonstrate provider network adequacy for SUD services and supports; improved member adherence and engagement to SUD treatment plans; and ability to serve priority populations.
- Reduce or eliminate the number of members on wait lists to access appropriate levels of care
- Reduce overdose and overdose deaths within their membership
- Increase member access to Medication Assisted Treatment and Office Based Opioid Treatment

OHA will seek feedback from CCOs about how to implement the proposed requirements.

How Oregon's SUD 1115 Demonstration will advance Health System Transformation:

Within the Medicaid delivery system, the cost savings will fund:

- A fee-for-service rate increase for residential levels of care that may impact CCO rates;
- An expanded SUD benefit package for all Medicaid members, to include outreach and engagement to establish an SUD diagnosis, and recovery support services for members who have successfully completed SUD treatment;
- More participating SUD residential treatment programs that are larger than 16 beds;
- Quality improvement measures and incentives; and
- More participating provider types (including peer-run organizations) to support billing and reimbursement for recovery support services.

The work under this demonstration will also improve licensing and certification requirements for specific levels of care defined by the American Society for Addiction Medicine.

To learn more:

For additional information or inquiries, please contact Nicole Corbin, Addiction Treatment, Recovery, and Prevention Services Manager at nicole.corbin@dhsoha.state.or.us.

Quality and Health Outcomes Committee
Public Health Division updates – January 2019

Help inform the priorities of the 2020-2024 State Health Improvement Plan

There's still time to help identify priorities for the next State Health Improvement Plan (SHIP). The SHIP identifies key health concerns for our state– along with strategies that will lead to improvements. A community-based committee, called the PartnerSHIP, has identified 14 strategic issues that need to be addressed. It's not feasible to address all 14 issues, so we need your help to understand which issues are most important to your community. There are a number of ways you can provide your feedback and help spread the word:

- **An online survey (in English and Spanish) will be available through January 31st to collect your feedback on these issues.** Please take and share this survey with your professional and personal networks via email listserves, social media platforms and other communication channels. **We are especially interested in hearing from the following groups of people who are underrepresented in the survey results thus far: people under 18 or over 65 years of age, people who haven't attended college or university, and people of color.** Please consider ways to share this survey with clients, consumers, patients, service recipients, youth, or other people with lived experience.

For more information about the SHIP, visit healthoregon.org/2020ship or contact Christy.j.hudson@state.or.us.

Now available: Student Wellness Survey Reports

State and county-level data and reports for the 2018 Student Wellness Survey are now available at: https://oregon.pridesurveys.com/. Reports contain results for all survey questions by grade level (6th, 8th, and 11th).

The Oregon Student Wellness Survey is an anonymous and voluntary survey sponsored by Oregon Health Authority and Oregon Department of Education. The survey is designed to assess a wide range of topics that include school climate, positive youth development, mental health, physical health, substance use, problem gambling, fighting and other problem behaviors.

For more information contact the OHA Health Promotion Chronic Disease Prevention section at: hpcdp.surveillance@state.or.us.

Help Inform the Future of Chronic Disease Self-Management Programming in Oregon

OHA's Health Promotion and Chronic Disease Prevention (HPCDP) Section is committed to supporting the growth and sustainability of self-management programs in Oregon. Consequently, we want to better understand your organization's needs and assets related to evidence-based and evidence-informed self-management and lifestyle change programs. HPCDP will be disseminating a survey within the next month to better understand what is needed to further develop and sustain the infrastructure for these programs throughout Oregon. The survey will be shared with a broad range of partners who support chronic disease self-management and prevention programming, including providers, clinics, health systems, payers, community-based organizations, medical associations, etc.

Evidence-based and evidence-informed self-management and lifestyle change programs reduce the burden of some of the leading causes of death and disability in Oregon, i.e., arthritis, asthma, diabetes, and hypertension, colorectal cancer, and their correlating risk factors, i.e., tobacco use, physical inactivity, poor nutrition, excessive alcohol use.

For the purpose of this survey, evidence-based and evidence-informed self-management and lifestyle change programs include:

- Oregon Tobacco Quitline
- Oregon Arthritis Program - Walk with Ease, Enhance Fitness
- National Diabetes Prevention Program
- Living Well with Chronic Disease
- Tomando Control de su Salud (CDSMP-Spanish)
- Chronic Pain Self-Management Program
- Diabetes Self-Management Education and Support (DSMES)
    - Diabetes Self-Management Program (DSMP)
    - Programa de Manejo Personal de la Diabetes (SDSMP)
- Tai Chi Moving for Better Balance

Your response to the survey is voluntary, yet vital to guide us in further developing and sustaining these evidence-based and evidence-informed programs, which promote health, wellbeing and equity while reducing costs.

Congenital Cytomegalovirus (cCMV) and Birth Anomalies

In 2017, Oregon joined a small and growing number of states with legislation related to cytomegalovirus, a common virus that can cause serious and permanent health effects for babies infected during pregnancy. Oregon's law created requirements related to congenital CMV for specific groups of health care providers and the OHA. The law requires:

- OHA to compile educational information about cCMV and make it available for use by hospitals, birthing centers, health care providers, diagnostic audiologists, and the public;
- Hospitals and birthing centers that perform newborn hearing screenings to provide information about cCMV to parents and guardians;

- Diagnostic audiology facilities to provide information about cCMV to parents and guardians of newborn infants diagnosed with hearing loss;
- OHA to provide a recommended schedule for newborn hearing screening and referral to health care providers for the purpose of determining whether testing for cCMV is indicated for a newborn child.

An estimated 1 in 200 infants are born infected with cCMV each year. Approximately 80% of these infected infants will have no health effects from the virus. However, 1 in 5 infected babies will have CMV-related health problems, such as hearing loss, vision loss, and intellectual impairment. Most babies born with CMV do not show signs at birth.

Babies born in Oregon are not typically tested for congenital CMV unless the baby shows signs. Testing must be done before baby is 21 days of age.

Women who are pregnant or considering getting pregnant should talk with their healthcare provider about how to prevent infections such as CMV and whether to be tested. The best way to prevent infection is to practice good hygiene.

For more information on cCMV and the new law in Oregon:
https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/COMMUNICABLEDISEASE/CDSUMMARYNEWSLETTER/Documents/2018/ohd6709.pdf

CDC — Congenital CMV Infection www.cdc.gov/cmv/clinical/congenital-cmv.html

CDC — Talking with pregnant patients about CMV: A resource for healthcare providers.
https://www.cdc.gov/cmv/downloads/pregnant-patients-cmv.pdf

Oregon Public Health Division — Early Hearing Detection and Intervention
http://healthoregon.org/ehdi

Oregon Public Health Division – Birth Anomalies Surveillance System
https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/DATAREPORTS/Pages/birth-anomalies.aspx

2018/19 Influenza Season

Influenza season is here. The flu vaccine may take up to two weeks to become effective and clinics should begin administering vaccines now to avoid missed opportunities to vaccinate. High risk groups include children, pregnant women, older adults, and patients with chronic medical conditions. Oregon had two flu-related deaths in children during the 2017-2018 flu season and continues to have race and ethnicity disparities in flu vaccination rates with Latino and African American seniors less likely to be vaccinated than Caucasians. For more information on flu vaccination trends and data in Oregon visit:

https://www.oregon.gov/oha/PH/DiseasesConditions/CommunicableDisease/DiseaseSurveillanceData/Influenza/Pages/index.aspx

QHOC Meeting Notes
October 8, 2018
9:00 a.m. – 3:00 p.m., HSB 137 A-D
500 Summer Street NE, Salem, OR 97301

Attendance

Advanced Health	Ganesh Kini, Jamilah Moodey, Anna Warner
AllCare	Kelley Burnett, Laura Matola, Laura McKeane
Cascade Health Alliance	David Shute, Susan Boldt
Columbia Pacific	Safina Koreishi
Eastern Oregon	
Health Share	Barbara Carey, Graham Bouldin, Charmaine Kinney
InterCommunity Health Network	Kevin Ewanchyna, Arik Olson, Barbara Koslow
Jackson Care Connect	
PacificSource Community Solutions	Stevi Bratschie, Mike Franz
Primary Health of Josephine County	Andrew Luther
Trillium Community Health Plan	Donna Erbs, Rae Baumen
Umpqua Health Alliance	Tanveer Bokhari, F. Douglas Carr
Willamette Valley Community Health	Jeanne Savage, Lisa Parks, Jeanne Savage, Summer Hunter
Yamhill Community Care	Jenna Harms, Bhavesh Rajani
Capitol Dental Care	Andrew Lee
CareOregon	Tanya Kapka, Carl Stevens
Providence	Kristin Garrett
Tuality Health Alliance	Katrina McPherson, Paola Paz
Washington County	Andy Wallace
OHA	Cat Livingston, Ariel Smits, Tracy Muday
Guests	Don Grostic (HSAG, Associate Director, PIP); Kristin Hartmann (HSAG, Project Manager, PIP); Jake Mazzola, health intern; Kristan Jeannis (Tuality Health Alliance), Collen Reuland (OPIP)
Attendance via Phone/Webinar	Barbara Boardman, Stuart Bradley, Geralyn Brennan, Mindi Burdick, Briona Campbell, Mary Canton, Renee Doan, Tiffany Dorsey, Ann Ford, Alyssa Franzen, Dana Gantz, Ying Han, Julian Huff, Nicole Jepeal, Mark Kantor, Andrea Ketelhut, Sara Kleinschmit, Laura Kreger, Cynthia Lacro, Nina Lara, Alison Martin, Ruth McBride, Molly McGrew, Christi Melendez, Rosa Pedraza, Yuberca Pena, Alissa Robbins, Allie Ryan, Traci Thomas, Cord Van Riper, Ann Wagoner, Sarah Wetherson, Courtney Whidden, Chanel Wick, Bobbi Choe Mouat, David Geels, Lisa Krois, Paola Paz, Ashley Richardson

Clinical Director Workgroup (9:00 a.m. – 11:00 a.m.)

Welcome/Announcements

- Meeting called to order at 9:06 a.m.
- The 2019 QHOC chair is Andrew Luther, MD. Dr. Luther is the Medical Director of Primary Health of Josephine County.
- Due to Veteran's Day on November 11th, QHOC is now on November 5, 10:30 a.m. – 3:00 p.m.
    - Location: HSB 137 A-D, 500 Summer Street NE, Salem, OR 97301
- CCO 2.0 updates are on the OHA website.
- Next OHPB meeting is on October 15, 2018. The agenda and meeting materials are posted on the OHPB website.
- Dana Hargunani informed the group that OHA would be reviewing hepatitis C denials. OHA is planning on routine reviews to ensure alignment with criteria set by the state.
- Tracy Muday has joined OHA on a temporary basis within the Provider Clinical Support unit as of October 1, 2018.

Pharmacy & Therapeutics Update

- Pharmacy and Therapeutics Committee met on September 27, 2018. The packet and materials are provided on the P&T website.

Health Evidence Review Commission Update

- HERC materials are in the meeting packet, pages 13 – 40.

Opioid Initiative Update: Acute Prescribing Guidelines, and PDMP Clinical Review

- Goal: standard for opioid prescribing across the state, including health care systems and practice settings
- OHA's role is as a convener with no mandate and no specific funding
- The recommendations made by Opioid Prescribing (published March 2016): chronic pain, non-cancer, non-palliative, non-end of life
- Oregon opioid prescribing guidelines for chronic pain:
    - Endorse CDC guideline as foundation for opioid prescribing in Oregon
    - Oregon-specific addenda:
        - Marijuana use
        - Chronic (legacy) patients
        - Naxolone
        - Prescription Drug Monitoring Program
        - OMB Material Risk Notice
- PDMP Clinical Review Committee
    - Oregon HB 3440, passed in 2017 requires OHA to establish a clinical review subcommittee
    - Subcommittee uses PDMP to develop criteria by which a practitioner may be required to receive education or training on the prescribing of opioids

    - Subcommittee reviews PDMP information on practitioners' prescribing histories to determine who meets the criteria for receiving education/training.
    - OHA provides practitioners who meet criteria educational information about prescribing opioids for pain.
- Unused opioid pills after a prescription:
    - Systematic review of orthopedic, thoracic, obstetric and general surgery: 67% - 92% of patients with unused opioids
    - Dental surgery: 54% unused
    - Hand surgery: 34% used
    - Shoulder surgery: 25% unused
    - C-section: 83% reported taking fewer than half
- In general, opioids should not be considered first line therapy for mild to moderate pain:
    - Evaluate patient
    - Assess history of long-term use/substance use disorder (SUD)
    - Provide patient education
    - Amount and type
    - Patient follow-up

Pre-Manage

- The Emergency Department Information Exchange (EDIE) and Pre-Manage are hospital event notification tools that provide real-time information to support two statewide efforts:
    - Reduce ED utilization
    - Improve care coordination and management
- State Coordinated Efforts for Medicaid
    - OHA leverages MMIS enhanced federal match (75/25) to fund a voluntary State Medicaid subscription for PreManage
    - OHA subscription covers:
        - Base package for key care coordinators for Medicaid Members
        - Medicaid EDIE data for OHA analytics purposes
        - Support for Medicaid metrics (1115)
- Challenges
    - HIPAA questions
    - Enrollment file-data included, timing
    - Standardization/Policy across APD
    - Role and participation in collaborative care coordination
    - Occasional IT issues
- Next Steps:
    - Adding populations and data to enrollment file
    - Building/joining internal and external learning communities and care collaboratives
    - APD Central Office use as tool for planning & monitoring
    - Determining APD role & data in care terms, care guidelines, insights and other sections of PreManage

Learning Collaborative: Child Health Complexity

- OPIP supports a meaningful, long-term collaboration of stakeholders invested in child health are quality, with the common purpose of improving the health of children and youth of Oregon.
- OPIP staff and projects are focusing on building health on improving outcomes for children and youth by:
    - Collaborating in quality measurement and improvement activities across the state
    - Supporting evidence-guided quality activities in clinical practices
    - Incorporating the patient and family voice into quality efforts
    - Informing policies that support optimal health and development
- OPIP efforts with practices and health systems focused on
    - Identifying children and youth with special health care needs
    - Care Coordination, methods for tiering patients
    - Complex Care Management Pilot within Kaiser Permanente Northwest
- Some areas of focus on the CCO 2.0 policy options being examined
    - Improve the behavioral health systems and address barriers to integration of care
    - Increase value and pay for performance
    - Focus on social determinants of health and health equity
    - Maintaining sustainable cost growth and encouraging financial transparency
- System-Level Approaches to Identify Children with Health Complexity, use of this to design better support systems for children and their families
    - August 2017-March 2019
    - Key partners
        - Oregon Health Authority
        - Kaiser Permanente Northwest – Publicly & Privately insured
        - Coordinated Care Organizations
- In-Person meeting on 11/28/2018, 8:00 a.m. – 5:00 p.m. at Clackamas Community College
    - Purpose of the day is to share ways that the CCOs may consider using the data and models of care coordination and casement for children to consider
- Next steps
    - CCO-level data release
        - Aggregate population-level report
        - Child-level data report
    - 11/28 meeting

Quality and Performance Improvement Session

Statewide PIP

- HSAG's PIP team has experience validating PIPs in 15 states, validates more than 400 PIPs annually and the team consists of clinicians, healthcare analyst and a biostatician
- PIP submissions forms align with CMS protocols, are CMS reviewed and approved and CCOs will complete Step VIII (improvement strategies and interventions)
- PIP validation tool aligns with CMS protocols and Step VIII (six evaluation elements with specific requirements)
- PIP submission process
    - Complete and submit PIP submission form to OHA on January 3, 2019
    - OHA forwards submissions to HSAG for validation
    - HSAG conducts validation and completes validation tool
    - Validation findings included in Statewide PIP Report

Health Transformation Report Metric Learning

- OHA is working to align with Dental Quality Alliance specifications (still in test). There may be areas of divergence, as OHA generally follows HEDIS in terms of (a) definition of members with diabetes and (b) continuous enrollment criteria
    - HEDIS has optional exclusions. Members who do not have a diagnosis diabetes, in any setting, during the measurement year or the year prior to the measurement year and:
        - Who had a diagnosis of gestational diabetes or
        - Steroid-induced diabetes
    - OHA has historically used these exclusions (meaning only patients with diagnosis of Type 1 or Type 2 diabetes have been included; patients with a diagnosis of secondary diabetes due to another condition have been excluded)
- Also, the DQA draft specifications include a 180 day continuous enrollment period. Per Metrics & Scoring Committee, OHA will use a longer period (12 months with one 45 day gap)

Meeting adjourned at 2:55 p.m.

Hepatitis C Direct-Acting Antivirals (Effective March 1, 2019)

Goals:

Approve use of cost-effective treatments supported by the medical evidence.
Provide consistent patient evaluations across all hepatitis C treatments.
Ensure appropriate patient selection based on disease severity, genotype, and patient comorbidities.

Length of Authorization:

- 8-16 weeks

Requires PA:

All direct-acting antivirals for treatment of Hepatitis C

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for treatment of chronic Hepatitis C infection (B18.2)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is expected survival from non-HCV-associated morbidities more than 1 year?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
4. Has <u>all</u> of the following pre-treatment testing been documented: a. Genotype testing in past 3 years is required if the patient has cirrhosis, <u>any</u> prior treatment experience, and if prescribed a regimen which is not pan-genotypic; b. Baseline HCV RNA level in past 6 months; c. Current HBV status of patient d. Pregnancy test in past 30 days for a woman of child-bearing age; <u>and</u> e. History of previous HCV treatment and outcome f. Presence or absence of cirrhosis as clinically determined (e.g., clinical, laboratory, radiologic evidence, etc)? Note: Direct-acting antiviral agents can re-activate hepatitis B in some patients. Patients with history of HBV should be monitored carefully during and after treatment for flare-up of hepatitis. Prior to treatment with a DAA, all patients should be tested for HBsAG, HBsAb, and HBcAB status. HIV testing is also recommended.	**Yes:** Record results of each test and go to #5 Note: If the patient has HIV or HBV co-infection, it is highly recommended that a specialist be consulted prior to treatment. Currently treatment is not recommended during pregnancy due to lack of safety and efficacy data	**No**: Pass to RPh. Request updated testing.
5. Which regimen is requested?	Document and go to #6	
6. Does the patient have clinical, radiologic or laboratory evidence of complications of cirrhosis (ascites, portal hypertension, hepatic encephalopathy, hepatocellular carcinoma, esophageal varices)?	**Yes:** Go to #7 .	**No:** Go to #8
7. Is the regimen prescribed by, OR is the patient in the process of establishing care with or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness. Recommend prescriber document referral to a specialist prior to initiating treatment.

Approval Criteria		
8. Is there attestation that the patient and provider will comply with all case management interventions to promote the best possible outcome for the patient and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load? Case management includes assessment of treatment barriers and offer of patient support to mitigate potential barriers to regimen adherence as well as facilitation of SVR12 evaluation to assess treatment success.	**Yes**: Go to #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. Is the prescribed drug: a) Elbasvir/grazoprevir for GT 1a infection; or b) Daclatasvir + sofosbuvir for GT 3 infection?	**Yes**: Go to #10	**No:** Go to #11
10. Has the patient had a baseline NS5a resistance test that documents a resistant variant to one of the agents in #16? Note: Baseline NS5A resistance testing is required.	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #11 Document test and result.
11. Is the prescribed regimen include a NS3/4a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir)?	**Yes:** Go to #12	**No:** Go to #13
12. Does the patient have moderate-severe hepatic impairment (Child-Pugh B or Child-Pugh C)?	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #13
13. Is the prescribed regimen for the retreatment after failure of a DAA due to noncompliance or lost to follow-up?	**Yes:** Pass to RPh; Deny and refer to medical director for review	**No:** Go to #14

Approval Criteria		
14. Is the prescribed drug regimen a recommended regimen based on the patient's genotype, treatment status (retreatment or treatment naïve) and cirrhosis status (see **Table 1**)?	**Yes:** Approve for 8-16 weeks based on duration of treatment indicated for approved regimen	**No:** Pass to RPh. Deny; medical appropriateness.

Table 1: Recommended Treatment Regimens for Chronic Hepatitis C.

Treatment History	Cirrhosis Status	Recommended Regimen
Genotype 1		
DAA-Treatment naive	Non-cirrhotic	EBV/GZR x 12 weeks** SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated Cirrhosis	EBV/GZR x 12 weeks** SOF/VEL x 12 weeks G/P x 12 weeks
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 week
Treatment experienced (Prior PEG/RBV)	Non-cirrhotic	EBV/GZR x 12 weeks** SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	EBV/GRZ 12weeks** SOF/VEL x 12 weeks G/P x 12 weeks
Treatment Experienced (Prior sofosbuvir)	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 12 weeks
Treatment Experienced (Prior NS3A/4A inhibitor)	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks EBV/GZR + RBV x 12 weeks** G/P x 12 weeks
Treatment Experienced (prior NS5A-containing regimen)	Non-cirrhotic or compensated cirrhosis	G/P x 16 weeks
Genotype 2		
Naïve	Non-cirrhotic	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks G/P x 12 weeks
	Decompensated	SOF/VEL + RBV x 12 weeks
Treatment Experienced (prior PEG/RBV)	Non-cirrhotic	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks G/P x 12 weeks

Treatment Experienced (SOF + RBV)	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 12 weeks
Treatment Experienced (prior NS5A-containing regimen)	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks
Genotype 3		
Naïve	Non-cirrhotic	SOF/VEL X 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL + RBV x 12 weeks G/P x 12 weeks
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 weeks
Treatment Experienced (prior PEG/RBV only)	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 16 weeks
Treatment Experienced (SOF + RBV)	Non-cirrhotic or compensated cirrhosis	G/P x 16 weeks
Experienced (prior NS5A-containing regimen)	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks
Genotype 4		
Treatment Naïve	Non-cirrhotic	SOF/VEL x 12 weeks EBV/GZR x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks EBV/GZR x 12 weeks G/P x 12 weeks
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 week
Treatment Experienced (prior PEG/RBV only)	Non-cirrhotic	SOF/VEL x 12 weeks EBV/GZR x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks EBV/GZR x 12 weeks G/P x 12 weeks
Treatment Experienced (prior NS5A-containing regimen OR sofosbuvir)	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks
Genotype 5/6		
Treatment Naïve or Experienced (prior PEG-IFN/RBV only)	Non-cirrhotic	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks G/P x 12 weeks
	Decompensated cirrhosis	SOF/VEL + RBV x 12 weeks
Experienced (prior NS5A-containing regimen OR sofosbuvir)	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks

Abbreviations: CTP = Child-Turcotte-Pugh; DAA = direct acting antiviral; EBV/GZR = elbasvir/grazoprevir; G/P = glecaprevir and pibrentasvir; PEG = pegylated interferon; RAV = resistance-associated variant; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir; SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir **No baseline NS5A RAVs. For genotype 1a patients with baseline NAS5A RAVs, extend duration to 16 weeks. ±Evidence is insufficient if the addition of RBV may benefit subjects with GT3 and cirrhosis. If RBV is not used with regimen, then baseline RAV testing should be done prior to treatment to rule out the Y93 polymorphism.
^ Rarely, genotyping assays may indicate the presence of a mixed infection (e.g., genotypes 1a and 2). Treatment data for mixed genotypes with direct-acting antivirals are limited. However, in these cases, a pangenotypic regimen is appropriate.
Ribavirin-containing regimens are absolutely contraindicated in pregnant women and in the male partners of women who are pregnant. Documented use of two forms of birth control in patients and sex partners for whom a ribavirin containing regimen is chosen is required.
Regimens other than glecaprevir/pibrentasvir (G/P;) and elbasvir/grazoprevir (EBV/GZR) should not be used in patients with severe renal impairment (GRF < 30 mL/min) or end stage renal disease requiring dialysis.
All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C).
There is limited data supporting DAA regimens in treatment- experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director.

P&T Review: *11/18; 9/18 (MH); 1/18; 9/17; 9/16; 1/16; 5/15; 3/15; 1/15; 9/14; 1/14*
Implementation: *TBD; 1/1/2019; 3/1/2018; 1/1/2018; 2/12/16; 4/15; 1/15*

Study of Oregon's Effective Contraceptive Use Metric: how do financial incentives impact contraceptive initiation and continuation?

Maria I. Rodriguez MD MPH
rodrigma@ohsu.edu

ecu
EFFECTIVE CONTRACEPTIVE USE METRIC STUDY

Family Planning Section

Missing: Jeff Jensen & Alyssa Colwill

Clinical Leaders

- State referral center for contraception & abortion care
- Medical Director of Planned Parenthood Columbia Willamette
- Medical Director, Oregon Health Authority (TitleX)
- Collaborative Heme/Contraceptive Clinic (Spots, Dots, & Clots)
- ACOG pp LARC programming

Research Leaders

- NIH contraceptive-related network center grant
- Gates Foundation Support for Oregon Permanent Contraception Research
- WHRU to support additional independent, NIH, & Pharma supported
- Active consultancies with the WHO, CDC, & Population council
- Active research mentors for students, fellows, and junior faculty

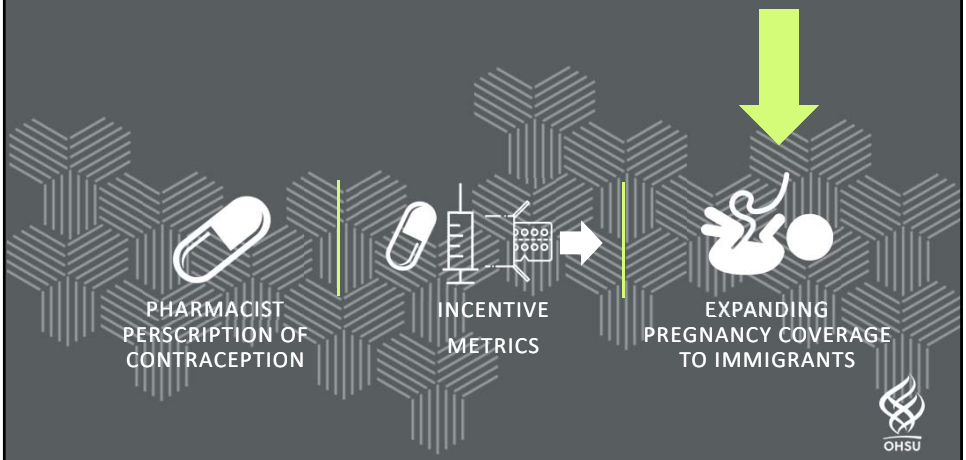
Global Health Consultants

- Research & Mentorship (to junior faculty/fellows)
- Extensive capacity-building and infrastructure experience (Asia, Africa, & LAC)
- Ongoing contracts with INST (Mexico "CDC"), WHO, Ipas, PSI.

OHSU

Three policy areas of focus

Focus on Medicaid



OHSU

Medicaid & reproductive health

- Largest payor for obstetric and contraceptive care nationally
- Sets precedent for private insurers
- Federal and state laws determine access
  - Emergency Medicaid
- Health care reform has introduced a wave of innovations

Incentive Metrics

- Financial incentives and quality metrics are increasingly common without robust evidence as to the impact they have on contraceptive use or health outcomes
- Effective Contraceptive Use metric
  - Assesses % of women at risk for pregnancy offered a Tier 1 or 2 method
  - Pool of 17 quality metrics
  - Implemented in Oregon in 2015
- Office of Population Affairs endorsed a similar national metric

Study Aims

- Describe how ECU metric was implemented in different CCOs
- Evaluate the association between a financial incentive for ECU and contraceptive initiation, continuation and unintended pregnancy rates
- Model the cost-effectiveness of different strategies for improving contraceptive use

Help needed!

- Understand CCO's approach to the ECU metric
- Requesting to interview a key informant
  - Phone or email
  - Structured questions
  - Goal is to understand what strategies were put into place to reach ECU metric
  - Identify any ECU clinicalchampions within each CCO


ecu
EFFECTIVE CONTRACEPTIVE USE METRIC STUDY
Thank You
rodrigma@ohsu.edu
OHSU

SMOKEFREE oregon

Winter Cessation Campaign

Helping CCOs reach members and providers and meet prevalence reduction metrics

Sarah Wylie, MPH
Health Promotion Strategist
January 14, 2019

Oregon Health Authority

Overview

- Campaign Purpose and Rationale
- Strategy and Reach
- Creative Elements
- Resources for CCO members and providers
  - Toolkit
  - TA
- Talking About Cessation
- Q & A

Oregon Health Authority

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Winter Cessation Campaign

- Three month statewide media campaign
  Kick-off December 31 to help people stick with New Year's quit resolutions. Continues through March 24, 2019
- Campaign Audiences
  - People who purchase and use tobacco: Quit
    - Targeted by the tobacco industry
    - Higher rates of smoking
    - Disproportionate tobacco impact
  - Health care providers: Talk to patients about quitting

Oregon Health Authority

Why a Campaign?

- **70% of people** who smoke **want to quit.** People who smoke **want their doctor to talk to them** about tobacco use.

- Studies show **two effective strategies** that help people quit smoking:
  - Media advertising
  - Hearing from one's health care provider

Oregon Health Authority

Reaching People Who Smoke

- Advertising in English and Spanish on:
  - Radio
  - Billboards
  - Online and on social media sites, search engines and other sites such as Pandora
- Ads will direct people to call 1-800-QUIT-NOW or to visit QuitNow.net/Oregon to enroll in cessation services online.

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Ads to Reach People Who Smoke

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Reaching Providers

- Digital advertising
  - Popular websites
  - Facebook
  - Instagram
  - LinkedIn
- Ads will direct providers to QuitNow.net/Oregon to access resources for their patients

Ads to Reach Providers

Toolkit and Resources for CCOs

- Tools for CCO and providers to engage members
  - Member fact sheet
  - Poster for waiting rooms and exam rooms
  - Short newsletter article and campaign ads
  - Social posts and graphics
  - Tips to help providers talk about cessation
- Tools for CCO to engage providers
  - Cover letter introducing the campaign
  - Short summary for email or newsletters
  - Ads for online and print communication

Technical Assistance

- One-hour technical assistance calls
  - Assistance on co-branding with logo and information
  - Strategies to engage your member and providers
- Online campaign ads served directly to people who visit cessation pages on your website

Questions and Discussion

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THANK YOU!

For more information:
Sarah Wylie, MPH
Health Promotion Strategist
Public Health Division – Health Promotion and Chronic Disease Prevention Section
971-673-1051
Sarah.A.Wylie@dhsoha.state.or.us

Oregon Health Authority

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SMOKEFREE oregon

2019 Winter Cessation Campaign Overview

The Oregon Health Authority's (OHA) *SmokeFree Oregon* is launching a three-month statewide media campaign on Dec. 31, 2018, to encourage people who use tobacco to quit and to encourage health care providers to talk to their patients about quitting.

We invite you to leverage this increased attention on quitting to encourage your members to quit, encourage your providers to proactively support their patients, and advance your CCO tobacco cessation metrics.

Remember, 70% of people who smoke want to quit,[1] *and* they want their doctor to talk to them about quitting. Two proven strategies to get people to quit are media advertising[2] and hearing from one's health care provider. Together, OHA and Oregon's CCOs can make a difference for people who want to quit their tobacco addiction.

The campaign launches Dec. 31, 2018, to help people stick with New Year's quit resolutions, and will continue through March 24, 2019. **This overview includes details about the campaign's messages and reach, and outlines tools available to CCOs to reach members and providers.**

CAMPAIGN OVERVIEW

The media campaign includes advertisements, in English and Spanish, to **reach people who use tobacco statewide.** Ads will appear on the radio, on billboards, and online on social media sites, search engines and other sites such as Pandora. These ads will direct people to call 1-800-QUIT-NOW or to visit QuitNow.net/Oregon to enroll in cessation services online.*

Mass-reach communication campaigns like this one are a key component of a comprehensive tobacco control program. These campaigns can reduce tobacco use, counter industry promotions, shift social norms around tobacco use, reduce health disparities and result in significant cost savings.

In addition, OHA will place digital ads (Facebook, Instagram, LinkedIn and other sites) to **reach providers**, inviting them to visit QuitNow.net/Oregon to access resources for their patients.

**When your members call the Oregon Tobacco Quitline they will be referred to your CCO's cessation resources.*

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[1] https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm

[2] [2] Media campaigns are an evidence-based strategy to help people quit. https://www.oregon.gov/oha/HPA/dsi-tc/Documents/Communications-and-Cessation.pdf

CAMPAIGN ADS

Here are the ads, shown through prior evaluations to motivate action, that you can expect to see through this campaign.

For people who smoke:

Radio ads, in English and Spanish, feature similar content.

For providers:

OPPORTUNITY TO SERVE CAMPAIGN MESSAGES DIRECTLY TO YOUR MEMBERS

We are offering you the opportunity to have **campaign ads served directly to people who visit cessation pages on your website.** Seeing these ads reinforces their desire to quit and encourages them to follow through on their commitment.

To do this, we will need you to place a pixel, or code, on your CCO's cessation page. You can do this at any time, ideally as early in the campaign as possible. For instructions, please see "Placing a Pixel on Your CCO's Cessation Page" at the end of this document. Please note that this requires no additional management from your team and will not affect the look or functionality of your webpage at all—it simply gives OHA's media agency the ability to show ads to people already visiting your site.

TECHNICAL ASSISTANCE

Toolkit
In early February, we'll share a toolkit of resources you can use as-is or customize with your CCO's logo and information. All tools will use language and images from the campaign so your communication aligns with the statewide themes. Here's what we'll provide:

To engage your members:
- Member-facing fact sheet about the options and coverage for cessation services
- Poster for waiting rooms and exam rooms
- Social media posts and graphics you can use on Facebook, Instagram and Twitter
- Short newsletter article and campaign ads
- Tips to help providers talk about cessation

To engage your providers:
- Cover letter to providers introducing the campaign and inviting them to use this opportunity to talk with their patients (to distribute with the fact sheet, poster and your own materials)
- Campaign summary for use in email or newsletters
- Campaign ads for electronic or printed communication to providers

Technical assistance calls
We are also offering one-hour consultations to help you make the most of this campaign. In these calls, we'll provide assistance on co-branding materials with your CCO's logo and information, how we can show ads to people already visiting your tobacco cessation website and strategies to engage your member and providers.

FOR MORE INFORMATION

For more information, to request that we place a pixel on your site, or to sign up for a technical assistance call, please contact:

Sarah Wylie, OHA Health Promotion Strategist
971-673-1051, Sarah.A.Wylie@dhsoha.state.or.us

Placing a Pixel on Your CCO's Cessation Page

Placing a pixel on your cessation page allows OHA to serve campaign ads directly to people searching for help to quit. This reinforces their commitment by providing encouragement and support.

This is the pixel you will use:
<!-- Advertiser Name : OHA-GRADYBRITTON -->
<!-- Beacon Name : OHA-GRADYBRITTON_OO-QUITNOW_RET -->
<img border="0" src="https://r.turn.com/r/beacon?b2=Xc9CoXP6zxR001OAHFR8_zliVA6-DsJGKgWgtCm8sxT7kS5QZNq2jMAYTCRrxGRJHdeSLId6d0ASmUhT9_oiTg&cid=">

Step 1:

Please embed the code on your cessation resource page between the <body> and </body> tag.

Step 2:

Please send the link to the site where the pixel appears to Sarah Wylie, Sarah.A.Wylie@dhsoha.state.or.us.

HERC Update

Ariel Smits, MD, MPH
Cat Livingston, MD, MPH
January 14, 2018

Recently approved topics of interest

- 2019 CPT, HCPCS, and CDT codes reviewed
- New coverage of Yttrium-90 therapy for liver cancer
- Divided up the genetic testing guideline
- Modify human donor breast milk guideline for high risk infants

- No change to
  - Noncoverage of pancreas only transplant
  - Noncoverage NIPT for average risk women

Upcoming topics of interest (VbBS)

- 2020 Biennial Review
  - Hidradenitis suppurativa
  - Sacroiliac joint dysfunction
  - Reprioritization of chronic pain conditions and opioid guideline
- New topics
  - Diabetes prevention program
  - Pulmonary rehabilitation
  - Failure to thrive
- Coverage Guidances
  - Newer Interventional procedures for GERD (Jan VbBS)
    - Transoral incisionless fundoplication (coverage with conditions)
    - Magnetic sphincter augmentation (noncoverage)
  - Temporary mechanical support with Impella Devices (Jan VbBS)

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Upcoming topics of interest (EbGS & HTAS)

Health Technology Assessment Subcommittee

2/21/2019	Extended Stay Centers Guideline (per HB 4020)
4/18/2019	Spinal Cord Stimulators for Chronic Back Pain Extended Stay Centers Guideline (review public comments)

Evidence-based Guidelines Subcommittee

2/7/2019	Planned Out of Hospital Birth (intro only) Community Health Workers
4/4/2019	Planned Out of Hospital Birth (begin evidence review) Community Health Workers (review pubic comments)

Oregon Health Authority

VbBS topics on the horizon

- Hysterectomy guidelines
- How to allow ophtho visits/screening tests for patients on high risk medications
- Lymphedema
  - Non-LANA therapist certification
  - Pneumatic compression devices
- Noninvasive testing for liver fibrosis

Others

- Topic nomination for Coverage Guidances OPEN NOW through 1/28 https://www.surveymonkey.com/r/KRBBZQG
- Your HERC concerns

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on November 8, 2018

For specific coding recommendations and guideline wording, please see the text of the 11/8/2018 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 1/1/2019 unless otherwise noted)

- Add the diagnosis codes used for latent tuberculosis infection to a covered line
- Add the procedure code for Yttrium-90 therapy to the covered liver cancer line with a new guideline
- Add the procedure codes for amniotic membrane transplant for eye conditions to three covered lines and removed from 3 other covered lines
- Add the 2019 CPT codes to various covered and uncovered lines on the Prioritized List with guideline note changes as needed to accommodate these codes
- Add the 2019 HCPCS codes to various covered and uncovered lines on the Prioritized List with changes to guidelines as required by placements
- Add the 2019 CDT codes to various covered and uncovered lines on the Prioritized List
- Add the procedure code for the iStent glaucoma surgery to a covered line with a new guideline

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- No change was made to the non-coverage of pancreas only transplant
- No change was made to the non-coverage of non-invasive prenatal screening for average risk women

RECOMMENDED GUIDELINE CHANGES (effective 1/1/2019 unless otherwise noted)

- Modify the non-prenatal genetic testing guideline, and remove the hereditary cancer testing section to make into its own guideline
- Modify the prenatal genetic testing guideline
- Modify the guideline on human donor breast milk for high-risk infants

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
November 8, 2018
8:30 AM – 1:30 PM

Members Present: Kevin Olson, MD, Chair; Susan Williams, MD (via phone); Mark Gibson; Holly Jo Hodges, MD; Vern Saboe, DC (via phone, left at 12:30); Gary Allen, DMD; Adriane Irwin, PharmD (via phone at 10:15, left at 1:30).

Members Absent: none

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

Also Attending: K. Renae Wentz, MD (Oregon Health Authority); Kevin Sasadeusz, MD (Providence interventional radiology); Ken Kolbech, MD (OHSU interventional radiology); Pippa Newell, MD (Providence hepatobiliary surgery, via phone); Devki Saraiya and Karen Heller (Myriad); Alice Austin (OR Assoc. of Behavior Analysis); Katy McDowell (Tonkin Torp).

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

  The meeting was called to order at 8:30 am and roll was called. Minutes from the October 2018 VbBS meeting were reviewed and approved with the addition of a guideline note entry for CardioMEMS to guideline note 173 in the appendix of the minutes. **Approved 6-0, Irwin absent.**

  Smits reviewed the two errata items. There was no discussion. Smits noted that the fusion for sacroiliac joint dysfunction discussion was tabled until January to allow the Washington HTA group to complete their evidence review.

  Coffman noted that this was Williams last meeting, and she was thanked for her excellent service to the VbBS and HERC.

- **Topic: Straightforward/Consent Agenda**

  Discussion: There was no discussion about the consent agenda item. The diabetes prevention program topic was discussed with the HCPCS code discussion later in the meeting (see topic below).

  Recommended Actions:
  1) Add ICD10 R76.11 (Nonspecific reaction to tuberculin skin test without active tuberculosis) and R76.12 (Nonspecific reaction to cell mediated immunity measurement of gamma interferon antigen response without active tuberculosis) to line 50 PULMONARY TUBERCULOSIS

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

- **Topic: Yttrium 90 therapy for limited circumstances in hepatocellular carcinoma (HCC)**

  Discussion: Smits reviewed the summary document and the staff proposed changes.

  Expert testimony was heard from Kevin Sasadeusz, MD (Providence interventional radiology); Ken Kolbech, MD (OHSU interventional radiology); and Pippa Newell, MD (Providence hepatobiliary surgery, via phone).

  Sasadeusz critiqued the SARAH trial. He noted that that trial used a different form of Y90 than what is used in the US. Another critique of the SARAH study was that the patient selection not what the OHSU and Providence oncology groups consider appropriate (for example, some had main portal vein thrombosis, which is a contraindication). Additionally, many patients had already had locoregional therapy and so this selected patients who were radiation resistant. Physicians in SARAH trial may also not have been experienced in use of Y90. Newell noted that a large percent of patients in SARAH did not receive the treatment they were randomized to receive. Kolbech noted that this trial, like many other Y90 trials, was industry driven.

  Sasadeusz stated that in using Y90 at Providence, patients are reviewed by a multidisciplinary group to see if they are appropriate for Y90. The Providence group does the best to try to keep cost down for Y90. Kolbech showed the OHSU HCC treatment algorithm, which is very similar to the algorithm from Providence in the meeting materials.

  There was a question about whether main portal vein thrombosis was different that unilateral portal vein thrombosis. It was explained that unilateral portal vein thrombosis involves only one branch of the portal vein and is not a contraindication to Y90, while main portal vein thrombosis is a contraindication. The VbBS group decided to add wording to the proposed guideline to clarify this distinction.

  It was noted that liver transplant for liver cancer is on line 560 CANCER OF LIVER AND INTRAHEPATIC BILE DUCTS. Based on this, the VbBS group discussed taking out #1 as criteria in the proposed guideline (use of Y90 to keep a patient on the transplant list). It was further noted that cirrhosis is covered on line 307 for liver transplant, so most patients with HCC would be eligible for liver transplant as they also have cirrhosis. Newell requested consideration for reprioritization of line 560, which will be done as a possible future biennial review topic. She noted that such a review

should wait until January 2019, as new guidelines are coming out for liver transplant recommendations in HCC.

Discussion then turned to the second proposed criteria (downsizing of patients who would be eligible for definitive treatment including liver transplant). Newell stated that the more common curative treatment offered to patients is ablation. Patients need to have their tumor downsized to less than 3 cm to be eligible for ablation or resection. Kolbech noted that OHSU is the only liver transplant provider in Oregon. It is a long, complex process to get on the liver transplant list. He did not advise keeping proposed criteria #1 (see above); but he felt proposed criteria #2 should be kept.

There was discussion that >90% of patients in Oregon are treated with Y90 by OHSU or Providence. Gibson asked if there was a registry of these patients to follow outcomes. Newell noted that a large, multicenter registry trial was currently underway. Kolbech noted that OHSU has a database for all their Y90 patients and uses the data for internal quality review. There was discussion about whether low volume providers should be allowed to use Y90. The experts felt that it was appropriate if done on the recommendation of a multidisciplinary team. VbBS members decided to add wording requiring that patients need an evaluation by a multidisciplinary team or tumor board prior to coverage of Y90 therapy. Kolbech noted that non-OHSU/Providence providers can submit patients to the OHSU tumor board for reviewed if desired.

Recommended Actions:

1) Remove CPT 79440 (Radiopharmaceutical therapy, by intra-articular administration) from all current lines except
    a. 201 CANCER OF BONES
    b. 400 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS
    c. 556 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE
2) Add Yttrium 90 therapy to line 315 CANCER OF LIVER
    a. CPT 79445 (Radiopharmaceutical therapy, by intra-arterial particulate administration for use in treating primary hepatocellular carcinoma or colorectal cancer metastatic to the liver)
    b. HCPCS C2616 (Brachytherapy source, non-stranded, yttrium-90, per source, for use in treating primary liver cancer or metastatic cancer to the liver)
    c. HCPCS S2095 (Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres, for use in treating primary liver cancer or metastatic cancer to the liver)
3) Remove the entry regarding Yttrium 90 from line 500/GN172 as shown in Appendix A
4) Add a new guideline to line 315 CANCER OF LIVER as shown in Appendix B

MOTION: To recommend the code and guideline note changes as modified. CARRIES 6-0. *(Absent: Irwin)*

- **Topic: Pancreas only transplant**

Discussion: Livingston reviewed the summary document. Coffman highlighted that the question was about transplanting the pancreas earlier rather than waiting until renal failure had occurred. Members discussed that pancreas transplant is a major surgery and the study showing increased risk

of renal failure associated with pancreas transplant alone is concerning. Members discussed that there was insufficient evidence to support benefit and there are significant harms. Olson said if pancreas transplant was a home run then it may be worth it, but the evidence does not show pancreas transplant alone is effective. Allen asked about Medicare coverage for pancreas transplant alone. Livingston said it was covered but clarified that there was insufficient evidence supporting improved outcomes for the patients identified in those coverage guidelines.

Recommended Actions:

1) Make no change to the noncoverage of pancreas transplant alone

- **Topic: Amniotic membrane transplant for ocular conditions**

Discussion: Smits reviewed the summary document. There was no discussion.

Recommended Actions:

1) Remove ocular amniotic membrane transplant CPT codes [65778 (Placement of amniotic membrane on the ocular surface; without sutures), 65779 (Placement of amniotic membrane on the ocular surface; single layer, sutured), 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers)] from the following lines:
    a. 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE
    b. 159 TOXIC EPIDERMAL NECROLYSIS AND STAPHYLOCOCCAL SCALDED SKIN SYNDROME; STEVENS-JOHNSON SYNDROME; ERYTHEMA MULTIFORME MAJOR; ECZEMA HERPETICUM
    c. 213 BULLOUS DERMATOSES OF THE SKIN
2) Add ocular amniotic membrane transplant CPT codes (same as above) to the following lines:
    a. 113 CANCER OF EYE AND ORBIT
    b. 470 KERATOCONJUNCTIVITIS
    c. 493 ECTROPION AND BENIGN NEOPLASM OF EYE

MOTION: To recommend the code changes as presented. CARRIES 6-0. *(Absent: Irwin)*

- **Topic: 2019 CPT code review**

Discussion: Smits reviewed the multiple summary documents and spreadsheets comprising the 2019 CPT code review. There was no discussion regarding the proposed placements of the straightforward, applied behavior analysis (ABA), or psychology testing codes.

There was specific discussion about the following CPT codes:

1) 76391 (Magnetic resonance (eg, vibration) elastography)
    a. Wentz suggested adding this code to line 500 with exception criteria rather than to line 199 CHRONIC HEPATITIS; VIRAL HEPATITIS as it is less cost effective than non-MR elastography. Hodges felt that it was better to follow the staff recommendation and place on line 199 and allow the CCOs to PA the test. Gingerich noted that MR elastography was added to the hepatitis C guideline for obese patients and other patients for whom the more cost-effective tests to not work, a decision that was based on expert testimony. The decision was to add to line 199. It was noted that the hepatitis C guideline would need revisions if the MR elastography code was added to line 500.

Alice Austin, Public Policy Chair of the Oregon Association of Behavior Analysis, testified in favor of the ABA code placements.

There was a question about whether the coverage guidance on molecular biomarkers should be updated based on the decisions regarding the new oncology CPT codes. Olson felt that things were moving to panels of genes for oncology. There is also the question about covering the genetic test or

the medications for treatment of a cancer found to have a genetic mutation not initially studied for that cancer. Gingerich noted that next generation sequencing has been tabled by HTAS as a topic.

Recommended Actions:
1) The 2019 CPT codes were placed as shown in Appendix C
2) Various guidelines were modified as shown in Appendix A

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

- **Topic: 2019 HCPCS code review**

Discussion: Smits reviewed the summary documents. There was no substantial discussion of any of the HCPCS code placement at the VBBS meeting.

Note: The placement of HCPCS G0069 (Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes) was changed at the subsequent HERC meeting on November 8, 2018. The revised placement is shown in Appendix D with the revision required to Guideline Note 173 shown in Appendix A. The VBBS decision was to recommend placement on lines 9,124,223,313,531,550,559, 566. The revised decision was to place on line 660 due to a recent MED report showing that evidence did not support home administration of immunotherapy because of concerns for anaphylaxis. HERC staff was directed to obtain the MED report and bring to the January meeting if the staff recommendation would be placement other than on line 660. See the HERC minutes for details.

Recommended Actions:
1) 2019 HCPCS code placement as shown in Appendix D
2) Guideline 173 entries as shown in Appendix A

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

- **Topic: Oral Health Advisory Panel report**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:
1) The 2019 CDT codes were placed as shown in Appendix E

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

- **Topic: Genetic Advisory Panel (GAP) report – 2019 CPT code placement**

  Discussion: Smits reviewed the various summary documents comprising the GAP report. There was no discussion regarding the recommended placement of the 2019 genetic CPT codes other than CPT 81443.

  CPT 81443 (expanded carrier screening was discussed in detail. Hodges was concerned about coverage for partners. The partner only needs to be tested for the few genes mom is positive for. Smits noted that a few gene tests may be more expensive than the panel, so just testing the few genes found in mom's test might be more expensive.

  There was general concern about how to interpret the results. The VBBS members felt that the interpretation would be difficult for most maternity care providers, and that patients should have genetic counseling with this test, which is a limited resource. There was discussion about unintended harm of too much genetic information being given to patients with an unclear idea of how to deal with this information. There was concern over interventions that might be done that might not be needed, or additional testing done that might not be needed. Medicaid is a vulnerable population and needs protections in place.

  There was also concern about how to control the quality of what genes are in the panel, to ensure that all include genes are recommended by ACOG guidelines.

  There was discussion that if VBBS/HERC chose not to cover panel testing, then CCOs could still cover it if they chose to do so. There was also discussion that if VBBS/HERC adopted coverage, that providers would not have to order the test if they did not feel comfortable interpreting the results.

  Public testimony:
  Devki Saraiya, Myriad Labs, testified that current OHP coverage for carrier screening is by ethnicity-based screening. Ethnicity-based screening finds only 53% of patients at risk for having a child with a condition vs expanded carrier screening approaches. ACOG has guidelines on when tests are included, and labs offering this type of test are following ACOG guidelines. Ethnicity screening is difficult to determine when appropriate for a patient. Labs offer genetic counseling to help to determine when a partner needs to be tested. Variants of uncertain significant are not reported by Myriad in the carrier screening testing. CPT is specific for carrier screening, so if mom is not affected but is a carrier, then the partner then needs to be tested; if he is a carrier, then pregnancy has a 25% chance of being affected. This is about pregnancy/preconception decision making. This type of testing might lead to need for prenatal diagnostic testing. Myriad tries to make genetic counseling available to patients and/or providers to help with interpretation. Wentz: "How does the provider know what information was given to the patient by Myriad?" Surai: "We try to send documentation to the provider when the patient allows us to do so."

  Olson noted that providers included in the current guideline know how to counsel folks and so are more comfortable with these tests. Hodges noted that this type of testing involved a long sequence: test mom, then need to test dad, then possibly test pregnancy. This sequence takes time, requires follow up. She expressed concern for timing of such testing during pregnancy (late gestation testing has few options for treatment). Hodges was also concerned about adequate shared decision making without genetic counseling. Smits asked whether this concern could be addressed with an entry in the prenatal genetic testing guideline about requiring genetic counseling.

Saraiya noted that OHP is already doing cystic fibrosis and spinal muscular atrophy testing for everyone. This expended carrier testing adds more autosomal recessive genes that typically don't have a family history. She reported that there is a study on clinical utility showing that 37% of couples who tested positive for both being carriers went on to have prenatal diagnostic testing such as amniocentesis. Therefore, this information is being used for pregnancy decisions.

Hodges noted that her CCO initially had a large demand from providers for expanded carrier screening, but that she found no push back from providers once she explained the lack of coverage for such a test by her CCO. She noted the initial push back came from providers that are being told that this is standard of care.

Gibson noted that ACOG is not evidence-based much of the time. There was discussion that expanded carrier screening was not appropriate to be ordered for every pregnancy. The group struggled with how to put reasonable guidance on who should get this test. There was discussion of not covering expanded carrier screening until the OB community brings this to HERC with a request for coverage and explains who really needs the testing and what to do with the data. Irwin wanted to hear from providers who order this test. It was noted that Dr. Adler, an OB/Gyn, would be at the later HERC meeting and could give input.

The decision on expanded carrier screening was to put the CPT code on line 660 with a GN173 entry and leave prenatal guideline entries expressly stating this test is not covered. The HERC should revisit expanded carrier screening in the future to see if this testing should be covered with GN changes if brought forward by OB/maternity care community.

Recommended Actions:
1) The 2019 genetics CPT codes were placed as shown in Appendix C
2) GN173 was modified as shown in Appendix A

MOTION: To recommend the code and guideline note changes as modified. CARRIES 6-0. *(Absent: Saboe)*

- **Topic: Genetic Advisory Panel (GAP) report – Changes to the non-prenatal genetic testing guideline**

Discussion: Smits reviewed the various summary documents comprising the GAP report. There was minimal discussion about the changes to the non-prenatal genetic testing guideline, apart from clarification that the hereditary cancer testing section was being removed in order to create a separate guideline note.

The proposed new hereditary cancer guideline note focused on the suggested removal of the definition of "suitably trained" providers doing genetic counseling. Hodges noted that the CCO medical directors were opposed to this change. The medical directors felt that there was a need to define who was adequately trained. A provider who does not have the outlined qualifications but convinces a medical director that they are indeed adequately trained can be allowed to do genetic counseling at a CCO's discretion.

Public testimony was heard from Karen Haller from Myriad Genetics. She discussed that the issue of access to genetic counseling is real and is discussed at GAP every year. There is a lack of providers in Oregon and in the US in general. NCCN delineates criteria for testing in these hereditary cases. NCCN and USPSTF do not state that genetic counselors need to see every patient, and list other types of providers equipped to give this type of counseling. This information is being used more and more frequently in care—screening changes, treatment changes, etc. Providers cannot adequately manage patients without this information. Multiple specialty societies have stated that this type of counseling is within the scope of their specialty.

Hodges noted that this section of the new hereditary cancer guideline is about elective testing of asymptomatic patients. Such testing is not time sensitive and can wait for genetic counseling. Olson also expressed concern that variants of uncertain significance is important factor in this situation.

The decision was made to not delete the definition of "suitably trained."

The next discussion centered on the proposed change regarding wording for panel testing for hereditary cancers. The group wanted only NCCN guidelines mentioned (not "or other expert" guidelines).

Recommended Actions:

1) Modifications to the non-prenatal genetic testing guideline as shown in Appendix A
2) Creation of a new hereditary cancer testing guideline as shown in Appendix B
    a. *Note: strikethrough and underlined language in the new guideline note reflects modifications from the wording as it originally appeared in the non-prenatal genetic testing guideline.*

MOTION: To recommend the guideline note changes as modified. CARRIES 6-0. *(Absent: Saboe)*

- **Topic: Genetic Advisory Panel (GAP) report – Changes to the prenatal genetic testing guideline**

Discussion: Smits reviewed the various summary documents comprising the GAP report. There was minimal discussion of the proposed changes to the prenatal genetic testing guideline other than non-invasive prenatal screening.

Non-invasive prenatal screening (NIPS) discussion:
Devki Sariaya, Myriad, testified that all guidelines say that using NIPS in the general population is appropriate, including ACOG. BCBS TEC report was redone in 2018 and found sufficient evidence that NIPS used in a general risk population improved health outcomes. She noted that any screening test performs less well in low-risk population because prevalence of the conditions being screened for are lower in this population. NIPS provides a 100-fold lower false positive rate, reduces rates of amniocentesis or CVS and avoids the cost and complications of these procedures. Evidence supports that it is a superior test to serum tests. Requested that coverage be extended to average risk population.

The VBBS members felt that NIPS should be reserved for high--risk women. If ACOG comes out with a guideline expressly recommending this test for all--risk women, then this coverage can be revisited.

Recommended Actions:

1) Modify the prenatal genetic testing guideline as shown in Appendix A
2) Make no changes to the lack of coverage for low--risk women for non-invasive prenatal screening

MOTION: To recommend the guideline note changes as modified. CARRIES 5-0. *(Absent: Saboe, Irwin)*

- **Topic: iStent and cataract removal**

Discussion: Smits reviewed the summary document. There was no discussion.

Recommended Actions:

3) Add CPT 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork) to line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
4) Add a new guideline note to line 139 as shown in Appendix B

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0. *(Absent: Saboe, Irwin)*

- **Topic: Human donor breast milk indications**

Discussion: Livingston reviewed the summary document and highlighted limitations of the evidence. Wentz discussed that recurrent necrotizing enterocolitis can occur and so ongoing donor breast milk is important, although this may be primarily in hospitalized infants. Livingston clarified that this guideline only applies to infants who have been discharged from the hospital and spoke about the rationale for the modified language which would require ongoing medical need for human donor breast milk.

Recommended Actions:

1) Revise the Guideline Note on Human Donor Breast Milk for High Risk Infants as shown in Appendix A.
2) Delay implementation until October 1, 2019 because a State Plan Amendment (SPA) is necessary. *[Note: After further review, staff found a SPA is not necessary and implementation can occur 1/1/19.]*

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0. *(Absent: Saboe, Irwin)*

- **Public Comment:**

No additional public comment was received.

- **Issues for next meeting:**
    - HERC staff will obtain the MED report on home immunotherapy administration for the VBBS/HERC information

- **Next meeting:**

  January 17, 2019, at a location TBD.

- **Adjournment:**

  The meeting adjourned at 1:50 PM.

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

A) Genetic tests are covered as diagnostic, unless they are listed below in section ~~F~~E1 as excluded or have other restrictions listed in this guideline. To be covered, initial screening (e.g. physical exam, medical history, family history, laboratory studies, imaging studies) must indicate that the chance of genetic abnormality is > 10% and results would do at least one of the following:
   1) Change treatment,
   2) Change health monitoring,
   3) Provide prognosis, or
   4) Provide information needed for genetic counseling for patient; or patient's parents, siblings, or children

B) Pretest and posttest genetic counseling is required for presymptomatic and predisposition genetic testing. Pretest and posttest genetic evaluation (which includes genetic counseling) is covered when provided by a suitable trained health professional with expertise and experience in genetics.
   1) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.

C) A more expensive genetic test (generally one with a wider scope or more detailed testing) is not covered if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context.

~~D) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history.~~
   ~~1) Services are provided according to the Comprehensive Cancer Network Guidelines.~~
      ~~a) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) V3.2017 (10/10/17). www.nccn.org.~~
      ~~b) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81211-81217 81212, 81215-81217) for women without a personal history of breast, ovarian and other associated cancers should be provided to high risk women as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and ovarian. V2.2019 (7/30/18) V1.2018 (10/3/17). www.nccn.org.~~
      ~~c) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81211-81217 81212, 81215-81217)) for women with a personal history of breast, ovarian, and other associated cancers and for men with breast cancer should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V2.2019 (7/30/18) V1.2018 (10/3/17). www.nccn.org.~~
      ~~d) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Colorectal Screening. V1.2018 (7/12/18) V3.2017 (10/10/17). www.nccn.org.~~

2) ~~Genetic counseling should precede genetic testing for hereditary cancer whenever possible.~~
   a) ~~Pre and post-test genetic counseling should be covered when provided by a suitable trained health professional with expertise and experience in cancer genetics. Genetic counseling is recommended for cancer survivors when test results would affect cancer screening.~~
      i) ~~"Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.~~
   b) ~~If timely pre-test genetic counseling is not possible for time-sensitive cases, appropriate genetic testing accompanied by pre- and post- test informed consent and post-test disclosure performed by a board-certified physician with experience in cancer genetics should be covered.~~
      i) ~~Post-test genetic counseling should be performed as soon as is practical.~~
3) ~~If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT 81211 81163) analyses is not. There is one exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).~~
4) ~~Costs for rush genetic testing for hereditary breast/ovarian and colon/endometrial cancer is not covered.~~
5) ~~Hereditary breast cancer-related disorders genomic sequence analysis panels (CPT 81432, 81433, 81479) are only included if the panel test~~
   a) ~~Includes at least 5 genes that the NCCN Clinical Practice Guidelines in Oncology - Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) V3.2017 (10/10/17). and/or NCCN Clinical Practice Guidelines in Oncology – Genetic/Familial High-Risk Assessment: Breast and Ovarian V2.2019 (7/30/18) V1.2018 (10/3/17) include(s) with specific guidance on clinical management; and,~~
   b) ~~Includes no more than a reasonable number of genes (e.g. 40 genes total).~~

D) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
   1) CPT 81228, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
   2) CPT 81229, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities; plus cytogenetic constitutional microarray analysis for single nucleotide polymorphism (SNP) variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to

diagnose Autism Spectrum Disorder; only if (a) consanguinity and recessive disease is suspected, or (b) uniparental disomy is suspected, or (c) another mechanism is suspected that is not detected by the copy number variant test alone.

3) CPT 81243, 81244, 81171, 81172, Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
4) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.

E) Related to other tests with specific CPT codes:
1) Certain genetic tests have not been found to have proven clinical benefit. These tests are listed in Guideline Note 173, INTERVENTIONS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN INTERVENTIONS
2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
b) Diagnostic testing for cystic fibrosis (CF)
i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
c) Carrier testing for cystic fibrosis
i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered once in a lifetime.
d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.
e) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

f) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

g) CPT 81247. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-) should only be covered
   i) After G6PD enzyme activity testing is done and found to be normal; AND either
      (a) There is an urgent clinical reason to know if a deficiency is present, e.g. in a case of acute hemolysis; OR
      (b) In situations where the enzyme activity could be unreliable, e.g. female carrier with extreme Lyonization.

h) CPT 81248. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s) is only covered when the information is required for genetic counseling.

i) CPT 81249. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; full gene sequence is only covered
   i) after G6PD enzyme activity has been tested, and
   ii) the requirements under CPT 81247 above have been met, and
   iii) common variants (CPT 81247) have been tested for and not found.

j) CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.

k) CPT 81221, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the anpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.

l) CPT 81329, Screening for spinal muscular atrophy: is covered once in a lifetime for preconception testing or testing of the male partner of a pregnant female carrier

m) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test

n) CPT 81430-81431, Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.

o) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.

p) CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.

* American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories. 2008 Edition, Revised ~~3/2011~~ 7/2018 and found at ~~https://www.acmg.net/StaticContent/SGs/CFTR%20Mutation%20Testing.pdf.~~ http://www.acmg.net/PDFLibrary/Cystic-Fibrosis-Population-Based-Carrier-Screening-Standards.pdf

DIAGNOSTIC GUIDELINE D2, IMPLANTABLE CARDIAC LOOP RECORDERS/SUBCUTANEOUS CARDIAC RHYTHM MONITORS

Use of an implantable cardiac loop recorder (ICLR)/subcutaneous cardiac rhythm monitor is a covered service only when the patient meets all of the following criteria:

1) The evaluation is for recurrent transient loss of consciousness (TLoC); and
2) A comprehensive evaluation including 30 days of noninvasive ambulatory cardiac monitoring did not demonstrate a cause of the TLoC; and
3) A cardiac arrhythmia is suspected to be the cause of the TLoC; and
4) There is a likely recurrence of the TLoC within the battery longevity of the device.

ICLRs and subcutaneous cardiac rhythm monitors are not a covered service for evaluation of cryptogenic stroke or any other indication.

DIAGNOSTIC GUIDELINE D6, BREAST CANCER SCREENING IN ABOVE-AVERAGE RISK WOMEN

Annual screening mammography and annual screening MRI without computer-aided detection (CAD) are covered only for women at above-average risk of breast cancer. This coverage, beginning at 30 years of age, includes women who have one or more of the following:

- Greater than 20% lifetime risk of breast cancer
- BRCA1 or BRCA2 gene mutation, or who have not been tested for BRCA but have a first-degree relative who is a BRCA carrier
- A personal history or a first-degree relative diagnosed with Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, or Li-Fraumeni syndrome
- Other germline gene mutations known to confer a greater than 20% lifetime risk of breast cancer

For women with a history of high dose chest radiation (≥ 20 Gray) before the age of 30, annual screening MRI without computer-aided detection (CAD) and annual screening mammography are covered beginning 8 years after radiation exposure or at age 25, whichever is later.

For women with both a personal history and a family history of breast cancer, annual mammography, annual breast MRI without computer-aided detection (CAD) and annual breast ultrasound are covered.

For women with increased breast density, supplemental screening with breast ultrasound, MRI, or digital breast tomosynthesis is not covered.

Breast PET-CT scanning and breast-specific gamma imaging are not covered for breast cancer screening.

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

The following types of prenatal genetic testing and genetic counseling are covered for pregnant women

A) Genetic counseling (CPT 96040, HPCPS S0265) for high risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
C) Validated questionnaire to assess genetic risk in all pregnant women
D) Screening high risk ethnic groups for hemoglobinopathies (CPT 83020, 83021)
E) Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency] (CPT 76813, 76814, 81508-81511, 81512, 82105, 82677)
F) Cell free fetal DNA testing (CPT 81420, 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).
G) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
H) CVS or amniocentesis (CPT 59000, 59015, 76945, 76946, 82106, 88235, 88261-88264, 88267, 88269, 88280, 88283, 88285, 88289, 88291) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
I) Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in #8 above.
J) FISH testing (CPT 88271, 88272, 88274, 88275) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
K) Screening for Tay-Sachs carrier status (CPT 81255) in high risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A
L) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
M) Screening for fragile X status (CPT 81243, 81244, 81171, 81172) in patients with a personal or family history of
    a. fragile X tremor/ataxia syndrome
    b. premature ovarian failure
    c. unexplained early onset intellectual disability
    d. fragile X intellectual disability
    e. unexplained autism through the pregnant woman's maternal line
N) Screening for spinal muscular atrophy (CPT ~~81401~~ 81329) once in a lifetime
O) Screening those with Ashkenazi Jewish heritage for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255). Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
P) Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

A) Serum triple screen
B) Screening for thrombophilia in the general population or for recurrent pregnancy loss
C) Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

GUIDELINE NOTE 76, DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE TREATMENT OF HEPATITIS C IN NON-CIRRHOTIC PATIENTS

Line 199

Given that a fibrosis score of ≥F2 is the threshold for antiviral treatment of Hepatitis C, the following are included on this line:

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

Blood tests (only if imaging tests are unavailable):
- Enhanced Liver Fibrosis (ELF™)
- Fibrometer™
- FIBROSpect® II
- FibroSure® (FibroTest®) or ActiTest®

If a fibrosis score of ≥F3 is the threshold for antiviral treatment of Hepatitis C, one or more of the following are included on this line:

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

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

The following tests are not included on this line (or any other line):
- Real time tissue elastography
- Hepascore (FibroScore)

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

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

Lines 157,184,191,230,263,271,329

The use of tissue of origin testing (e.g. CPT 81504) is included on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For early stage breast cancer, the following breast cancer genome profile tests are included on Line 191 when the listed criteria are met. One test per primary breast cancer is covered when the patient is willing to use the test results in a shared decision-making process regarding adjuvant chemotherapy. Lymph nodes with micrometastases less than 2 mm in size are considered node negative.

- Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.
- EndoPredict (using CPT 81599) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.
- MammaPrint (using CPT 81521 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

EndoPredict, Prosigna, and MammaPrint are not included on Line 191 for early stage breast cancer with involved axillary lymph nodes. Oncotype DX Breast Recurrence Score is not included on Line 191 for breast cancer involving four or more axillary lymph nodes or more extensive metastatic disease.

Oncotype DX Breast DCIS Score (CPT 81479) and Breast Cancer Index (CPT 81518 ~~may use CPT 81479, 81599, 84999, S3854~~) are included on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For melanoma, BRAF gene mutation testing (CPT 81210) is included on Line 230.

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on Line 263 only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on this line.

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on Line 157. BRAF (CPT 81210) and Oncotype DX are not included on this line. Microsatellite instability (MSI) is included on the Line 660.

For bladder cancer, Urovysion testing is included on Line 660.

For prostate cancer, Oncotype DX Genomic Prostate Score, Prolaris Score Assay, and Decipher Prostate RP are included on Line 660.

The development of this guideline note was informed by a HERC coverage guidance on Biomarkers Tests of Cancer Tissue for Prognosis and Potential Response to Treatment; the prostate-related portion of that

coverage guidance was superseded by a Coverage Guidance on Gene Expression Profiling for Prostate Cancer. See https://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

GUIDELINE NOTE 172, INTERVENTIONS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

Line 500

The following interventions are prioritized on Line 500 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

~~79445~~ ~~C2616~~ ~~S2095~~	~~Radiopharmaceutical therapy, by intra-arterial particulate administration for use in treating primary hepatocellular carcinoma or colorectal cancer metastatic to the liver~~ ~~Brachytherapy source, non-stranded, yttrium-90, per source, for use in treating primary liver cancer or metastatic cancer to the liver~~ ~~Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres, for use in treating primary liver cancer or metastatic cancer to the liver~~	~~Low cost-effectiveness compared to equally effective but less expensive standard chemotherapies; concern for possible harms compared to standard chemotherapy~~	~~May, 2018~~

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 660

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
C8937	Computer aided detection of breast MRI	Insufficient evidence of effectiveness	November, 2018

C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy	Insufficient evidence of effectiveness	November, 2018
C9754 C9755	Percutaneous arteriovenous fistula formation	Insufficient evidence of benefit	November, 2018
G0069	Subcutaneous immunotherapy in the home	Insufficient evidence of effectiveness; evidence of harm	November, 2018
33274 33275	Leadless cardiac pacemakers	Insufficient evidence of effectiveness; evidence of harm	November, 2018
33289, 93264 C2624, C9741	CardioMEMS™ – Implantable wireless pulmonary artery pressure monitor for heart failure monitoring	Insufficient evidence of effectiveness	October, 2018 Coverage guidance
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor	Insufficient evidence of effectiveness	November, 2018
64635-64636 C9752 C9753	Radiofrequency ablation of the lumbar and sacral spine	Insufficient evidence of benefit	November, 2014 Coverage Guidance Blog
76978 76979	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac)	Insufficient evidence of effectiveness	November, 2018
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)	Insufficient evidence of effectiveness	November, 2018
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis	Insufficient evidence of effectiveness	November, 2018
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)	Insufficient evidence of effectiveness	November, 2018
81345	TERT (telomerase reverse transcriptase) (eg, thyroid	Insufficient evidence of effectiveness	November, 2018

	carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)		
81443	Expanded carrier screening	Insufficient evidence of effectiveness	November, 2018
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy	Insufficient evidence of effectiveness	November, 2018 Coverage Guidance May, 2018
Breast Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999, S3854)	• Mammostrat • Oncotype DX Breast DCIS Score ~~• Breast Cancer Index~~ • IHC4	Unproven intervention	May 2018 Coverage Guidance Blog
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	Insufficient evidence of effectiveness	November, 2018
96116 96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities)		November, 2018

GUIDELINE NOTE XXX HUMAN DONOR BREAST MILK FOR HIGH RISK INFANTS

Line ~~2,~~ 16, ~~18,~~ 34, 88, 101

Donor breast milk (T2101) is included on these lines for infants up to 6 months of age (adjusted for gestational age) who meet all of the following criteria:

- Low birth weight (<1500g) OR with severe underlying gastrointestinal disease

- Human donor milk was continued through neonatal hospital discharge for a clear medical indication
- Persistent outpatient medical need for human donor breast milk due to ongoing severe concerns with persistent diarrhea or malabsorption with improvement on breast milk compared to formula
- When maternal breast milk is not available, appropriate or sufficient to meet the infant's needs, despite lactation support for the mother.

Donor human milk may only be obtained through a milk bank with appropriate quality and infection control standards.

GUIDELINE NOTE 184 ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE INSERTION

Line 139

Anterior segment aqueous drainage device (e.g. iStent©) insertion is only included on this line when done at the same time as cataract removal and when the two procedures are billed together as a bundled service.

GUIDELINE NOTE ~~XXX~~185, YTTRIUM 90 THERAPY

Line 315

Yttrium 90 therapy is only included on this line for treatment of hepatocellular carcinoma (HCC) and only when recommended by a multidisciplinary tumor board or team in the following circumstances:

1) Downsizing tumors in patients who could become eligible for curative treatment (transplant, ablation, or resection), OR
2) Palliative treatment of incurable patients with unresectable or inoperable tumors that are not amenable to ablation therapy and
    a. who have good liver function (Child-Pugh class A or B) and
    b. good performance status (ECOG performance status 0-2), and
    c. who have intermediate stage disease with tumors > 5 cm OR advanced stage HCC with unilateral (not main) portal vein tumor thrombus.

~~**GUIDELINE NOTE XXX ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE INSERTION**~~

~~*Line 139*~~

~~Anterior segment aqueous drainage device (e.g. iStent©) insertion is only included on this line when done at the same time as cataract removal and when the two procedures are billed together as a bundled service.~~

Note: strikethrough and underlined language for new diagnostic guideline D25 reflects modifications from the wording as it originally appeared in the non-prenatal genetic testing guideline

DIAGNOSTIC GUIDELINE ~~DX~~D25, HEREDITARY CANCER GENETIC TESTING

A) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history.
    1) Services are provided according to the Comprehensive Cancer Network Guidelines.
        a) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) ~~V3.2017 (10/10/17)~~. www.nccn.org.
        b) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, ~~81211-81217~~ 81212, 81215-81217) for ~~women~~ patients without a personal history of breast, ovarian and other associated cancers should be provided to high risk ~~women~~ patients as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and ovarian. V2.2019 (7/30/18) ~~V1.2018 (10/3/17)~~. www.nccn.org.

c) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, ~~81211-81217~~ 81212, 81215-81217)) for women with a personal history of breast, ovarian, ~~and~~ or other associated cancers and for men with breast ~~cancer~~ or other associated cancers should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V2.2019 (7/30/18) ~~V1.2018 (10/3/17)~~. www.nccn.org.

d) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V2.2019 (7/30/18) or Genetic/Familial High-Risk Assessment: Colorectal ~~Screening~~ V1.2018 (7/12/18). ~~V3.2017 (10/10/17)~~. www.nccn.org.

2) Genetic counseling should precede genetic testing for hereditary cancer whenever possible.

a) Pre and post-test genetic counseling should be covered when provided by a suitable trained health professional with expertise and experience in cancer genetics. Genetic counseling is recommended for cancer survivors when test results would affect cancer screening.

i) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.

b) If timely pre-test genetic counseling is not possible for time-sensitive cases, appropriate genetic testing accompanied by pre- and post- test informed consent and post-test disclosure performed by a board-certified physician with experience in cancer genetics should be covered.

i) Post-test genetic counseling should be performed as soon as is practical.

3) If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT ~~81211~~ 81163) analyses is not. There is one exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).

4) Costs for rush genetic testing for hereditary breast/ovarian and colon/endometrial cancer is not covered.

5) Hereditary breast cancer-related disorders genomic sequence analysis panels (CPT 81432, 81433, 81479) are only included for patients meeting the criteria for hereditary cancer syndrome testing per NCCN guidelines

~~i) Includes at least 5 genes that the NCCN Clinical Practice Guidelines in Oncology - Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) V3.2017 (10/10/17). and/or NCCN Clinical Practice Guidelines in Oncology - Genetic/Familial High-Risk Assessment: Breast and Ovarian V2.2019 (7/30/18) V1.2018 (10/3/17) include(s) with specific guidance on clinical management; and,~~

~~ii) Includes no more than a reasonable number of genes (e.g. 40 genes total).~~

Appendix C
2019 CPT Codes

code	long_code_description	Placement
10004	Fine needle aspiration biopsy, without imaging guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	Diagnostic Procedures File
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	Diagnostic Procedures File
10008	Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	Diagnostic Procedures File
10010	Fine needle aspiration biopsy, including CT guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	Diagnostic Procedures File
10012	Fine needle aspiration biopsy, including MR guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	Diagnostic Procedures File
11103	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); each separate/additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	Diagnostic Procedures File
11105	Punch biopsy of skin (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	Diagnostic Procedures File
11107	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
20932	Allograft, includes templating, cutting, placement and internal fixation, when performed; osteoarticular, including articular surface and contiguous bone (List separately in addition to code for primary procedure)	Ancillary Procedures File
20933	Allograft, includes templating, cutting, placement and internal fixation, when performed; hemicortical intercalary, partial (ie, hemicylindrical) (List separately in addition to code for primary procedure)	Ancillary Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
20934	Allograft, includes templating, cutting, placement and internal fixation, when performed; intercalary, complete (ie, cylindrical) (List separately in addition to code for primary procedure)	Ancillary Procedures File
27369	Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography	Diagnostic Procedures File
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming	Diagnostic Procedures File
33286	Removal, subcutaneous cardiac rhythm monitor	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Appendix C
2019 CPT Codes

code	long_code_description	Placement
33440	Replacement, aortic valve; by translocation of autologous pulmonary valve and transventricular aortic annulus enlargement of the left ventricular outflow tract with valved conduit replacement of pulmonary valve (Ross-Konno procedure)	82 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 106 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 186 RHEUMATIC MULTIPLE VALVULAR DISEASE 189 CHRONIC ISCHEMIC HEART DISEASE 224 DISEASES AND DISORDERS OF AORTIC VALVE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 366 ALLERGIC BRONCHOPULMONARY ASPERGILLOSIS
33866	Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)	284 DISSECTING OR RUPTURED AORTIC ANEURYSM 325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
36572	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age	Ancillary Procedures File
36573	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older	Ancillary Procedures File
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	Diagnostic Procedures File
43762	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract	Ancillary Procedures File
43763	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract	Ancillary Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
50436	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, with postprocedure tube placement, when performed;	180 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER 231 URINARY FISTULA 352 URINARY SYSTEM CALCULUS
50437	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, with postprocedure tube placement, when performed; including new access into the renal collecting system	180 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER 231 URINARY FISTULA 352 URINARY SYSTEM CALCULUS
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
76391	Magnetic resonance (eg, vibration) elastography	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
76978	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
76979	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection (List separately in addition to code for primary procedure)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
76981	Ultrasound, elastography; parenchyma (eg, organ)	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
76982	Ultrasound, elastography; first target lesion	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
76983	Ultrasound, elastography; each additional target lesion (List separately in addition to code for primary procedure)	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
77046	Magnetic resonance imaging, breast, without contrast material; unilateral	Diagnostic Procedures File
77047	Magnetic resonance imaging, breast, without contrast material; bilateral	Diagnostic Procedures File
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral	Diagnostic Procedures File
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis	Diagnostic Procedures File
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	Diagnostic Procedures File
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis	Diagnostic Procedures File
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	Diagnostic Procedures File
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	Diagnostic Procedures File
81171	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81172	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)	Diagnostic Procedures File
81173	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence	Diagnostic Procedures File
81174	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant	Diagnostic Procedures File
81177	ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81178	ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81179	ATXN2 (ataxin 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81180	ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
81181	ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81183	ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence	Diagnostic Procedures File
81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant	Diagnostic Procedures File
81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81188	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81189	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; full gene sequence	Diagnostic Procedures File
81190	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; known familial variant(s)	Diagnostic Procedures File
81204	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)	Diagnostic Procedures File
81233	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)	418 CHRONIC LEUKEMIAS WITH POOR PROGNOSIS
81234	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles	Diagnostic Procedures File
81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81239	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)	Diagnostic Procedures File
81271	HTT (huntingtin) (eg, Huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81274	HTT (huntingtin) (eg, Huntington disease) gene analysis; characterization of alleles (eg, expanded size)	Diagnostic Procedures File
81284	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles	Diagnostic Procedures File
81285	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)	Diagnostic Procedures File
81286	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence	Diagnostic Procedures File
81289	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; known familial variant(s)	Diagnostic Procedures File
81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant	Diagnostic Procedures File
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81312	PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
81333	TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)	Diagnostic Procedures File
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence	Diagnostic Procedures File
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)	Diagnostic Procedures File
81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81344	TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81596	Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
82642	Dihydrotestosterone (DHT)	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
90689	Influenza virus vaccine, quadrivalent (IIV4), inactivated, adjuvanted, preservative free, 0.25 mL dosage, for intramuscular use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
92273	Electroretinography (ERG), with interpretation and report; full field (ie, ffERG, flash ERG, Ganzfeld ERG)	Diagnostic Procedures File
92274	Electroretinography (ERG), with interpretation and report; multifocal (mfERG)	Diagnostic Procedures File
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

Appendix C
2019 CPT Codes

code	long_code_description	Placement
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)	Diagnostic Procedures File
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	Diagnostic Procedures File
96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)	Diagnostic Procedures File
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 173 POSTTRAUMATIC STRESS DISORDER 193 AUTISM SPECTRUM DISORDERS 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

Appendix C
2019 CPT Codes

code	long_code_description	Placement
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)	92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 173 POSTTRAUMATIC STRESS DISORDER 193 AUTISM SPECTRUM DISORDERS 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes	Diagnostic Procedures File
96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)	Diagnostic Procedures File
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes	Diagnostic Procedures File
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)	Diagnostic Procedures File
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only	Diagnostic Procedures File
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.

Appendix C
2019 CPT Codes

code	long_code_description	Placement
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
99451	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time	All lines with E&M codes
99452	Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes	All lines with E&M codes

Appendix C
2019 CPT Codes

code	long_code_description	Placement
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment	Ancillary Procedures File
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	Ancillary Procedures File
99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month	Ancillary Procedures File
99491	Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.	All lines with E&M codes

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS 361 SCOLIOSIS 440 TRIGEMINAL AND OTHER NERVE DISORDERS 527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C8937	Computer-aided detection, including computer algorithm analysis of breast mri image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation (list separately in addition to code for primary procedure)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9752	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9753	Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (list separately in addition to code for primary procedure)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
C9754	Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9755	Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
G0068	Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, and/or inotropic infusion drug(s) for each infusion drug administration calendar day in the individual's home, each 15 minutes	All lines with E&M codes
G0069	Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
G0070	Professional services for the administration of chemotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes	All lines with "chemotherapy" in the treatment description line
G0071	Payment for communication technology-based services for 5 minutes or more of a virtual (non-face-to-face) communication between an rural health clinic (rhc) or federally qualified health center (fqhc) practitioner and rhc or fqhc patient, or 5 minutes or more of remote evaluation of recorded video and/or images by an rhc or fqhc practitioner, occurring in lieu of an office visit; rhc or fqhc only	All lines with E&M codes
G0076	Brief (20 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0077	Limited (30 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G0078	Moderate (45 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0079	Comprehensive (60 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0080	Extensive (75 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0081	Brief (20 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0082	Limited (30 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0083	Moderate (45 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0084	Comprehensive (60 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0085	Extensive (75 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G0086	Limited (30 minutes) care management home care plan oversight. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0087	Comprehensive (60 minutes) care management home care plan oversight. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G2000	Blinded administration of convulsive therapy procedure, either electroconvulsive therapy (ect, current covered gold standard) or magnetic seizure therapy (mst, non-covered experimental therapy), performed in an approved ide-based clinical trial, per treatment session	Excluded List
G2010	Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment	All lines with E&M codes
G2011	Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and brief intervention, 5-14 minutes	All lines with G0396 and G0397
G2012	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	All lines with E&M codes

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9978	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: a problem focused history; a problem focused examination; and straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are self limited or minor. typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9979	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: an expanded problem focused history; an expanded problem focused examination; straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of low to moderate severity. typically, 20 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9980	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: a detailed history; a detailed examination; medical decision making of low complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate severity. typically, 30 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9981	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: a comprehensive history; a comprehensive examination; medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 45 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9982	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: a comprehensive history; a comprehensive examination; medical decision making of high complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 60 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9983	Remote in-home visit for the evaluation and management of an established patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires at least 2 of the following 3 key components: a problem focused history; a problem focused examination; straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are self limited or minor. typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9984	Remote in-home visit for the evaluation and management of an established patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires at least 2 of the following 3 key components: an expanded problem focused history; an expanded problem focused examination; medical decision making of low complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of low to moderate severity. typically, 15 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9985	Remote in-home visit for the evaluation and management of an established patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires at least 2 of the following 3 key components: a detailed history; a detailed examination; medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 25 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9986	Remote in-home visit for the evaluation and management of an established patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires at least 2 of the following 3 key components: a comprehensive history; a comprehensive examination; medical decision making of high complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 40 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9987	Bundled payments for care improvement advanced (bpci advanced) model home visit for patient assessment performed by clinical staff for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and ensuring beneficiary connections to community and other services; for use only for a bpci advanced model episode of care; may not be billed for a 30-day period covered by a transitional care management code	Ancillary List

Appendix E
2019 CDT Codes

CDT Code	Code description	Proposed Placement
D0412	blood glucose level test – in-office using a glucose meter	Diagnostic Procedures File
D1516	space maintainer – fixed – bilateral, maxillary	53 PREVENTIVE DENTAL SERVICES
D1517	space maintainer – fixed – bilateral, mandibular	53 PREVENTIVE DENTAL SERVICES
D1526	space maintainer – removable – bilateral, maxillary	53 PREVENTIVE DENTAL SERVICES
D1527	space maintainer – removable – bilateral, mandibular	53 PREVENTIVE DENTAL SERVICES
D5282	removable unilateral partial denture – one-piece cast metal (including clasps and teeth), maxillary	588 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH)
D5283	removable unilateral partial denture – one-piece cast metal (including clasps and teeth), mandibular	588 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH)
D5876	add metal substructure to acrylic full denture (per arch)	451 DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE)
D9130	temporomandibular joint dysfunction – non-invasive physical therapies	547 TMJ DISORDER
D9613	infiltration of sustained release therapeutic drug – single or multiple sites	Excluded File
D9944	occlusal guard – hard appliance, full arch	644 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT
D9945	occlusal guard – soft appliance, full arch	644 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT

Appendix E
2019 CDT Codes

CDT Code	Code description	Proposed Placement
D9946	occlusal guard – hard appliance, partial arch	644 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT
D9961	duplicate/copy patient's records	Excluded File
D9990	certified translation or sign-language services – per visits	Ancillary Procedures File

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
November 8, 2018

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, Vice-Chair (by phone until 3:30); Mark Gibson; Leda Garside, RN, MBA; Susan Williams, MD (by phone until 3:30 pm); Angela Senders, ND (by phone); Gary Allen, DMD; Leslie Sutton (by phone until 3:30 pm); Adriane Irwin, PharmD (by phone); Michael Adler, MD (by phone until 3:30 pm); Kevin Cuccaro, DO (by phone).

Members Absent: Lynnea Lindsey, PhD; Devan Kansagara, MD.

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

Also Attending: Renae Wentz, MD, MPH (Oregon Health Authority); Val King, MD, MPH (OHSU Center for Evidence-based Policy); Devki Saraiya and Karen Heller (Myriad); Duncan Neilson, MD (Legacy Health); Sharron Fuchs; Alice Austin (OR Assoc. of Behavior Analysis).

Call to Order

Kevin Olson, Chair of the Health Evidence Review Commission (HERC), called the meeting to order; roll was called.

Minutes Approval

MOTION: To approve the minutes of the 10/4/2018 meeting as presented. CARRIES 10-0. *(Absent: Irwin)*

Director's Report

Membership
Coffman offered his appreciation to Susan Williams as this marks her final meeting as a Commissioner. The Governor's office is taking more time recruiting a replacement with a possible appointment in February, 2019.

Coffman said a member of the Health Technology Assessment Subcommittee (HTAS), Mark Bradshaw, is relocating out of state. Coffman recommended Mary Engrav, CareOregon Medical Director and ED physician, as a replacement.

MOTION: To appoint Mary Engrav to HTAS. Carries 11-0.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials pages 58-204

Ariel Smits reported the VbBS met earlier in the day, November 8, 2018. She summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (effective 1/1/2019)
- Add the diagnosis codes used for latent tuberculosis infection to a covered line
- Add the procedure code for Yttrium-90 therapy to the covered liver cancer line with a new guideline
- Add the procedure codes for amniotic membrane transplant for eye conditions to three covered lines and removed from 3 other covered lines
- Add the 2019 CPT codes to various covered and uncovered lines on the Prioritized List with guideline note changes as needed to accommodate these codes
- Add the 2019 HCPCS codes to various covered and uncovered lines on the Prioritized List with changes to guidelines as required by placements
- Add the 2019 CDT codes to various covered and uncovered lines on the Prioritized List
- Add the procedure code for the iStent glaucoma surgery to a covered line with a new guideline

RECOMMENDED GUIDELINE CHANGES (effective 1/1/2019)
- Modify the non-prenatal genetic testing guideline and remove the hereditary cancer testing section to make into its own guideline
- Modify the prenatal genetic testing guideline
- Modify the guideline on human donor breast milk for high-risk infants

Modified from the VbBS report:
Place HCPCS G0069 (Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes) on line 660, CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS, with a corresponding entry on Guideline Note 173.

MOTION: To accept the VbBS recommendations on *Prioritized List changes*, as modified. See the VbBS minutes of 11/8/18 for a full description. Carries: 11-0.

Planned Out-of-hospital Birth Scoping Statement
Meeting materials pages 210-224
Handout

This item was moved up in the agenda to accommodate members who needed to leave early.

Livingston gave an overview of the current coverage guidance which was approved in November of 2015 after an 18-month process. Though the HERC does not do an automatic rescan of current coverage guidances, we have been asked to reconsider looking at this coverage guidance by multiple parties. The question before the Commission is should the coverage guidance be reopened.

Some providers hope to make the coverage guidance more restrictive while advocates hope it will be more flexible.

Adler asked for an overview of how the pre-authorization process works and Livingston and Smits gave a brief summary of the OHA process. Adler expressed concern about signs and symptoms of preeclampsia.

Livingston reviewed the rescan/scope statement document.

King gave a presentation focusing on the Snowden study from Oregon. She also spoke about the Grünebaum and the Tilden studies.

Invited commenter
The co-author of the Grünebaum study, Dr. Frank Chervenak, joined the meeting by phone. He spoke about patient safety in planned home birth. He said in 2017 a scientific paper identified two additional evidence-based contraindications for planned home birth: nulliparity (or first delivery) and gestational age of 41 weeks or more (1 in 400 deaths and 1 in 600 deaths, respectively).

Staff assessment
The evidence reviewed in the rescan generally supports the current understanding of the literature: that planned out-of-hospital birth significantly decreases women's risk of interventions such as cesarean section and assisted vaginal delivery, but that there are increased risks of serious but rare neonatal harms including death. The additional evidence available on VBAC (vaginal delivery after caesarian) would be informative but not change the coverage guidance, which already considers VBAC a high-risk coverage exclusion criteria. There are several potential new indications that could arise out of a review of the literature (gestational age over 41 weeks, over 35 years old, and nulliparity or a combination of those). However, there are significant limitations to the Grünebaum study that might suggest these criteria be examined, and it is not clear given those limitations how much this would change the coverage guidance if re-reviewed.

Public comment from the out-of-hospital birth community received during the posting of the draft scope statement proposed modifying the consultation criteria (to delete some required consultation criteria such as obesity). It also included the submission of studies related to out-of-hospital birth, some of which did not meet the search criteria.

It seems unlikely, based on the rescan, that there would be significant new information to lead to modifying those consultation criteria, although there are some updates to guidelines used in the 2015 review that may result in minor modifications.

Public comment also proposed modifications to add additional exclusion criteria such as additional neonatal transfer criteria.

Altogether reopening the coverage guidance may result in limited changes to the current coverage language.

Discussion
Olson asked if the Commission can apply a different rule to the Prioritized List than what is stipulated in the current coverage guidance. Coffman explained in the past when something like that occurred, a coverage guidance has been retired.

Gibson said he is reluctant to create a conflict with the recommendations that come out of the Commission. He feels they should be consistent. He said before we decide, we should think though the implications and that he is okay with opening up this coverage guidance for review.

Garside asked if we have all the risks in the current guideline from the 2015 review. Livingston said there is a possibility of adding more or removing some, depending on the conclusions drawn from an updated literature review. Garside said she is in favor of a new review in case it is determined that changes need to be made.

Olson said we tend to favor data that indicates there may be harms, even if the data is imperfect. We want to be able to say we gave this topic its due attention.

Cuccaro said if there is evidence of harm we should open it back up.

Irwin questioned whether we should open the topic based on a single low-quality study.

MOTION: Return the Planned Out-of-hospital Birth Coverage Guidance to EbGS for review. Carries: 7-0. *(Absent: Hodges, Williams, Sutton, Adler)*

Public comment
Sharon Fuchs commented that she is on one of the out-of-hospital workgroup committees. She delivered her first child outside the hospital in 1979 and filed her first concern with the state about that in 1980. She said there is no other committee doing the work that HERC is doing. She wanted to express appreciation for Dr. Chervenak and for the work of the HERC.

Duncan Neilson, MD, of Legacy Health, said we have heard an impassioned plea based on a large study to add another risk factor. He would like to make sure we keep the topic in proper perspective: home births are going to happen. We should do the best we can to ensure patient safety. He expressed a desire to be involved in continued discussions.

Multisector Intervention Topics
Meeting materials pages 206-208

Livingston reviewed the scoping statement of the following proposed two topics:

> *Community Health Worker (CHW):* Engagement with a CHW for adults or children with at least one of the following: asthma, diabetes, hypertension, heart failure, HIV, serious mental illness, high utilizers
>
> *Multisector Interventions to Reduce the Frequency of Asthma Exacerbations:* Case management programs, school-based interventions, home-based interventions, provider- or pharmacist- directed programs

MOTION: To approve Community Health Worker & Interventions to Reduce the Frequency of Asthma Exacerbations as new multisector intervention topics. Carries: 7-0. *(Absent: Hodges, Williams, Sutton, Adler)*

Priorities for Evidence-based Reports
Meeting materials pages 226-227

King said CEBP preferrs not to start out-of-hospital birth in February, but to wait until a late date in 2019.

The other priorities were left to EbGS's discretion.

Public Comment

There was no further public comment at this time.

Adjournment

Meeting adjourned at 4:15 pm. Next meeting will be from 1:30-4:30 pm on Thursday January 17, 2019 at a location yet to be determined.

MINUTES

Health Technology Assessment Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
November 15, 2018
1:00-4:00pm

Members Present: Kathryn Schabel, MD (acting chair); Leda Garside, RN, MBA; Mary Beth Engrav, MD; Mike Adler, MD, Vinay Prasad, MD, MPH (chair, by telephone); Brian Duty, MD, Kevin Cuccaro, DO (by phone).

Members Absent: none

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

Also Attending: Doug Riggs (Oregon Ambulatory Surgical Association); Mellony Bernal (OHA Public Health Division); Chris Skagen (Oregon Ambulatory Surgery Association, by phone); Adam Obley, MD & Craig Mosbaek (OHSU Center for Evidence-based Policy); Fouad Otaki, MD (by phone).

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1. CALL TO ORDER

Schabel, who acted as chair since Prasad was attending by phone, called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:00 pm.

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2. MINUTES REVIEW

Minutes from the September 20, 2018 meeting were reviewed and approved 7-0 (Duty absent).

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3. STAFF REPORT

Coffman welcomed Dr. Duty and Dr. Engrav to the subcommittee. Staff and members introduced themselves and welcomed the new members. Duty is a urologist at OHSU; he is also working on his healthcare MBA, and this is one of his first ventures into health policy. Engrav has a background in emergency medicine; she practiced 27 years at Legacy and Providence hospitals. Her biggest interest is integrated medical and behavioral care for patients with behavioral health or substance use disorders. She has specific interest in the opioid epidemic and fraud.

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4. REVIEW PUBLIC COMENT: NEWER INTERVENTIONAL PROCEDURES FOR GERD

Adam Obley reviewed the public comments and responses from the meeting materials. Shaffer introduced Fouad Otaki, an OHSU gastroenterologist with an interest in foregut disease, esophageal

disorders and Barrett's esophagus. Schabel asked for his views on the recommendation. He said that he agreed with the evidence review. He said transoral incisionless fundoplication has demonstrated effectiveness, and the MUSE system is an up-and-coming alternative technique but not in clinical use; magnetic sphincter augmentation has a bright future but at this time he agrees with the overall review.

Shaffer reviewed the revisions, which highlight that the evidence that was reviewed used the Esophyx device. The MUSE system is newer. The CPT code would likely be the same for both devices. He said that the MUSE system is different in device components and surgical technique, so the recommendation was altered so that the recommendation for coverage is now specific to the Esophyx device.

A motion was made to refer the draft coverage guidance to HERC. **Motion approved 8-0.**

DRAFT HERC Coverage Guidance

Transoral incisionless fundoplication (TIF) is recommended for coverage of GERD treatment only when the following criteria are met *(weak recommendation)*:

- 18 years of age or older
- Confirmed diagnosis of esophageal reflux by endoscopy, ambulatory pH, or barium swallow testing
- History of GERD symptoms for one year, occurring at least two to three times per week in the past month
- History of daily proton pump inhibitor therapy for the most recent six months
- Body mass index (BMI) ≤ 35
- Absence of all of the following conditions
    - Hiatal hernia larger than 2 cm
    - Esophagitis with LA grade of C or D
    - Barrett's esophagus greater than 2 cm
    - Achalasia
    - Esophageal ulcer
    - Esophageal motility disorder
    - Altered esophageal anatomy preventing insertion of the device
    - Previous failed anti-reflux surgery or procedure

EsophyX® was the only device identified in the evidence reviewed for this coverage guidance. Other transoral fundoplication devices or systems are not recommended for coverage.

For patients who have recurrent symptoms or fail the initial TIF procedure, repeat TIF is not recommended for coverage *(strong recommendation)*.

Magnetic sphincter augmentation for treatment of GERD is not recommended for coverage *(weak recommendation)*.

5. EXTENDED STAY CENTERS (ESCs) AND AMBULATORY SURGERY CENTERS (ASCs)

Doug Riggs offered public testimony. He is with the Oregon Ambulatory Surgery Center Association (OASCA). He helped draft the bill and worked since 2014 to get the bill adopted. He said by the end, the allies included Oregon Medical Association, Oregon Association of Hospitals and Health Systems as well as patient advocate groups and unions. He said that the bill would allow people to extend their recovery period after surgery. This was a key to address the deluge of joint surgeries that are needed with the aging of an active population. These surgeries are expected to double in the next 10 years.

He said there are two rulemaking processes ongoing within the Oregon Health Authority. One, with the Public Health Division is complete, related to licensing rules. Those should be effective in January. Another, related to facility guidelines (or an FGI process) to align building standards at the federal level, is nearing completion as well. A third provision in the statute is related to the HERC, which was adopted last. It's important to understand that one of the hospitals in Southern Oregon wanted this provision adopted. He and other proponents of the bill saw the provision shortly before a vote and didn't have a chance to change it. He said it wasn't quite what his group was hoping for. There are only a handful of states that have recovery facilities. What was intended was to begin to collect data on the outcomes from patients who use extended stay centers and develop evidence around outcomes for these patients. However, that's not quite what the bill says. He believes there will be a legislative effort to modify the bill, which he would share within a couple of weeks. He said Chris Skagen, executive director of OASCA, would testify later about the procedures that will be done related to extended stay centers and about profitability of ASCs. He said profitability is poor; the number of ambulatory surgery centers is actually contracting in Oregon because of low reimbursement. He offered to be a resource in the guideline development and continues to work with the hospital association and Oregon Medical Association. He said Colorado also has data that may be helpful.

Schabel asked about the goals of the legislative provision. He said he spoke with the hospital association and he thinks they agreed that the goal was to collect data about the procedures leading into an ESC, which will tend to be knee, spine, joint and shoulder surgeries. It won't be a lot of daily pain management or complicated surgery with higher morbidity. It will begin to look into the issue but collect data on actual results on the ground in Oregon. The bill set up the opportunity to create new licenses only for a five-year period. After that the legislature would need to act for new facilities to be approved, though existing facilities could continue operations. The existing bill appears to request the HERC to determine which procedures would be appropriate in an ASC that has an ESC. He said it shouldn't be the procedure that determines this but rather the patient and their needs. For example, an elderly patient may need a little extra time for managing pain or bodily functions. Another patient might not have a caretaker at home but need one after 23 hours and 59 minutes. Or if the caretaker can't arrive because it is 6 a.m. and snowing, an ESC would be available so that the patient could be stabilized and wouldn't need to be transferred to the hospital emergency room at higher cost.

Riggs also clarified that an extended stay center is not for a patient whose condition is deteriorating, but a patient that is recovering. He said the data from Colorado support that patients who encounter complications either have this happen in the surgery center or are transferred to the hospital.

Obley asked whether there are procedures that are not currently performed at an ambulatory surgery center which would be with the option of an extended stay center. Riggs said he doesn't think so. It would be the ability to perhaps expand the types of patients and life situations that people have and allow them to be 'screened in' to have surgery in an ASC. ASCs already have a good track record at

screening patients to make sure they are appropriate for surgery in an outpatient setting. He said he doesn't see the surgeries that will be performed expanding, except where technology improves. For example, spine surgery technology has improved greatly over the past 10 years.

Schabel asked to clarify, would it be that patients would be scheduled for an ESC or whether it would just be available for patients if needed for their recovery. Riggs said Skagen could better answer that question but that it would likely be a little of both. He said there are about 12 of these in Colorado and most tend to be midsized (10-15 beds). Some patients may know that an extra 6 or 12 hours of recovery could be of benefit because of the time of year or lack of a caregiver at home. In other cases a patient might have a little additional trouble managing pain or bodily functions after surgery. The ESCs aren't a profit center because most plans don't pay for this service, though they are working to get reimbursement. He said Medicaid hasn't approved the waiver yet. Shaffer added that the bill directs the Oregon Health Authority to apply for such a waiver. Adler asked about the location of extended stay centers. Others said that they would need to be on the same site, though they would be licensed separately.

Shaffer and Schabel thanked Riggs for his participation and offers of assistance. Shaffer said that it's good to know that there may be statutory revisions, but the HERC will proceed until instructed otherwise.

Shaffer then reviewed the status of the report. Today's meeting will be phase 1 of the evidence review. He is hoping to get further direction on looking for evidence and getting experts for advice. He said we don't want to go too far if there's a feeling that we won't have enough information on which to base evidence-based guidelines. He introduced Valerie Halpin, a bariatric surgeon who will be calling in while returning from a national conference on bariatric surgery. He said we have had challenges recruiting external experts. We have Adler for gynecologic surgery, Schabel for joint replacements, and Duty for urologic procedures. Cuccaro received training in anesthesia though his practice is more focused on pain management. We are still seeking experts on quality and safety monitoring, otorhinolaryngology, and recovery nursing.

Shaffer reviewed the requirements. The HERC's task is not to provide any regulations, as these were created by the Public Health Division. The scope of this work is to come up with patient characteristics and appropriate procedures for ambulatory surgery centers that have an associated extended stay center. We don't expect much evidence as similar models only exist in a few places. It's possible we will come up with insufficient evidence, but we need to look for it. Our main goal should be patient safety and avoidance of harms. The concern is that more complex procedures will be done on more complex patients. This may have benefits as the costs may be lower, but it also may be that the evidence will suggest some boundaries on what should be recommended.

Schabel said that the existing data for ambulatory surgery centers is cherrypicked and ASCs typically operate on less complex patients. Assuming that the high quality/low-cost results will continue in the changed model is definitely a leap. She asked whether there is a role for this committee in stipulating that data be collected. Gingerich explaned that OHA has two rulemaking processes. The first is the licensing requirements. Mellony Bernal from the Public Health Division is here to provide any needed information on that rule. The statute authorizing ESCs also contains provisions requiring discharge data collection from ESCs. Another part of OHA has developed rules for re-initiating discharge data for ASCs (data collection stopped in 2014). Once ESCs are in operation a similar rule would be developed for ESCs.

Shaffer and Obley reviewed the facility rules and initial partial draft guideline provided in the meeting materials. Shaffer noted that the facility rules do have some limits on patient characteristics, including ASA Class I, II or III. Several members expressed concern that ASA class III patients have significant systemic disease. Schabel gave the example of a patient getting a colonoscopy in an ASC who also has heart failure that has been stable for a long time. Could this patient be admitted to an ESC? According to the rule, such a patient could be admitted to the ESC.

Duty asked whether the new Center for Health and Healing Building 2 at OHSU follows ASC rules. Schabel said no, because it is affiliated with a hospital. Duty said this facility has requirements about who can use the facility and it includes ASA class III patients. Shaffer also reviewed the staffing requirements in the licensing rule as well as the rules related to pharmacy, labs and imaging.

Garside asked whether there would be regulations requiring certain levels of nursing staffing. Bernal said that there would have to be nurses available at all times. The rule specifically says that the staffing levels should be based on the number and complexity of patients. Bernal said her section will visit ESCs. She said that the ESC rule uses identical language to the ASC rule. This was discussed at length. They reached out to the Bureau of Labor and Industries and the Board of Nursing and chose to keep it vague since Public Health doesn't relate to employment. The rule does, however, require an RN to be on duty at all times. Gingerich said that some ASCs do less invasive surgies like cataracts, so staffing requirements may vary; some ASCs would have no interest in creating an extended stay center. Bernal clarified that the ASC rules are now out for public comment.

Obley asked specifically about the origin of the ASA classification part of the rule. Bernal said it was based on AORN and ASPEN guidelines. They did not receive any comments on that part of the rule during the rules advisory committee meeting. Schabel said it would be helpful to have quality and nursing experts to understand these issues.

She also asked about whether adverse events would be reported. Bernal said that there is voluntary adverse event reporting through the Oregon Patient Safety Commission (OPSC). Gingerich clarified that the requirement is that if you report, the report should contain all incidents. Bernal said this is how the requirement is for all health facilities in Oregon.

Skagen said that ASCs are required to report certain adverse events to the Center for Medicare and Medicaid Services Quality Reporting Program. Measures include falls, wrong site/wrong side/wrong patient incidents, transfers to hospital and other outcomes the subcommittee may have interest in.

Obley reviewed the evidence section of the partial draft report.

Prasad asked to review the goal of the report. Shaffer said the goal is to create a guideline on appropriate procedures and characteristics for the setting of an ASC with an ESC available. Schabel said that the question isn't whether an ASC can do a particular procedure, as that is a foregone conclusion. The data presented shows whether certain procedures can be performed safely at an ASC. One type of data that might be helpful is reporting on failed outpatient surgeries. What percentage of patients end up being transferred to a hospital or emergency department and what are the rates for various procedures. Comparative studies might not get us to the answer for this question.

Prasad said he wasn't sure it could be done. Even if you have data that shows that if a patient has a certain surgery in an ASC there is a 3 percent chance of hospital transfer. Is that acceptable or not acceptable? In the absence of comparative studies how can anyone know?

Engrav said ASCs have an interest as it would expand their patient population. Is this going to skew it to taking higher-risk patients? Schabel said having an ESC could result in boundaries being pushed both in patient selection and procedure type. However, there is very poor evidence to guide us here. For instance, in orthopedics one of the issues that pushes people to a hospital setting is urinary retention. She said without an ESC, an ASC would have to send the patient home fully catheterized and the primary care physician could remove the catheter a week later. With an ESC the patient could stay overnight, work on urinating and then go home without a catheter and avoiding a transfer to hospital. This isn't a complication with the procedure but rather the anesthesia. The methodology of these case series is generally poor as they aren't looking for all the potential emergency department visits a patient could require. The case series generally make the procedures appear safe, and collecting a robust data set is difficult. Looking at the pool of patients who fail attempted ASC or hospital outpatient-based surgeries would be interesting. Obley said this data is summarized in the appendices. In many cases the outcomes selected are things like patient satisfaction rather than safety or quality metrics.

Shaffer invited Dr. Halpin to testify about bariatric surgeries performed in ASC settings. She said there are two centers near Seattle doing bariatric procedures in ASCs. One of them presented data today at the American Metabolic and Bariatric Surgery meeting. About 2000 patients underwent laparoscopic sleeve gastrectomy at their ASC. Their rate of transfer to the hospital was about 1 percent. The hospitalizations were for things like bleeding and cardiac events. The readmission and complication rates were similar to what is seen in a hospital setting. Many complications occur after discharge, so the surgical setting doesn't make that big of a difference. Selection criteria were ages 18-65, with a BMI less than 55 for men or 60 for women. They did report one early death related to sleep apnea, so patients with sleep apnea now stay overnight (about 70% of bariatric patients have sleep apnea). She said they also do Roux-en-Y surgeries but didn't report those results today.

Schabel said there is some differentiation in patient population—BMIs will be higher in a hospital. You would expect the outcomes data to be improved, not similar. A group of younger, healthier patients should have lower—not equivalent—complication rates. Halpin said bariatric patients are at least ASA class II by definition. Without directly comparing them it is hard to say whether their outcomes should be better than what we see nationally. However, data collection in bariatric surgery is pretty robust, with the vast majority of surgeons contributing to a robust data set. She said the second group that did ASC bariatric surgery keeps all of their patients overnight. Schabel said that having an ESC could therefore expand the population eligible for bariatric surgery. Still, with little data it is a foreboding task to do what we've been asked to do from an evidence-based standpoint.

Gingerich said that staff have been instructed that it would be acceptable for the subcommittee to decide there is insufficient evidence on which to base a guideline.

Prasad asked about propensity-matched or instrumental variable studies. Obley said that if there were such studies they would have been identified in the search. Prasad said the best we can do is look for case series or cohorts that report complications or transfers. Obley said such studies do exist.

Prasad said one possibility would be to present a table listing different patient groups, with those with the lowest risk at the top. Over time as providers gain comfort performing surgeries for more complex patients in this setting they could move down the table.

Shaffer said that from reviewing the abstracts, an issue may be that the patients are "carefully selected". He said reading the full articles may or may not reveal whether there were specific exclusion criteria or whether exclusions were based on clinical judgment. Prasad said that if the only answer is clinical judgment, we haven't made any progress. There would need to have been a protocol for patient selection. Halpin said that in bariatric surgery they would have specific criteria.

Schabel said we may not have as robust data in orthopedics. There is a study that used risk calculators and case series analysis to estimate that about 15 percent of the Medicare population meets criteria for outpatient joint replacement. That's a small but not insignificant percentage. Studies like this will also be important.

Prasad said the search could include only studies where there were delineated criteria for conducting the surgery in an ASC setting. Obley said a robust accounting of the patient characteristics might suffice; Prasad agreed.

Gingerich noted that one of the studies was an externally defined national dataset. Schabel said that the large databases come from hospitalized patients. Obley said he'd have to delve into the study more deeply to answer that question.

Coffman asked whether an additional search might need to be done. Obley said the search was conducted in such a way to pick up these kinds of studies if the surgeries were conducted in ASCs. For these, the remaining work would be to analyze them based on today's discussion. There could be additional studies that would report on "outpatient" procedures without specifying ASC as the site of care.

Schabel said it's becoming clear that developing a robust evidence-based guideline is out of reach but being able to state that the data isn't there could be important. She said looking at 1-day hospital procedures versus an ASC is a very different thing, as the available services are very different. Obley recommended focusing on the ASC-based studies, and Schabel suggested that the subcommittee might state that there is no way to comment on expanding the eligible population, for which there is no data in an ASC setting.

Schabel asked Skagen what the goal of the ESC was? Was it to increase the number of patients? Skagen said that the goal was to enhance the patient experience and that the admission criteria for an ASC does not change based on the recovery center.

Shaffer asked Skagen to offer the rest of his comments. Skagen thanked Bernal for her work on the licensing rules. He has consulted with some of the firms in the Washington area. He offered the names of some experts who might be able to assist. He can also put the group in touch with physicians as well as CEOs in Colorado who could share their expertise. They may be able to report internal data, which would not be peer-reviewed. He said that having all ESCs report data is appropriate, but having all ASCs report discharge data would be going too far. Skagen said that with respect to the ASA classifications, the ASC facility medical board would approve procedures that would matriculate into a recovery center. The types of procedures include joint replacements (hip, shoulder, knee, ankle). Arthroscopies and

sports medicine, spinal fusion and hand and upper extremity surgeries are also common. He said there is a lot of data out there, but there will be a specific list for each facility, followed by a retroactive review of complications for each procedure. He said he has additional information and looks forward to continuing the dialog.

Engrav asked where the CMS quality data or LeapFrog data can be accessed. Gingerich explained that the workplan involves collecting available data from CMS quality reporting and the ASC Quality Collaboration Report. Gingerich also explained that facilities which accept Medicare payments must have uniform discharge criteria for all patients (not just Medicare patients) and prior to the surgery must reasonably expect discharge within 24 hours. However, procedures not on the Medicare ASC list can be done on patients who aren't on Medicare. He also said that the HERC public comment survey indicated concerns about surgeries including neck dissections and prostate surgery, but that the volume would likely be in hip replacements, knee replacement and spine surgery. Shaffer added that each ASC has a list of procedures allowed in that facility. Also, each insurer would need to approve procedures done in an ASC in order for the insurer to provide payment. Schabel said some major payers do follow the CMS rules about which procedures can be done in an ASC, so hip replacements aren't allowed, but knee replacements are newly allowed since they have been removed from the inpatient only list.

Adler said he is in favor of ESCs and said that they would expand gynecologic surgeries. There are certain hysterectomies, vaginal repairs and bladder surgeries that would benefit. It makes him wonder if there is any reason a gynecologicist couldn't do an abdominal hysterectomy. Normally a patient would stay more than 24 hours and it wouldn't be done in an ASC. Obley said hysterectomies were included in this search, but the vast majority of procedures described were for vaginal hysterectomies, not abdominal hysterectomies. Adler said that knowing you had a 48 hour time period, a younger patient with a normal weight who has large fibroids may benefit from an abdominal hysterectomy in an ASC. Schabel said that the caveat is that not all hospital services are available. Also, CMS rules state that the patient would need to meet the criteria for reasonable probability of a 24-hour discharge. She said these are the slippery slopes that are going to happen with the development of ESCs.

Duty said he was hearing that the ESC is mostly a buffer for patients needing additional recovery time. For transurethral resection of the prostate (TURP), most patients spend one night in the hospital with a catheter and continuous bladder irrigation. The next day if things look OK, the catheter is removed, or the patient is discharged with the catheter. He said if the ESC is simply a buffer, it would not be appropriate for TURP to be done with an ESC. However, he said if we're looking at doing procedures we wouldn't typically do, a TURP would be reasonable in that setting since the vast majority of people go home within one day and certainly within 48 hours. Gingerich said we are hearing today that it's a buffer, but the public comments from the survey indicated that people were looking to expand the types of procedures offered. Schabel said we should consider for this guideline a recommendation for the ESC to be a buffer for patient comfort and experience rather than an expansion for criteria for an ASC. Duty said the new OHSU Center for Health and Healing (CHH2) would have a huge expansion in procedures offered. Schabel said she believes CHH2 is considered a hospital-affiliated facility. Obley asked whether CHH2 would have 24-hour anesthesia coverage. Schabel said no—it's essentially an ASC. Schabel suggested that HERC could put the 24-hour reasonable expectation of discharge in its guideline, even though it's already in the Medicare rules.

Duty asked whether it's more about anesthesia-related recovery. Schabel said that maybe it's more about patient characteristics, as Riggs suggested earlier in the meeting. The expansion of patient criteria

could now include patients with conditions like sleep apnea that may require nursing observation but not hospital care.

Gingerich gave the example of a TURP patient. If the patient was admitted at 10 a.m. on Monday with the expectation of discharge by 9 a.m. Tuesday, that would meet the ASC requirement, though a provider may be reluctant to do the surgery because it's close to 24 hours. Would the availability of an ESC change the calculus? Duty said it could. Duty said he found an article on hospital visits after urologic ambulatory surgery procedures. The article looked at TURP and there was a 12 percent rate of patients having unexpected hospital visits. With this procedure there is a significant risk of bleeding, so he would be concerned about having to guarantee they would be gone in 23 hours. Schabel said if the reason you are keeping people for observation is a serious condition requiring hospital care, that's not the kind of procedure you'd want to be expanded with an ASC+ESC because its not a hospital. However, when the concern is sedation, airway protection and other conditions not requiring hospital-based care, expanding procedures or patient selection into those realms would be appropriate. If the potential complication is airway compromise from massive bleeding in the neck, that would not be appropriate. Duty said nursing staff might have perspective on which complications would be reasonable. He'd also have concerns about a catheter being maintained properly. He said it's a tough job for nursing staff to be specialists in all the different procedures.

He asked whether they could take patients back to the operating room in the middle of the night. Bernal said they can. For example, in a breast reconstruction, the patient could return to the operating room to fix the bleed, but the 48 hours provision doesn't restart. And if there is no surgeon and anesthesia coverage available they may need to be transported; Bernal didn't recall anything regarding night hours coverage for anesthesia or surgery.

Engrav said the 24 hours at a hospital is different than at an ASC. In a hospital, after 24 hours it would convert to inpatient, while at an ASC the patient would need to be transported. Because it's a one-day procedure at a hospital doesn't mean it would be appropriate in an ASC. Schabel said we need to discourage thinking that the presence of an ESC would expand the scope of services, though it might expand the scope of patients eligible when the additional care is nursing intensive.

Discussion turned to the risk calculators. The subcommittee looked at the results for several procedures using the ACS NSQIP surgical risk calculator, including laparoscopic Roux-en-Y bariatric surgery, sleeve gastrectomy and knee replacement. Two potential patients were reviewed for each procedure, one being ASA class 3 and under 65 with no other risk factors, and the other patient had a higher BMI, age over 65 and hyptertension with a prior heart attack. Schabel noted that the hospital length of stay for knee arthroplasty made sense with data from a few years ago but not today.

Schabel asked about the age ranges. Obley said the ACS risk calculator is only for adults and it is by far the most comprehensive risk calculator available. There are additional procedure-specific calculators.

The subcommittee suggested a few other procedures for the calculator. Schabel said that the utility of this is for hospitalized patients. Gingerich asked about other risk factors that might be tenable for ASC patients. Schabel said only a few—possibly systemic steroid use. Many of the risk factors would preclude ASC surgery. Patients over 85 wouldn't likely be appropriate for an ASC+ESC.

Shaffer asked whether the complication rates that are reported would be helpful for decisionmaking? There was agreement that only complications that would arise during the ESC stay would affect

decisionmaking. Schabel said predicted length of stay may not be helpful as the ASC is a different environment and patient optimization can reduce length of stay. Engrav said that those who own an ASC and have a financial interest in a skilled nursing facility sometimes perform a procedure at an ASC and transfer them to the nursing facility. This is completely unregulated and fraught with hazards and complications. This will likely continue no matter what. Schabel said patients are more often discharged from an ASC to a nursing facility on the East Coast.

Schabel said the whole ASC movement is a financial boon to the people doing it. In particular with arthroplasty, there is high profit potential for a well-run ASC. The conflicts of interest aren't in HERC's scope but they loom large.

Gingerich entered a hypothetical TURP patient in the calculator, undergoing the procedure described by CPT 52601, age 65-74, overweight male who uses tobacco with mild systemic disease, diabetes, and hypertension. The calculator returned a stay of 1.5 days. Duty said if that's the typical length of stay you would expect the patient to be in the hospital. But fundamentally the question is whether the ESC is a buffer or mechanism to do additional procedures. Engrav asked what would happen if the patient had a bleed at 2 a.m. in a hospital. Duty said the patient would return to the operating room. If that couldn't happen at the ASC in the middle of the night, there would need to be an emergency transfer.

Obley asked to put in a healthly patient for an anterior cervical discectomy and fusion (CPT 22551) on the healthiest possible patient. The calculator returned a 1-day length of stay with relatively low risk of complications. For neck dissection (CPT 38720) the length of stay was two days. Schabel said the potential complication is serious bleeding. Members were concerned about the potential risks to the patient. For abdominal hysterectomy (CPT 58150) on a healthy young woman of normal weight and no other risk factors the calculator returned a length of stay of two days.

Discussion turned to the selected procedures to search for observational data. The subcommittee selected five additional procedures. The subcommittee discussed arthroscopy, but decided not to select, since these have been done in ASCs for many years. The complete list of procedures selected is:

- Lumbar laminectomy/foraminectomy
- Cervical laminectomy/foraminectomy
- Lumbar fusion
- Total knee replacements
- total hip replacements
- Cholecystectomy
- Neck dissections
- Mastectomy
- Transurethral resection of the prostate
- Bariatric surgery
- Hysterectomy

Gingerich asked about cardiac catheterization, which is proposed for addition to the ASC list for 2019. Obley said generally you want a cardiothoracic surgeon onsite for these surgeries. Engrav said they have people do a catheterization in rural areas and if they find anything amiss they ship the patient to Portland. Obley said this might be for diagnostic angiograms, and the subcommittee decided not to include this.

Schabel returned to the discussion of what the purpose of the guideline is. Shaffer said it's patient safety. Though the ASC advocates are trying to reassure us, some hospital stakeholders were concerned it could also bring about more complex procedures on more complex patients. Despite the 24-hour box, the boundaries can be stretched. Schabel said we won't have data to specify the boundaries. Obley said the published peer-reviewed literature will be of little help. Schabel said if the literature is about patient experience this doesn't address the concern about expanding the boundaries into unsafe waters.

Schabel said we can let CMS rules guide, except for facilities which don't accept Medicare. It may be appropriate to have a separate section for these. Bernal said that an ESC can only be affiliated with an ASC that is certified by CMS, so they have to meet the Medicare criteria. Schabel said this helps and with that said, we could be done with this now if we want to acknowledge the limits of what evidence is available. We can focus most of our efforts around patient criteria.

Duty said we need anesthesia representation. Schabel also recommended nurses who work in these centers. Schabel asked Engrav whether she's seen patients transferred to the emergency room. Engrav said that she's seen neurosurgeons do a procedure then take the patients directly to a skilled nursing facility, creating a hazard. There have been some other transfers, but an ESC could reduce those transfers for young patients or rural patients. Duty said he has cancelled patients who don't have a ride home.

Schabel said that if we're doing this, it should be for patient comfort and convenience, not to expand the procedures. It could be for patients without a caregiver or a ride home. There was agreement that one day could make a difference.

Shaffer proposed that when using the calculator for the next meeting we design a healthy patient, then include some with some level of complications. There was agreement not to include septic patients, but include complications similar to those discussed earlier.

Shaffer said we will also include additional analysis of the other states' experience including any available data. Schabel said even rates of use or expansion over time would be useful. Obley said we may be able to get that data.

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6. ADJOURNMENT

The meeting was adjourned at 4:00 pm. The next scheduled topic is spinal cord stimulators for chronic pain, but due to limited resources, this may not be discussed at the next meeting. The next meeting is scheduled for February 21, 2019 from 1:00-4:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
November 1, 2018
2:00-5:00pm

Members Present: Devan Kansagara, MD, Chair; Alison Little, MD, MPH; Angela Senders, ND; Lynnea Lindsey, PhD (by phone); Leslie Sutton (by phone).

Members Absent: Eric Stecker, MD, MPH, Vice-Chair.

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

Also Attending: Adam Obley, MD, Moira Ray MD and Craig Mosbaek (OHSU Center for Evidence-based Policy); T.A. Merritt; Silke Akerson and Kelsey A. Fisher (Oregon Midwifery Commission); Mohamed Abdiasis and Shelly Das (Oregon Health Authority), Duncan Neilson (Legacy Health Systems); Amin Medjamia (Abiomed); Crispin Davies, MD (OHSU, by phone).

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1. CALL TO ORDER

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

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2. MINUTES REVIEW

Minutes from the 9/7/2018 meeting were reviewed and approved 5-0.

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3. STAFF REPORT

Coffman had nothing to report.

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4. SCOPE STATEMENTS FOR MULTISECTOR INTERVENTIONS

Livingston reviewed the draft scope statement for the topic of Multisector Interventions to Reduce the Frequency of Asthma Exacerbations. She reported that staff got a limited amount of conflicting feedback from the survey requested in June. Based on this feedback, staff eliminated several interventions including air quality alerts and reducing diesel emissions as they would be challenging for a CCO to influence. In addition, health behavior interventions were excluded and scope was limited to multisector interventions rather than clinical interventions.

Kansagara asked Livingston to explain the concept of multisector interventions. Livingston referenced a paper by the Centers for Disease Control, which describes three buckets of preventive interventions. The first is clinical prevention. The second is preventive interventions delivered to individuals in community settings, such as diabetes prevention programs or home assessments for asthma patients. The third category is community-wide interventions such as tobacco taxes or media campaigns. Much of the time the multisector interventions of interest to coordinated care organizations would be in the second category, though there may some interventions in the third category.

She said the asthma topic is of particular interest as there is an health plan incentive metric on-deck related to asthma. This report may be of interest as plans strategize efforts related to this metric.

Next was the scope statement on Community Health Workers for Patients with Chronic Disease. She said the population of high utilizers were added, and the language around substance use disorders was corrected to reflect contemporary usage. Obley recommended changing a period to a comma in the population description.

There was no public comment.

A motion was made to approve the draft scope statements as amended. **Motion approved 5-0.**

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5. Newer Interventions for Osteoarthritis of the Knee

Adam Obley reported that there were no public comments. Livingston said staff recommends no changes to the coverage guidance.

A motion was made to refer the draft coverage guidance to HERC as presented. **Motion approved 5-0.**

DRAFT HERC Coverage Guidance

Whole body vibration

Whole body vibration is not recommended for coverage (*strong recommendation*).

TENS

TENS is not recommended for coverage (*strong recommendation*).

Glucosamine/chondroitin

Glucosamine/chondroitin is not recommended for coverage (*weak recommendation*).

Glucosamine alone is not recommended for coverage (*strong recommendation*).

Chondroitin alone is not recommended for coverage (*weak recommendation*).

Platelet-rich plasma

Platelet-rich plasma is not recommended for coverage (*weak recommendation*).

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6. Planned Out-of-Hospital Birth

Livingston told the history of the existing coverage on this topic. The original report took about a year and a half and was controversial. She said there was no evidence from randomized controlled trials, since women were not willing to be randomized. EbGS did an evidence review and came up with an extensive list of risk factors. If a woman had or developed one of these risk factors, then an out-of-hospital birth would not be covered by OHP, including prior cesarean section, prior uterine rupture, breech presentation and twins. In addition, based on guidelines, the coverage guidance includes recommendations for other risk factors that should lead to a transfer of care to a hospital setting or a consultation with a hospital provider.

She summarized the evidence from the previous review. There was evidence that out-of-hospital birth offers many better outcomes for the mother, including a lower risk of cesarean section. However, there was also evidence babies born as a result of a planned out-of-hospital birth faced an increased risk of neonatal death; the risk may be about double compared to babies born in a hospital setting. Though rare, this increased risk was reflected in Oregon vital records data from 2012.

Livingston said several groups of stakeholders have requested revisions to the current coverage guidance. Some stakeholders requested removing requirements for consultation or transfer for conditions such as obesity. Others requested requiring additional documentation at specific gestational ages. Still others requested adding additional high-risk exclusion criteria, such as not covering out-of-hospital birth for women over the age of 35, primaparous women, or women at 41 or more weeks of gestation. Another OHA workgroup also asked OHA to determine if there was sufficient new evidence to reopen the coverage guidance. These requests are the reasons for today's rescan. The subcommittee needs to recommend whether or not to reopen the coverage guidance.

Moira Ray reviewed the rescan document from the meeting materials. She said that overall the evidence is consistent with the current coverage guidance, though some evidence suggests increased risks of harm to certain groups of patients.

Little asked whether the Oregon-based study included in the rescan was included in the current version of the coverage guidance. Obley said he believes that the information was available from vital statistics, but it was not available in the peer-reviewed literature at that time.

Livingston discussed how an updated literature search could potentially change the current coverage guidance. She said there is only one study identified that may shift the coverage guidance for certain high-risk groups (nulliparous women, women at or beyond 41 weeks 0 days of gestation and women over 35 years of age). However, there are strong values and preferences favoring out-of-hospital birth, and these increased risks were known at some level at the time of development of the prior coverage guidance. In addition, some of the guideline-based consultation or transfer criteria may be updated based on a review of the updated guidelines from various other groups.

Kansagara said it's important to think about the level of evidence you'd need to re-open the coverage guidances based on the low event rates and the preference-sensitive nature of this service. You would need pretty compelling data to dive into it again. He expressed doubt about whether the evidence presented would meet that standard. Otherwise, the subcommittee would be wading into what should be part of shared decisionmaking.

Kansagara invited public testimony.

Silke Akerson, a licensed direct-entry midwife and director of the Oregon Midwifery Council, spoke first. She declared no other conflicts of interest. While she agreed with the overall assessment that there isn't a huge amount of new evidence about the high-risk exclusion criteria, there are a number of consultation requirements which are not evidence-based. These criteria are functioning more as a practice guideline more than as an evidence-based coverage guidance. The level of detail in the consultation requirements is actually taking the place of shared decisionmaking.

She said that because the cost of a birth is something that is paid in total, the criteria completely removes access to the option of out-of-hospital birth when the guideline criteria are met for most people on OHP. She would like to see the consult criteria based on strong evidence. For example, all the consult requirements currently require consultation with a provider with hospital privileges. In some cases this adds significant cost and stress for the patient. Some could be addressed by a primary care provider. In other cases, a provider is consulting with a provider with hospital privileges such as maternal fetal medicine, but OHA is saying it is not an appropriate consultation, and instead consulting with another type of provider. For example, a midwife consulted with maternal fetal medicine on a case with anemia, but OHA consulted with a hematologist-oncologist and overruled the consultation. There was no cancer involved. She said the way the guidance is implemented is resulting in increased costs and complications in some specific instances (though not in the majority of the consultation requirements).

She also clarifed that the vital records report was reviewed during the original coverage guidance development before the Snowden study came out. At the time her group was concerned as the report looked at about 4000 births total (we have about 2000 out-of-hospital births per year in Oregon). Because the negative outcomes are rare, looking at only a few years' data can distort the picture. She said there has been a rigorous quality improvement program since the study period of 2012-2013. In

2012, the perinatal mortality rate was 3.9 per thousand for planned out-of-hospital births. In 2015 it was 0.98 per thousand; in 2016 it was 1.03 per thousand. She advised caution in looking at the Snowden study, or at small ranges of time for vital records. She said Oregon's data from birth certificates are more reliable in terms of correctly allocating outcomes by intended place of birth than birth certificates from other states. She also said that cerfified professional midwives are now regulated in 38 states and are not illegal in about half of states as previously stated.

Kelsey Fisher, a licensed direct entry midwife from Oregon, spoke next. She also serves as a member of the Board of Direct Entry Midwifery. She has no additional conflicts of interest. She said her board's rules are open right now. While she recognized that her board's roles are separate, she said there was evidence from the Midwives Alliance of North America (MANA) (which she described as a prospective data collection, typically looked at in an intention-to-treat model) showing that vaginal birth after cesarean can be safe for women who've previously had a successful vaginal birth. This data shows that risk for these women is much lower than for women without a prior vaginal birth. In fact, the outcomes are better than for primaparous women. The indication for cesarean can impact outcomes as well as other prior obstetrical history. She had a woman with several vaginal births, then a cesarean for breech who had to elect planned hospital birth despite a history of precipitous labor because OHP would not pay for out-of-hospital birth.

Ray said that the MANA study doesn't make comparisons to planned hospital birth so was not included in the scope for the draft review. In addition, providers voluntarily report data to this database in some states, though reporting is mandatory in Oregon.

Livingston introduced Duncan Neilson, who served as an appointed expert for the prior coverage guidance. He said his impression is that the the literature since the last HERC review hasn't added anything substantive and he agrees with what he has read in the meeting materials. In another forum he has heard the concerns Akerson raised and they are real. But addressing these isn't the job of the HERC. He said that the remaining work in this area for Oregon is threefold: addressing implementation issues with the current prior authorization process, disseminating the evidence as it has been compiled by HERC and addressing perceptions among providers statewide and among payers about out-of-hospital births. He said some payers don't understand the actual risks and are reticent to get involved or to be constructive. His primary issue is patient safety, and if things aren't implemented well and if the delivery community doesn't understand what is and isn't safe, we have actually compromised patient safety. Specifically, he said developing relationships for transfer of care for patients who do risk out of out-of-hospital births is important as relationships are crucial to successful transfers.

Livingston said there is a group working to address the implementation issues discussed, and these would not be in HERC's purview, except for the suggestion to drop some consultation criteria. Coffman said that if the other workgroup requests changes in the HERC guideline note associated with the Prioritized List, HERC could consider that request.

The subcommittee also briefly reviewed the scope statement from the meeting materials. The scope statement is new to the process since the 2015 report was initiated. If the coverage guidance were to be re-opened, this scope statement would be used for the new review, and it was used for conducting the rescan evidence search.

During this discussion, staff discovered that an old version of the scope statement had made its way into the rescan document. The correct version has delivery mode as a critical outcome rather than an

important outcome, and adds breastfeeding as an important outcome. There is a new key question about whether the harms vary by provider characteristics and a contextual question about the expected rate of transfer to hospital for out-of-hospital birth.

A motion was made to approve the staff recommendation not to re-open the coverage guidance. **Motion approved 5-0.** *(Note: On November 8, 2018, HERC did not accept the EbGS recommendation and asked EbGS to re-open this coverage guidance.)*

After a break, another motion was made to approve the scope statement as corrected, including the revisions mentioned by Livingston and displayed during the meeting (rather than the version from the meeting materials). **Motion approved 5-0.**

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7. Temporary Percutaneous Mechanical Circulatory Support with Impella Devices

Livingston reviewed the discussion questions from the public comment disposition as presented in the meeting materials. Livingston clarified one item in the public comment disposition (the last item in the discussion table); there *were* inoperable patients in the PROTECT II study, but no subgroup analysis of these patients was performed. She also noted that Dr. Stecker was not able to be present but sent a letter (included in the meeting materials) suggesting revisions to the staff proposal, and reviewed this letter with the subcommittee.

Coffman introduced Crispin Davies, the appointed expert for this topic who reported no conflicts of interest. Davies said the issue of surgical turndowns is partially addressed by the Society of Thoracic Surgery (STS) score but not in the way you would expect. People with higher STS scores who could not have coronary artery bypass grafting (CABG) actually do worse. This could be because if you're more sick you might not do well with anything. He also echoed Stecker's concern about the proliferation of medical devices where we don't have good evidence. He acknowledged the cost of about $25,000 per device.

Despite that, he said he worries that Impella may be a useful tool. It's difficult when you're examining something that is like a seatbelt or airbag, when it may not be deployed for an individual. He believes PROTECT II is so poor it doesn't provide useful information. He would like to see a better study with the correct endpoint (not changed mid-trial) and using the Impella 3.5, which could make quite a bit of difference. Such a study may also include interventionalists who are more skilled in placing the device. He said that a national payer might force the company to conduct a better study but that Oregon on its own may harm Oregonians by denying payment for this device without motivating the manufacturer to conduct a trial. He said that he found the previous indication for the device somewhat troubling, but the extension of the FDA indication in February to those with normal left ventricular function even more disturbing, as this opens it up to all comers. A small change in these criteria can make a big difference in terms of population. He would not recommend coverage be extended to patients with normal ventricular function.

Little requested Obley give a brief recap regarding the PROTECT II trial. Obley reviewed the inclusion criteria, interventions and results from PROTECT II. Kansagara noted that the cardiologists did more rotational atherectomy on patients with Impella. Kansagara said that additional rotational atherectomy may open the arteries more, benefitting patients, but may also have harms by sending material downstream. He also noted that need for revascularization was the primary demonstrated benefit (and

was not originally included). Obley said that most people would prefer to avoid repeat revascularization but that it would not generally be considered a critical outcome. In addition, an elective decision in an unblinded trial can introduce an element of bias. Davies said that revascularization can be important to patients, as it can affect employment. In addition, blinding a trial with Impella is not possible because the device is visible on procedure-related x-rays.

Kansagara also noted that the study was stopped for futility. Davies noted that about 200 additional patients were randomized before the study was stopped, and that there was a temporal trend which might have produced a more positive result if the study had been allowed to continue. Obley agreed that the improvements were better after the first year of the trial.

Obley then reviewed a table showing which populations have and have not been studied, including noncomparative data.

Amin Medjamia, MD, of Abiomed, offered public testimony. He participated in the PROTECT II trial though he did not design it. He noted that, while the study was cancelled based on preliminary data from a smaller subset of patients, the results reviewed today include results from a larger group of patients, some of whom where randomized while the preliminary data was being analyzed. The larger data is more positive than the preliminary data. He also said Impella is different from other alternatives in that it reduces the ischemic threshold of the heart. It is difficult to conduct a clinical trial in an emergent setting. Out of 10 trials attempted, only 2 have completed, and these are only powered to show improved hemodynamic support. Others have stopped for low enrollment.

He focused on the high-risk percutaneous coronary interventions (PCI) population. He said it's a small population. It's the surgical turn-downs (those not eligible for surgery). In PROTECT II they asked the physicians to call for a surgical consult to see whether they were eligible for CABG. Sixty-seven percent were not eligible, but the remaining patients were so compromised that the physicians didn't bother to call for a surgical consultation; it was obvious. He said at the time the study was designed, the assumption was that the complication rate was really low in these patients. This was the reason for the composite outcome including 10 adverse events. He described several issues with the PROTECT II study which may have skewed the results towards ineffectiveness and harms. He said that a lack of coverage in Oregon would create tiered coverage, with the sickest, most vulnerable patients lacking coverage for this device. He also mentioned several professional societies which reference the device in guidelines.

Kansagara said that the subcommittee feels the responsibility to provide the best coverage. The approval of coverage for some things takes away from other things. Livingston asked Obley to address Medjamia's comments. Obley said that giving the most generous interpretation of the subsidiary analyses of the PROTECT II study, if you were to re-do PROTECT II and add an operator experience requirement, accept the newer definition of MI and include only the newer models of Impella, it might well be a very different trial, though he would not say whether it would be better or worse. However, post hoc analyses introduce bias. In particular, redefining MI post hoc is problematic as one could have chosen any enzyme cutoff which produced the most positive outcome.

Davies said post hoc analysis of a negative trial always makes him feel very uncomfortable. Obley addressed the ischemic protection in the cardiogenic population. He said the left ejection fraction didn't differ between those using balloon pumps and those using Impella. While he understands the concept, he doesn't know that it has been proven in the trials. He said there is an ongoing trial comparing venoarterial extracorporeal membrane oxygenation (ECMO) with Impella. It is a small trial.

Kansagara said the PROTECT II trial itself was reasonably well-designed, but the results may not be applicable to current practice. For instance, it didn't use the Impella 3.5 devices currently in use. In addition, the way the trial was conducted in such a way that it adds risk of bias for revascularization but not mortality. He also commented that it is replacing intra-aortic balloon pumps, though these have issues as well. Davies added that the intra-aortic balloon pumps don't work very well according to the hemodynamic analysis, though it could be that neither device works.

Referring to Obley's table, he said there are several populations for which there is essentially no trial evidence. Then there is elective high-risk PCI. The latter have not had a myocardial infarction, and who have stable coronary disease. He asked Davies about the prognosis for these patients, without PCI. Davies said they would have lifestyle-limiting angina, but their rate of death and myocardial infarction wouldn't change after PCI. He said this sort of chest pain is significant for patients, as it affects whether they can get to their mailbox or play with their grandchildren. Kansagara asked whether the PROTECT II patients had refractory angina. Davies said in theory yes, but it isn't clear how refractory it was. In 2018 the only patients who should get stenting are those whose symptoms can't be managed with medication.

Davies said there is another important group to consider which hasn't been studied, people requiring high-risk PCI who have non-ST elevation myocardial infaction (NSTEMI). These people have a small myocardial infarction (MI) and are then stuck in the hospital. These are about half of the people receiving PCI now, and the consensus is that for these patients, the procedure is lifesaving. He said this group is wholly unrepresented in the data, but is in the sweet spot for benefit from stenting.

Livingston said that you should be able to study this population. Davies agreed. He said for some reason it was an exclusion from PROTECT II because it has to be done in a limited timeframe while the patient is in the hospital. Obley asked whether in that scenario you would use Impella if the patient had a normal ejection fraction. Davies said it would be unlikely; generally you would use it only with ejection fraction of 30 or less and only after a diagnostic angiogram.

Kansagara reviewed the draft recommendation for coverage only as a bridge to transplant. He said this is based on broad clinical consensus about this population despite lack of evidence. Davies said this is an important population, especially in a state that now has no transplant program, so that patients can travel to a state where they can get a transplant. Livingston reviewed the staff recommendation for this population, which requires a team decision. The group agreed on this portion and went on to discuss other populations.

Discussion turned to additional populations. Livingston presented some options for additional language. Kansagara said that the committee needs to consider precedent. He said the decision is not dissimilar in terms of evidence from some other topics discussed earlier in the year. He wanted to make sure this decision doesn't disrupt our standards for evidence.

There was extensive discussion about adding coverage for two populations. For those with stable angina, the subcommittee found no rationale to add coverage, as this would go against previous decisions for nonfatal conditions. For the NSTEMI population, the subcommittee elected to add coverage based on the rationale that PCI is potentially lifesaving for this population. There is no current evidence but a compelling rationale for efficacy, and in the absence of Impella these patients may not

receive PCI due to liability concerns of providers. Additionally, given the widespread use of Impella devices, it is less likely that a randomized controlled trial would be published examining this population.

The draft coverage guidance will be referred to HERC as amended. **The motion was approved 4-0, with Sutton not present.**

[NOTE: Following the EbGS meeting, HERC staff decided that given the subcommittee decision to add coverage for NSTEMI, it was appropriate to add a GRADE table about the acute myocardial infarction population. This population was within scope, but a separate GRADE table was not initially included because of the lack of evidence found. By adding this GRADE table post-hoc, the evidence review and the rationale for including coverage of the NSTEMI population could be made more transparent].

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8. Adjournment

The meeting was adjourned at 5:00 pm. Gingerich said that next topics depend on what HERC decides with regards to the scope statements discussed previously. The next meeting is scheduled for February 7, 2019 from 2:00-5:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070.

HERC & VbBS meetings 1/17/2019

Contacts: Allyson Hagen, 503-449-6457, allyson.hagen@state.or.us (media inquiries)
Daphne Peck, 503-373-1985, herc.info@state.or.us (meeting information or accommodation)

Oregon Health Evidence Review Commission meets January 17th in Wilsonville

What: A public meeting of the Health Evidence Review Commission

When: January 17, 1:30-4:30 p.m.

Where: Wilsonville Holiday Inn, Dogwood Room, 25425 SW 95th Avenue, Wilsonville, Oregon
The public also may attend via a listen-only conference line 1-888-204-5984, participant code 801373

Agenda:

HERC will consider the following topics:

- Value-based Benefits Subcommittee Report*
- Coverage guidances and associated changes to the Prioritized List:
  - Temporary Percutaneous Mechanical Circulatory Support with Impella Devices
  - Newer Interventional Procedures for GERD

*Topics which remain unresolved at the conclusion of the morning's VbBS meeting will not be heard by HERC until a later date. Public notice of tabled topics will be announced 28-days prior their next scheduled discussion***. *A vote by HERC will not be taken on the potential reprioritization of certain chronic pain conditions until the March meeting.***

For more information about the meeting, visit the committee's website at https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Meetings-Public.aspx. The meeting agenda and materials will be available one week before the meeting.

HERC's Value-based Benefits Subcommittee meets January 17th in Wilsonville

What: A public meeting of the Health Evidence Review Commission's Value-based Benefits Subcommittee

When: January 17, 8:00 a.m.-1:00 p.m.

Where: Wilsonville Holiday Inn, Dogwood Room, 25425 SW 95th Avenue, Wilsonville, Oregon
The public also may attend via a listen-only conference line 1-888-204-5984, participant code 801373

Agenda:

Items scheduled for discussion could include, but may not be limited to, the following topics:

- Fecal calprotectin
- Pulmonary rehabilitation
- Procalcitonin
- Failure to thrive
- Revisions to existing guidelines:
    - Human donor breast milk
    - Diabetes prevention program
- 2020 Biennial review:
    - Hidradenitis suppurativa
    - Reprioritization of certain chronic pain conditions
    - Sacroiliac joint dysfunction
- Changes to the Prioritized List arising from coverage guidances:
    - Temporary Percutaneous Mechanical Circulatory Support with Impella Devices
    - Newer interventional procedures for GERD
- Various straightforward coding and guideline changes and corrections

For more information about the meeting, visit the committee's website at https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Meetings-Public.aspx. The meeting agenda and materials will be available one week before the meeting.

# # #

Everyone has a right to know about and use Oregon Health Authority (OHA) programs and services. OHA provides free help. Some examples of the free help OHA can provide are:

- Sign language and spoken language interpreters
- Written materials in other languages
- Braille
- Large print
- Audio and other formats

If you need help or have questions, please contact Daphne Peck at 503-373-1985, 711 TTY or herc.info@state.or.us at least 48 hours before the event. Written comments are also welcome at herc.info@state.or.us.

Health Technology Assessment Subcommittee:

2/21/2019: Extended Stay Centers Guideline (per HB 4020)

4/18/2019 Spinal Cord Stimulators for Chronic Back Pain
Extended Stay Centers Guideline (review public comments)

Evidence-based Guidelines Subcommittee

2/7/2019 Community Health Workers
Topic Orientation: Planned Out-of-Hospital Birth

4/4/2019 Community Health Workers (review public comments)
Planned Out-of-Hospital Birth (review initial draft report)

2019 Transformation and Quality Strategy

OHA Transformation Center Technical Assistance for CCOs

Coordinated care organization (CCO) staff are invited to participate in technical assistance for developing the 2019 Transformation and Quality Strategy (TQS). This series is hosted by the OHA Transformation Center.

Background: In 2018 CCOs submitted their first TQS, which aimed to move health transformation by aligning and coordinating internal CCO health transformation and quality initiatives. The programs and projects included in each CCO's TQS are a showcase of current CCO work that aims to make significant movement in health system transformation. Additionally, the work highlighted in the TQS is not a comprehensive catalogue or full representation of the CCO's body of work.

Audience: CCO transformation staff, quality staff and subject area leads, depending on webinar topic

Contact: If you have questions, please contact Anona Gund (anona.e.gund@state.or.us or 971-673-2832).

Webinars	
Webinars will be recorded and available on the Transformation Center website, as well as at the registration links below: www.oregon.gov/oha/HPA/dsi-tc/Pages/Transformation-Quality-Strategy-Tech-Assist.aspx	
January 16, 9:30-10:30 a.m.	**2019 TQS Technical Assistance: TQS Purpose and Template Walk-through** Register here: https://attendee.gotowebinar.com/register/6935482248329845506 OHA staff will share the purpose of the TQS, compare the TQS to other required reports, review the 12 components, discuss timeline and format, walk through the required template and answer questions.
January 23, 2:30-3:30 p.m.	**2019 TQS Technical Assistance: Social Determinants of Health** Register here: https://attendee.gotowebinar.com/register/277356600984415747 This webinar will provide a deeper dive on the Social Determinants of Health component of the TQS. OHA staff will discuss expectations and rationale specific to this component, provide examples, and answer questions.
February 6, 2:30-3:30 p.m.	**2019 TQS Technical Assistance: Health Equity and CLAS Standards** Register here: https://attendee.gotowebinar.com/register/4841980223207634945 This webinar will provide a deeper dive on the Health Equity and CLAS Standards components of the TQS. OHA staff will discuss expectations and rationale specific to these components, provide examples, and answer questions.
February 7, 2:30-3:30 p.m.	**2019 TQS Technical Assistance: Access** Register here: https://attendee.gotowebinar.com/register/3725948433224254977 This webinar will provide a deeper dive on the Access component of the TQS. OHA staff will discuss expectations and rationale specific to this component, provide examples, describe what resources are available to CCOs, and answer questions.

Office Hours	
CCO staff are invited to join by webinar or conference line to ask questions about developing and submitting their CCO's Transformation and Quality Strategy. CCO staff may join the office hours at any point during the scheduled time. The office hours will not be recorded, but the online FAQ document will be updated after each call. All technical assistance materials for the 2019 TQS, including the FAQ, are available here: www.oregon.gov/oha/HPA/dsi-tc/Pages/Transformation-Quality-Strategy-Tech-Assist.aspx	
Conference line for all scheduled office hours: 866-390-1828; **Participant code:** 4628003	
January 24, 11:30 a.m.-12 p.m.	Register here: https://attendee.gotowebinar.com/register/5279820047040048643
February 13, 11:30 a.m.-12 p.m.	Register here: https://attendee.gotowebinar.com/register/8077189833846492931
March 6, 11:30 a.m.-12 p.m.	Register here: https://attendee.gotowebinar.com/register/3424714133051893763

DRAFT - as of 1/9/2019

PIP Metric: New Opioid Patients Days Supply of First Opioid Prescription

Measure Basic Information

Name and date of specifications used: Percent of patients with at least one opioid prescription in one year, who have no opioids prescribed in the prior six months, among patients in the population by days' supply (i.e., ≤3, 4–7, 8–13, and ≥14).

Data Source: MMIS/DSSURS

Measurement Period: 12 months

Negative Medication History: 6 months

Baseline Period: 1/1/2018 – 12/31/2018

Denied claims: Included ☐ Not included ☒

Member type: CCO A ☒ CCO B ☒ CCO G ☐

Measure Details

Denominator: Count of patients at least one opioid prescription filled in the measurement year, who have no opioids prescription filled in the prior six months.

Required exclusions for denominator: People with a diagnosis of cancer, or palliative care, or hospice care in the measurement year.

All buprenorphine prescriptions (use the drug codes in CDC NDC list)

Prescriptions not typically used in outpatient settings or over the counter medications.

Numerator: Number of patients with at least one opioid prescription in measurement year, who had no opioids filled in the prior six months, among patients in the population by days supply (i.e., ≤3, 4–7, 8–13, and ≥14) in their first filled opioid prescription.

What are the continuous enrollment criteria: 6 months from negative medication history start date to first opioid prescription fill date.

What are allowable gaps in enrollment: none

Ages: 12 years of age and older as of first opioid prescription fill date

Define Anchor Date (if applicable): first opioid prescription fill date

Grievance System

Grievance System Reporting
January 2019

July 1, 2018 began the data collection period when the new Grievance and Appeal Log and the Grievance System Report are required to be submitted at the end of the quarter.

Grievance System Reporting

- The current documents are:
  Grievance and Appeal Log Instructions – July 1, 2018
  Grievance and Appeal Log Version 2 – July 1, 2018
  Grievance System Report – July 1, 2018
  These documents are located on the website here:

http://www.oregon.gov/oha/HSD/OHP/Pages/CCO-Contract-Forms.aspx

- The published reports are on this website:

https://www.oregon.gov/oha/HSD/Medicaid-Policy/Pages/2017-2022-Quarterly-Annual-Reports.aspx

Grievance and Appeals Reporting

- ✓ CCOs must ensure all members have equal access to your CCO grievance system. If part of the grievance process is delegated, the CCO must ensure the subcontractor meets the requirements consistent with OAR 410-141-3225 through 410-141-3255. This includes reporting grievances filed by all CCO members. Exhibit I (1)(c).
- ✓ Standardization of codes and formats when submitting the reporting tool ensures accuracy when compiling CCO data.
- ✓ CCOs should review their data on the Website to ensure it accurately reflects what their CCO submitted.
- ✓ All CCOs are to use the enrollment numbers from their 834 information – the average number over the 3 months of the quarter.
- ✓ Over the past two quarters the data submissions have improved.

Questions?

Twelve month look at complaints
in the six main categories and the sub categories.

	10/01/2017 - 12/31/2017	01/01/2018 - 03/31/2018	04/01/2018 - 06/30/2018	07/01/2018 - 09/30/2018*	12 month total
ACCESS TO CARE					
a) Provider's office unresponsive, not available, difficult to contact for appointment or information.	413	377	278	114	1182
b) Plan unresponsive, not available, difficult to contact for appointment or information.	33	27	48	68	176
c) Provider's office too far away, not convenient	26	45	70	55	196
d) Unable to schedule appointment in a timely manner.	81	113	162	134	490
e) Unable to be seen in a timely manner for urgent/emergent care	24	28	32	39	123
f) Provider's office closed to new patients.	20	28	14	16	78
g) Referral or 2nd opinion denied/refused by provider.	17	23	37	34	111
h) Referral or 2nd opinion denied/refused by plan.	12	22	10	9	53
i) Provider not available to give necessary care	146	147	156	220	669
j) Eligibility issues	212	91	83	46	432
k) Female or male provider preferred, but not available	2	3	7	3	15
l) NEMT not provided, late pick up w/missed appointments, no coordination of services	1355	1303	2178	2750	7586
m) Dismissed by provider as a result of past due billing issues	1	5	0	2	8
n) Dismised by clinic as a result of past due billing issues	1	1	1	1	4
TOTAL:	2343	2213	3076	3491	11123

INTERACTION WITH PROVIDER OR PLAN					
a) Wants to change providers; provider not a good fit.	119	102	120	187	528
b) Provider rude or inappropriate comments or behavior	292	509	346	324	1471
c) Plan rude or inappropriate comments or behavior	29	39	46	60	174
d) Provider explanation/instr. inadequate/incomplete	617	697	465	214	1993
e) Plan explanation/instr. inadequate/incomplete	142	153	142	165	602
f) Wait too long in office before receiving care	47	46	35	21	149
g) Member not treated with respect and due consideration for his/her dignity and privacy	27	28	25	29	109
h) Provider's office or/and provider exhibits language or cultural barriers or lack of cultural sensitivity, interpreter services not available.	7	3	7	10	27
i) Plan's office or staff exhibits language or cultural barriers of lack of cultural sensitivity.	3	5	5	2	15
j) Member has difficulty understanding provider due to language or culteral barriers.	3	0	3	0	6
k) Lack of communication and coordination among providers.	57	61	50	56	224
l) Dissmissed by provider (member misbehavior, missed appts. etc.)	14	23	24	21	82
m) Dissmissed by clinic (member misbehavior, missed appts. etc.)	17	16	15	14	62
TOTAL:	1374	1682	1283	1103	5442

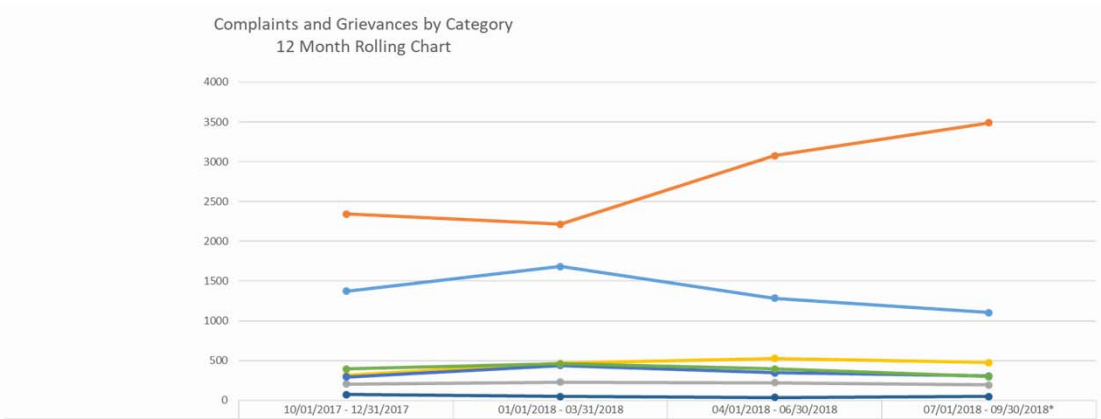
CONSUMER RIGHTS					
a) Provider's office has a physical barrier	17	17	13	0	47
b) Concern over confidentiality.	26	23	22	24	95
c) Client not involved with treatment plan. Member choices not reflected in treatment plan. Member disagrees with treatment plan.	84	103	90	97	374
d) No choice of clinician	15	26	42	12	95
e) Fraud and financial abuse	10	18	13	16	57
f) Provider bias barrier (age, race, religion, sexual orientation, mental/physical health status)	34	22	17	26	99
g) Complaint/appeal process not explained, lack of adequate or understandable NOA	6	7	2	0	15
h) Not informed of consumer (Member) rights	2	6	5	7	20
i) Denied member access to medical records	4	1	4	6	15
j) Did not respond to members request to amend in-acurrate or incomplete information in the medical record (includes right to submit a statement of disagreement)	4	5	6	3	18
k) Advanced or Mental Health Directive not discussed, offered or followed.	1	2	6	2	11
l) Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as spedified in other Federal regulations on the use of restraints and seclusion. Restraint or seclusion used other than to assure members immediate safety.	2	0	0	2	4
TOTAL:	205	230	220	195	850

QUALITY OF CARE					
a) Adverse outcome, complications, misdiagnosis or concern related to provider care.	78	147	191	182	598
b) Testing/assessment insufficient, inadequate or omitted	45	50	60	56	211
c) Concern about prescriber or medication or medication management issues	108	152	142	124	526
d) Member neglect or physical, mental or psychological abuse	10	7	13	22	52
e) Unsanitary environment or equipment	35	79	72	36	222
f) Lack of appropriate individualized setting in treatment	37	31	48	56	172
TOTAL:	313	466	526	476	1781

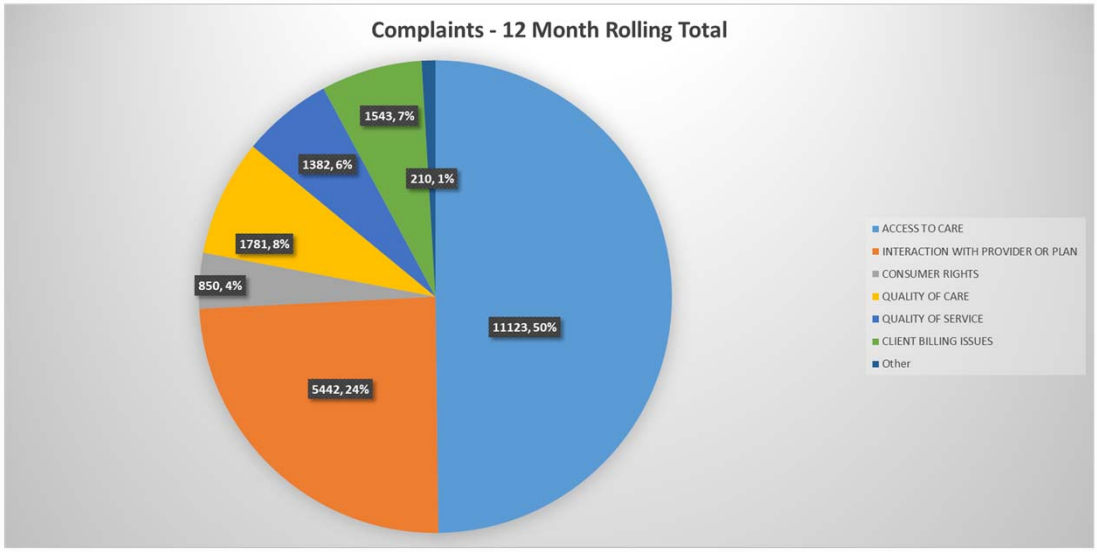
QUALITY OF SERVICE					
a) Delay, quality of materials and supplies (DME) or dental	122	175	137	157	591
b) Lack of access to medical records or unable to make changes	10	7	3	4	24
d) Benefits not covered	161	257	205	144	767
TOTAL:	293	439	345	305	1382
CLIENT BILLING ISSUES					
a) Co-pays	5	16	17	60	98
b) Premiums	1	0	103	0	104
c) Billing OHP clients without a waiver	387	441	274	239	1341
TOTAL:	393	457	394	299	1543

Twelve month totals	**10/01/2017 12/31/2017**	**01/01/2018 03/31/2018**	**04/01/2018 06/31/2018**	**07/01/2018 09/30/2018**
Total complaints received	4995	5537	5882	5917
Total average CCO enrollment	1,106,876	1,179,176	1,217,091	1,185,394
Rate per 1000 members	4.51	4.70	4.83	4.99

Beginning Calendar Year 2017 4th Quarter the Fee for Service data is included.



	10/01/2017 - 12/31/2017	01/01/2018 - 03/31/2018	04/01/2018 - 06/30/2018	07/01/2018 - 09/30/2018*
ACCESS TO CARE	2343	2213	3076	3491
INTERACTION WITH PROVIDER OR PLAN	1374	1682	1283	1103
CONSUMER RIGHTS	205	230	220	195
QUALITY OF CARE	313	466	526	476
QUALITY OF SERVICE	293	439	345	305
Client Billing	393	457	394	299
Other	74	50	38	48



Looking at the data from a
Physical Health,
Behavioral Health,
Dental,
NEMT
and LTC/LTSS
perspective.

CY 2018 Quarter 3 July – Sept 2018	Physical Health	Behavioral Health	Dental	NEMT	LTC/LTSS
ACCESS	279	26	231	2782	0
INTERACTION WITH PROVIDER/PLAN	601	83	183	233	1
CONSUMER RIGHTS	117	9	69	0	0
QUALITY OF CARE	296	21	84	57	1
QUALITY OF SERVICE	75	0	32	1	0
BILLING ISSUES	231	0	10	3	0
GRAND TOTAL	**1599**	**139**	**609**	**3076**	**2**

2019 Delivery Service Network Reporting

DSN Capacity and Narrative Reports

Allison Tonge, Quality Assurance

Oregon Health Authority

CFR and OAR applicable to DSN Reports

42 CFR 438.66
42 CFR 438.68
42 CFR 438.206 and 457.1230
42 CFR 438.207

OAR 410-141-3220
OAR 410-141-3160

Oregon Health Authority

2019 CCO Contract

- Exhibit B, Part 4 Providers and Delivery System
- Exhibit G

2019 CCO Contract Exhibit G

CCOs submit two reports to OHA on July 1st

- Delivery Service Network (DSN) Narrative Report
- Delivery Service Network (DSN) Capacity Report

The template for 2019 DSN Capacity and Narrative Reports is posted on OHA's website:

https://www.oregon.gov/oha/HSD/OHP/Pages/CCO-Contract-Forms.aspx

General DSN 2019 Requirements

- DSN Capacity Report represents the CCO provider network at the time of Contract execution – January 1st
- DSN service providers reported to OHA in DSN Capacity Report, whether employed by or under subcontract with the CCO, must have agreed with CCO to provide the described services or items to Medicaid and Fully Dual Eligible Members.
- DSN Capacity Report is a 'snapshot in time' of CCO provider network. CCOs must update the DSN reports any time there has been a Material Change in the CCO's operations that would affect adequate capacity and services, and upon OHA request.

OHA Review of 2019 DSN Reports

To comply with Agency oversight and monitoring requirements in 42 CFR 438.66 and 42 CFR 438.206 & 207, OHA will review and evaluate CCO DSN Reports. Results of this evaluation will be posted on OHA's website, annually.

In 2019, OHA has contracted with Health Services Advisory Group (HSAG) to:

- Perform an annual review of CCO DSN Reports
- Perform review(s) of CCO provider network material changes, as needed

2019 Review Plan for DSN Reports

- OHA is coordinating with HSAG to develop 2019 DSN review protocol
- CCOs will be provided copies of final review protocol
- CCOs will be provided an opportunity to review initial HSAG evaluation results and provide a response to HSAG and OHA prior to the 2019 report being finalized
- The posted DSN report required by 42 CFR §438.66(e)(3) will refer only to final analysis

Questions?

HSD Quality Assurance Coordinators at
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Tressa Perlichek, HSD Hearings and Quality Assurance Manager at
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