Oregon Health Authority

Quality and Health Outcomes Committee
AGENDA

MEETING INFORMATION
Meeting Date: February 13, 2017
Location: HSB Building Room 137A-D, Salem, OR • **Parking**: Map ◦ Phone: 503-378-5090 x0
Call in information: Toll free dial-in: 888-278-0296 Participant Code: 310477
All meeting materials are posted on the QHOC website.

Time	Topic	Owner	Materials
Clinical Director Workgroup			
9:00 – 9:15	**Welcome** - **Introductions and Announcements**	Mark Bradshaw	-Speaker's contact sheet *(1)* -Nov. 2016 notes *(2 – 8)* -Metrics update *(9 – 10)* -PH update *(11 – 12)*
9:15 – 9:25	**P&T Update**	Roger Citron	P&T website
9:25 – 9:35	**Hep-C Case Management Implementation check in**	All	-Recommendations -HCV Case management *(13 – 14)* -Hepatitis C Case management *(15 – 18)* -Treatment considerations
9:35 – 10:15	**HERC update**	Cat Livingston	HERC materials *(17 – 97)*
10:15 – 10:35	**LARC Benefit Implementation**	Kim Wentz	-Presentation slides *(97 – 107)* -Coverage guidance *(108)* -Grade-Informed Framework *(109 – 114)* -Guideline Note *(115)* -HERC letter *(116 – 117)* -LARC Update *(118-120)* -CMS letter: planning services and supplies *(121 – 127)* -Improving access to LARC contraception *(128 – 153)*
10:35 – 10:45	**Back Guideline check in** - **Taper plans**	All	Long-acting opioids Short-acting opioids
10:45 – 11:00	**BREAK**		
Learning Collaborative			
11:00 – 12:30	**Applied Behavioral Analysis**		-Agenda *(154)* -Current rule *(155 – 156)* -ABA Guideline note (157-158) -ABA provider resources *(159-164)* -Presentations *(165 – 191)*
2:30 – 1:00	**LUNCH**		
Quality and Performance Improvement Session			
1:00 – 1:10	**QPI Update – Introductions**	Lisa Bui	
1:10 – 1:30	**Complaints & Grievances**	Barbara Carey Lisa Bui	-Questions to CCOs re: quarterly data reporting *(192)*
1:30 – 2:15	**2017 QAPI**	Lisa Bui Darcy Strahan	-Presentation Slides *(193 – 198)*
2:15 – 2:45	**T Plan / Quality Strategy**	Lisa Bui	-Presentation Slides *(199 – 204)*
2:45 – 3:00	**Items from the floor**	All	

Upcoming March QHOC: EDIE / Pre-Manage

Chair contact info: mark.bradshaw@allcarehealth.com
OHA contact info: lisa.t.bui@state.or.us

Topics may be subject to change due to availability

SPEAKER CONTACT SHEET
QHOC – February 2017

AGENDA TOPIC	SPEAKER	CONTACT INFO
P&T Committee Update	Roger Citron, RPh	Roger.a.citron@state.or.us
Health Evidence Review Commission (HERC) Update	Cat Livingston, MD, MPH	Catherine.livingston@state.or.us
Long-Acting Reversible Contraceptive (LARC)	Kim Wentz, MD, MBA	Kim.r.wentz@state.or.us
Hepatitis –C Case Management	Kim Wentz, MD, MBA	Kim.r.wentz@state.or.us
Learning Collaborative: Applied Behavioral Analysis	Sara Wetherson Eric Frombonne, MD Bob Nickel, MD Tracy Muday, MD Sondra Marshall, MD	Sarah.e.wetherson@state.or.us fombonne@ohsu.edu nickelr@ohsu.edue tmuday@docshp.com sbmarshall@stcharleshealthcare.org
Complaints And Grievances Reporting	Lisa Bui Barbara Carey	Lisa.t.bui@state.or.us barbara@healthshareoregon.org
2017 Quality Assessment Performance Improvement (QAPI)	Darcy Strahan Lisa Bui	Darcy.strahan@state.or.us Lisa.t.bui@state.or.us
Quality And Transformation Plan	Lisa Bui	Lisa.t.bui@state.or.us
QHOC CHAIRS		
Medical	Mark Bradshaw, MD	Mark.bradshaw@allcarehealth.com
Behavioral Health	Athena Goldberg, LCSW	Athena.goldberg@allcarehealth.com
Oral Health	Dayna Steringer	dsteringer@live.com
Quality	Jennifer Johnstun	jen@ohms1.com
OHA LEADS		
Medical	Kim Wentz, MD, MBA	Kim.r.wentz@state.or.us
Behavioral Health	Royce Bowlin, MS, CPRP	Royce.a.bowlin@state.or.us
Oral Health	Bruce Austin, DMD	Bruce.w.austin@state.or.us
Quality	Lisa Bui, MBA	Lisa.t.bui@state.or.us

QHOC Website:
http://www.oregon.gov/oha/hpa/csi/Pages/Quality-and-Health-Outcomes-Committee.aspx

Questions:
OHA.qualityquestions@state.or.us or call Lisa Bui at 971-673-3397

Outcomes Committee (QHOC)

016 Meeting Notes

Chair- Mark Bradshaw (All Care)

Co-Chairs- Jennifer Johnstun (Primary Health)

Attendees: (*in person*) Susan Arbor (OHA/HSD); Sarah Bartlemann (OHA/Analytics); Maggie Bennington-Davis (HealthShare); Graham Bouldin (HealthShare); Mark Bradshaw (All Care); Jim Calvert (CHA); Barbara Carey (Health Share); Jody Carson (HealthInsight); Roger Citron (OHA/OSU); Cheryl Cohen (Health Share); Laurence Colman (GOBHI); Donna Erbs (HealthInsight); Linda Fanning (HealthInsight); (IHN/CCO); Mike Franz (PacificSource); Jim Gaudino (OHSU/Gaudino Consult.); David Geels (WOAH/Coos Co MH); Walter Hardin (Tuality); Rosanne Harksen (OHA/HSD); Theresa Heidt (Yamhill CCO); Hank Hickman (OHA/HSD); Todd Jacobsen (GOBHI); Jennifer Johnstun (Primary Health); Charmaine Kinney (Mult. Co./Health Share); Alison Little (PacificSource); Cat Livingston (HERC); Andrew Luther (OHMS); Laura Matola (AllCare); Laura McKeane(AllCare); Kevin McLean (FamilyCare); Bhavesh Rajani (Yamhill CCO); Nancy Siegel (HealthInsight); Ariel Smits (OHA/HERC); Dayna Steringer (DK Strategies); Anna Stern (WVCH); Anna Warner (WOAH); Kim Wentz (OHA/HSD); and Amarissa Wooden (WOAH/NBMC)

By phone: Jim Amato (FamilyCare); Ellen Altman (IHN/CCO); Kevin Ewanchyna (IHN/CCO); Ruth Galster (UHA); Debbie Standridge (UHA; Tiffany Garcia; Cindy Weber (Providence); Kimberly Carter; Kathy Cereghino (OHA); PacificSource; WVCH; AllCare; HealthShare; Trillium

CLINICAL DIRECTORS SESSION	
Introductions/ Announcements	**Announcements:** ▪ Seeking nominations for new Chair-person; ▪ There will be no December QHOC meeting.
Pharmacy & Therapeutics Update- Roger Citron	▪ Next meeting this Thursday. Will discuss Drug Use Review and quarterly reports; ▪ Synages (new) will need to be on the agenda; ▪ PA criteria- look at the appropriateness; ▪ New drugs- CF, Opioid analgesics, MS;
Back Guideline Check-in	▪ Updates given and CCO's asked what their experiences have been.
Public Health Hep C presentation- Dr. Ann Thomas, OHA Public Health	▪ Overview; ▪ Acute cases of HCV, Oregon vs US, 2007-2013; ▪ Chronic HCV infection; ▪ Total reported cases of chronic HCV; ▪ Chronic viral hepatitis cases by year of liver cancer diagnosis, Oregon, 1996-2012; ▪ Age-adjusted mortality from HCV and HIV in Oregon and from HCV nationally, 1999-2013; ▪ Rationale for Baby Boomer Recommendation: NHANES 2003-2010; ▪ US Preventive Service Task Force recommendation for one-time screening of all persons born between 1945-1965; ▪ Comparison of HCV cost effectiveness with other preventive services;

	▪ Strategies to improve rates of HCV testing; ▪ Reflex testing for HCV; ▪ Strategies for CDS using Epic; ▪ Impact of CDS on HCV screening; ▪ Linkage to other preventative services; ▪ New funding opportunity; ▪ Proposal – Year 1; ▪ Proposal-Years 2-4.
Other discussion	▪ Have all CCO's received the survey from Jonnaliz Corbett? ▪ For January the Learning Collaborative will be focused on Autism ABA. Anyone with expertise are invited to join in the presentation; ▪ Discussed OARs and guideline notes. More discussion is needed on ABA.
USDOJ/OHA Agreement- Mike Morris	▪ Setting the stage: USDOJ/OHA Performance Plan; ▪ Joint accountability; ▪ History: Americans with Disabilities Act; ▪ Olmstead: 1999 Supreme Court decision; ▪ USDOJ history in Oregon; ▪ Oregon Performance Plan; ▪ What the plan covers; ▪ Mobile crisis; ▪ Assertive Community Treatment (ACT); ▪ Supported housing; ▪ Peer delivered services; ▪ Supported employment;

	▪ Criminal justice diversion; ▪ Secure residential treatment facilities; ▪ Emergency departments; ▪ Acute psychiatric care; ▪ Oregon State Hospital; ▪ QA/QI requirements.
HERC Update- Dr. Cat Livingston and Dr. Ariel Smits	Minutes from October 6, 2016 meeting: ▪ Recommended code movements- added coverage; ▪ Recommended guideline changes- new guideline for tobacco cessation prior to elective surgery; ▪ October biennial review- adding gastric banding to the SRNC table. Other Discussion: ▪ November HERC meeting; ▪ HepC codes, all approved with placements, will be available; ▪ Two codes coming but not out yet. A spreadsheet on the website has all the code placements; ▪ GN 6- re-reviewing. Is this guideline actually doing anything? ▪ SIJ Joint infusion to uncovered lines; ▪ Bariatric surgery-removing lower obesity line, discussed increased coverages, repeat bariatric surgery, marijuana usage, 6 mos. Tobacco cessation, and accreditation for bariatric centers; ▪ Please send in nominations for Coverage guidances; ▪ Coverage guidance- Digital Breast Tomosynthesis for breast cancer screening in average risk women;

	▪ Coverage Guidance- Low back pain –corticosteroid injections; ▪ Coverage Guidance- Metabolic and bariatric surgery; ▪ Coverage Guidance- Noninvasive testing for liver fibrosis in patients with chronic hepatitis C; ▪ Dental Advisory Group will be meeting in a few weeks.
Items from the floor	1. Kevin Ewanchyna discussed ovarian cancer prevention and alternatives to tubal ligation. 2. Behavioral health- who gets to be billed. Mixed information. Chris Norman to follow up with OHA staff.
JOINT LEARNING COLLABORATIVE SESSION	
	Updates from Oregon Researchers on Opioid Prescribing
QUALITY AND PERFORMANCE IMPROVEMENT SESSION	
QPI Update and Introductions-	▪ December QHOC meeting is cancelled; ▪ Taking nominations for a chair person for this meeting.
External Quality Review Activities 2017 Schedule	External Quality Review Activities for OHA CCOs: ▪ Compliance; ▪ Information Systems Capability Assessment (ISCA); ▪ Statewide PIP; ▪ Trainings; ▪ Review Process;

	2017 EQRO Schedule draft: ▪ Dental Plan Network (DPN) – ISCA/ PH Tech – ISCA follow-up ▪ CCO/MHO – ISCA follow-up, compliance Other discussion: ▪ Full compliance reviews will be a 1 ½ day process; ▪ When will 2016 reports be available? Varies by CCO; ▪ A memo about scoring will be coming out soon.
PIP Reporting Template	▪ Pluses/minuses discussion on new form; ▪ Problem/Aim statement- where do they go? ▪ Recommendations on measurement plans (add a column); ▪ Barriers (pg. 3) Does this need clarification? ▪ Add root cause after problem statement
CCO Contract Review- Kathy Cereghino	▪ Information was shared on the CCO contracting process; ▪ Lisa and Kathy will present at the January QHOC meeting and address a timeline and where we are at in the process; ▪ Also want to take time in the January and February meetings to look at the quality component.
PIP	▪ Update from Southern Oregon: ▪ Tool kit, tapering forms and videos are now available for our changes on opiates; ▪ Letters were sent last week to members who need to taper; ▪ Letter on tapering agreement can be found on the website. Other CCO's can use this material.

Issues from the floor	▪ Nancy Siegel shared information on the 2017 review of Standard 8. She stated that they will be using a met/partially met/not met scoring. Will be looking for a progress report for January. Also, will be looking at Part I only. The progress report takes the place of Part II. Participation in research is optional; ▪ Reminder that the December QHOC meeting is cancelled.
NEXT MEETING: January 9, 2017	*Salem - HSB Conference Room 137 A-D* Toll free dial-in: 888-278-0296 Participant Code: 310477 Parking: Map Office: 503-378-5090 x0

Metrics Update for QHOC

February 2017

CCO Metrics

Metrics & Scoring Committee

The Committee held their annual retreat on December 2nd and their regularly scheduled meeting on December 16th. The meeting on the 16th included presentations from the Medicaid Advisory Committee's Oral Health Access group, and CCO Oregon's Dental Metrics Workgroup, as well as continued discussion on the potential equity measure.

The Committee also has removed the claims-based SBIRT measure from the 2017 incentive measure set, given additional coding complications. The Committee encourages CCOs and practices to continue implementing SBIRT while an EHR-based measure is developed in 2017. The Committee intends to reinstate the EHR-based measure to the incentive set for CY 2018.

The Committee also met on January 20th to review their workplan for selecting 2018 measures, begin a discussion on patient experience measures, and to come to a decision about a health equity measure. The Committee has agreed to adopt the Emergency Department Utilization measure for people experiencing severe and persistent mental illness (SPMI) as the equity measure for 2018. Additional details about the proposal are available in the January meeting materials online.

http://www.oregon.gov/oha/analytics/Pages/Metrics-Scoring-Committee.aspx

2017 CCO Incentive Measure Specifications

Final specifications for the 2017 measurement period were posted in December. Notification was sent to the Metrics TAG and all materials can be found online at:
http://www.oregon.gov/oha/analytics/Pages/CCO-Baseline-Data.aspx

In response to CCO request, OHA has also provided a document that summarizes specification changes between 2016 and 2017, and a Q&A document that provides responses to several questions CCOs asked while reviewing the draft 2017 specifications.

2016 Mid-Year Report

OHA has published its next public metrics report, covering the July 2015 – June 2016 measurement period and using measure results that were included in the October 2016 monthly metrics dashboard. The report is available online at http://www.oregon.gov/oha/Metrics/Pages/HST-Reports.aspx.

Health Plan Quality Metrics Committee

Members of the new Health Plan Quality Metrics Committee, which is charged with identifying an aligned menu of measures for CCOs, PEBB, OEBB, and health plans sold on the insurance exchange, are pending appointment by the Governor's Office.

http://www.oregon.gov/oha/analytics/Pages/Quality-Metrics-Committee.aspx

Hospital Performance Metrics Advisory Committee

Oregon's waiver renewal recently approved by CMS extended the Hospital Transformation Performance Program (HTPP) for an additional year, through 2017. The HTPP extension included limited changes to the overall structure of the program, with the domain structure, payment structure, and 11 incentive measures from Year 3 continuing into Year 4. However, the measurement period does shift from the federal fiscal year to the calendar year to better align with the CCO incentive measure program.

For more information

Please contact us at metrics.questions@state.or.us

PUBLIC HEALTH DIVISION
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Kate Brown, Governor

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Quality and Health Outcomes Committee
Public Health Division updates – February 2017

Public health modernization – Oregon Health Authority, Public Health Division released the *Health and Economic Benefits of Public Health Modernization* report in January. This report estimates the value of prevention and public health interventions on a select set of common and unhealthful health conditions, as well as the cost of medical care and poor health outcomes due to health disparities. The report and other resources for public health modernization are available at: www.healthoregon.org/modernization. For more information, contact Sara Beaudrault at sara.beaudrault@state.or.us or (971) 673-0432.

Facing Addiction in America. The Surgeon General's Report on Alcohol, Drugs and Health – In November, the Surgeon General released its first ever report on alcohol, drugs and health. This report contains key information and findings related to substance use, misuse and substance use disorders from prevention to recovery. One chapter is dedicated to the health care system's role in prevention, screening, treatment and recovery. This report is available online at: https://addiction.surgeongeneral.gov/.

Text4baby -The Oregon Health Authority, Public Health Division is an official Text4baby partner. Text4baby is for pregnant women and moms with infants under age one–and their partners and loved ones. Participants sign up by texting BABY (or BEBE for Spanish) to 511411 to receive at least three free text messages a week containing health tips and safety information, timed to their due date or baby's birth date. Participants can also download the app free from iTunes and Google Play. Text4baby can be used to set up text reminders on your cell phone to keep track of your health care appointments. The Public Health Division has created a Text4baby toolkit and publishes an occasional newsletter which can be found at: http://public.health.oregon.gov/HealthyPeopleFamilies/Babies/Pages/text4baby.aspx. For questions about Text4baby in Oregon, contact Anna Stiefvater at anna.k.stiefvater@state.or.us or (971)673-1490.

Clinician-Assisted Tobacco Cessation Training for CCOs: Register Today! - Rx for Change Clinician-Assisted Tobacco Cessation is a comprehensive training program that equips health professionals and practicing clinicians of all disciplines with evidence-based knowledge and skills to help patients quit. This training supports the CCO cigarette smoking prevalence incentive metric and is based on a recent CCO-identified need for additional support implementing comprehensive cessation programs.
The training will take place at the DoubleTree Hotel (1000 NE Multnomah St, Portland, OR) on February 14, 2017, 8:30-4:15pm. Representatives from all CCOs are welcome to attend at no cost. Participants should be willing to use the information from the course to train others in the future. To register, or for more information, contact Tom Cogswell at thomas.cogswell@state.or.us or 971-673-3366.

CDC Community Guide Recommends Using Community Health Workers for Diabetes Prevention - Based on sufficient evidence of effectiveness in improving glycemic control and weight-related outcomes among people at increased risk for type 2 diabetes, the Community Preventive Services Task Force recommends interventions engaging community health workers for diabetes prevention. When implemented in underserved communities, these interventions can improve health, reduce health disparities, and enhance health equity. The task force findings can be accessed at https://www.thecommunityguide.org/findings/diabetes-interventions-engaging-community-health-workers. Several Oregon CCOs are either directly engaging CHWs in delivery of programs through the National Diabetes Prevention Program, or are referring patients at high risk for diabetes to community-based programs that engage CHWs. For technical assistance related to the National Diabetes Prevention Program, or for information on upcoming lifestyle coach training opportunities, please contact Don Kain at kaind@ohsu.edu.

2016 Tri-County Region Opioid Trends Report – In February Clackamas, Multnomah and Washington counties released the 2016 Opioid Trends Report. This report provides the public, community advocates, physical and behavioral health providers, and policy makers with accurate quantitative data about opioid addiction and overdose. The report includes chapters on fatal overdoses; 9-1-1 overdose responses (non-fatal overdoses); opioid prescribing trends; syringe exchange trends and client survey; and substance use treatment. While deaths have diminished since the peak in 2011, there has been little decrease in fatal overdoses in the tri-county region over the last three years. The Tri-County Region Opioid Trends Report is available at: http://portlandprofessional.oregonpainguidance.org/.

HCV Case Management – outline for cancelled QHOC meeting 1-9-17

This was mostly going to be an opportunity for Q and A as all the information has been presented already.

1. History
    a. OHA created a Risk Corridor effective 1-1-17, which incorporates minimum requirements for case management by CCOs of members receiving DAA treatment for chronic HCV infection.
    b. This minimum required case management is based on the following sources:
        i. FFS contractor (KEPRO) for case management's protocol for FFS members treated with DAAs and feedback re feasibility (see attachment for Dr. McWilliams presentation of the KEPRO protocol 11-15-16 to the CCO Pharmacy Directors Meeting)
        ii. FFS and contractor review of utility of components from February 2016 to present
        iii. Veteran's Administration (VA) Guidelines
        iv. American Association for the Study of Liver Diseases (AASLD)
        v. Feedback obtained from CCOs in the December 2016 comment period
2. Goals of case management
    a. Triple Aim: improve rate of sustained viral response (SVR), improve member's experience of treatment, decrease costs of treatment
    b. Rate of SVR will be improved by increasing adherence, mitigating barriers to successful treatment, ensuring no gaps in supply, and testing during treatment in case change in medication or dosage is needed, etc.
    c. Experience of treatment will be improved by support for patient, mitigation of barriers, and education for member, PCP, prescriber, alerting drug-drug interactions
    d. Costs will be minimized and cost-effectiveness maximized by gathering data regarding efficacy which will inform value-based

purchasing or payment, ensuring adherence and maximizing rate of SVR, catching financial issues such as TPL or churn, etc.

3. Please note: CCOs will be held responsible for the minimum requirements in the risk corridor language; KEPRO's protocol, and some CCO's protocols, go above and beyond that.

OHA developed the following definition of adequate case management to ensure CCOs continue to provide quality case management for this high cost drug regimen into 2017, when the cost risk is mitigated by the risk corridor. The following requirements will be reviewed during the risk corridor settlement period and may affect a CCO's administrative settlement (~10% load), but the case management will not impact the medical/pharmacy cost component of the settlement.

> **Goal**: The goal is to ensure the following; adherence to medication regimen, compliance with viral load testing, data needed to evaluate program, support patient and providers, and prevent gaps in medication supply.

Data collection requirements for adequate case management

OHA requires CCOs collect the following information from providers for any member that starts treatment of Hepatitis C DAA drugs in calendar year 2017, as specified in the Hepatitis C DAA risk corridor. This information is compulsory and most items are required as part of the prior authorization terms for treatment.

- List of Medicaid ID for members scheduled for completed Hepatitis C DAA treatment in 2017
- Genotype
- Metavir Fibrosis Stage
- HIV & HBV status
- Liver transplant status
- Treatment Regimen
- Polymorphism Resistance Testing (if indicated)
- Record of adverse effects of treatment; reasons for discontinuation if applicable
- Viral load test results after 4 weeks of therapy, and 12 weeks post treatment completion (SVR) are required at a minimum. 24 week post treatment completion is strongly recommended to confirm the value of DAA medications to prevent relapse.
- Attestation of case management protocol or opt-out (see below)

Case Management Protocol

The following outlines the general protocol CCOs have to attest occurred with each member that starts treatment of Hepatitis C DAA drugs in calendar year 2017, as specified in the Hepatitis C DAA risk corridor.

- Initial Evaluation of barriers to adherence within the prior authorization for approval and plan to address (e.g. transportation, compliance with MH or SUD treatment, etc.)
- Expectation that a care management team, or case manager, is assigned to the member for the duration of the treatment and will evaluate if additional support is required
- Check on appropriate billing (e.g. churn or switch to TPL)
- Medication Reconciliation; Check on drug-drug interactions

- Coordinate with patient, PCP, prescriber, and pharmacy regarding treatment
- Prevent gaps in medication supply and ensure refills are accessed in timely fashion
- Contact patient at least once a week, or daily if needed, to verify medication is taken
- Ensure compliance with viral load testing and reporting: 4 weeks into treatment, and 12 weeks post completion (SVR). 24 week post treatment completion is strongly recommended to confirm the value of DAA medications to prevent relapse.
- Provide education for patient and PCP as needed
- Warm hand-off in case of eligibility/enrollment changes (churn)
- Transition to chronic illness case management if needed

Opt-out Protocol

OHA has consulted with the Department of Justice and has developed the following protocol for the rare occurrence when a member pursues an opt-out of the protocol. Case management is strongly recommended and valuable for the member to successfully complete treatment; however, members may opt-out after signing an attestation that they understand:

- The goal of case management is to support the client to successfully complete treatment and get required tests performed (prescription coordination, testing scheduling, transportation)
- Benefits of participation include:
    - Coordination with prescriber(s), pharmacy and labs
    - Options for education and support in accessing care – mental health, SUD, specialist
    - Support for adherence
- Members will be responsible to schedule, coordinate transportation and to have the required lab tests performed after 4 weeks of treatment and 12 weeks after they finish their prescription
- Member's treating physician endorses the opt-out
- Failure to refill prescriptions and adhere to therapy, or schedule and have required lab tests performed, may result in their prior authorization being rescinded
- Members may rejoin the case management program at any time

Please note, if a significant amount of clients opt-out of a CCO's case management, the administrative revenue associated with the Hepatitis C adjustment may be reviewed during the settlement and a portion may be withheld due to low utilization of the program. (Per Exhibit C, Section 6.(3).d)

MINUTES

Evidence-based Guidelines Subcommittee

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

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

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

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

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

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1. CALL TO ORDER

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

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2. MINUTES REVIEW

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

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3. STAFF REPORT

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

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

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

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

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4. Low Back Pain: Corticosteroid Injections

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Chan invited public comments.

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

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

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

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

DRAFT COVERAGE GUIDANCE

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

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5. 2016 Coverage Guidance Rescan

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

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

- *Imaging for Low Back Pain* – There was no discussion. The staff recommendation is to affirm that the coverage guidance is up-to-date.

- Low Back Pain: *Non-Pharmacological Noninvasive Interventions* – Westbrook asked about different types of yoga and psychotherapy other than those previously recommended. Obley said that all the studies of psychotherapy were of cognitive behavioral therapy. The studies of yoga also showed effectiveness for ayengar yoga. Westbrook expressed concern that not adding coverage for the additional modalities may limit access to effective therapies. However, Gingerich observed that the Oregon Health Plan guideline note does not differentiate between types of yoga and that the billing codes do not differentiate between types of yoga or psychotherapy. Yoga is billed with a generic code for group exercise classes. Obley noted that Tai Chi has also shown effectiveness, as well as cognitive behavioral therapy delivered by tele-devices. He said recent evidence has cast some doubt on the effectiveness of massage therapy. The staff recommendation is to affirm that the coverage guidance is up-to-date, recognizing that there are are some detailed recommendations which may change. Waldmann said that acupuncture, spinal manipulation and so forth are effective after four weeks, while the Oregon Health Plan's new coverage criteria allow these modalities earlier. Livingston said that the HERC's low back pain task force was aware of this coverage guidance when they made their recommendations, and even in the absence of evidence they recommended that certain treatments be available. Livingston also noted that with the new HERC methodology, each intervention would require an in-depth review (the previous methodology allowed HERC to reference trusted sources rather than perform an in-depth review of each intervention). The staff recommendation was to affirm that the coverage guidance is up-to-date. Gingerich said

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

- *Nonpharmacologic Interventions for Treatment-Resistant Depression* – There was minimal discussion. In response to a question about the two studies suggesting an update may be needed, Obley said there was some evidence questioning the clinical significance of the benefits of transcranial magnetic stimulation. Still, he suggested most patients would likely prefer a trial of transcranial magnetic stimulation prior to electroconvulsive therapy. Therefore, the staff recommendation was to affirm the existing coverage guidance.

- *Low Back Pain: Pharmacologic and Herbal Therapies* – Staff did not conduct an evidence search for this topic due to staff resource limitations. Livingston said staff determined that since the coverage guidance is about treatment strategies (rather than coverage/noncoverage), staff believes searching for new evidence may not be worthwhile. Coffman mentioned that there has been a lot of work related to opioids in Oregon, so adding a new coverage guidance may not be helpful. This coverage guidance cannot be affirmed as there has been no new evidence search, but it will be changed to passive monitoring status.

- *Neuroimaging for Mild Cognitive Impairment or Dementia* – This topic was also not rescanned, as clinical use of this technology has remained low (though research is ongoing) and an updated coverage guidance would be unlikely to impact practice. Staff's recommendation is to let the topic go to passive monitoring status. There was minimal discussion.

- *Planned Cesarean Birth* – Staff recommendation is to let this topic go to passive monitoring, as no evidence search has been conducted. The Center for Evidence-based Policy (CEBP) staff recommendation was not to dedicate resources to rescanning this topic as there has not been a significant change in the evidence for this procedure.

- *Routine Ultrasound in Pregnancy* – Staff recommendation is to let this topic go to passive monitoring, as no evidence search has been conducted. The CEBP staff recommendation was not to dedicate resources to rescanning this topic as there has not been a significant change in the evidence for this procedure.

- *Prenatal Genetic Testing* – Staff recommends retiring this coverage guidance as it includes a variety of tests, which would be cumbersome to update in our new coverage guidance process. In addition, this field is rapidly changing with new genetic tests being released and expanded indications. The Prioritized List guideline notes on Prenatal and Non-prenatal genetic testing would remain in place and be updated as necessary through the Value-based Benefits Subcommitee. There was brief discussion.

- *Low Back Pain: Minimally Invasive and Non-Corticosteroid Percutaneous Interventions* – This topic is already planned for review by EbGS, beginning in February.

- *Chronic Otitis Media with Effusion in Children* – Livingston reviewed current coverage criteria, which do not allow for adenoidectomy alone or at the time of first pressure equalization tube

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

Summary of decisions:

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

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

6. ADJOURNMENT

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

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

The meeting was adjourned at 4:15 pm. The next meeting is scheduled for February 2, 2017 from 2:00-5:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070.

MINUTES

Health Technology Assessment Subcommittee

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

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

Members Absent: None

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

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

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1. CALL TO ORDER

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

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2. MINUTES REVIEW

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

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3. STAFF REPORT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Saha invited public testimony.

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

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

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

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

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

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

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

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

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

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

DRAFT HERC COVERAGE GUIDANCE

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

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5. COVERAGE GUIDANCE TOPIC MONITORING

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

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

on passive monitoring status per the new administrative rule.

Obley reviewed the rescanned topics.

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

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

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

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

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

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

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

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

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

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

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

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6. NEXT TOPICS

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

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7. ADJOURNMENT

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

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

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

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

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

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

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

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

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

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

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

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

Members Absent: None.

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

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

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

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

  Smits reviewed the errata; there was no discussion.

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

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

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

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

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

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

Recommended Actions:

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

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

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

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

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

Recommended Actions:

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

a. Advise HSD to place H2023 on the Ancillary File.

3) Remove H2011 (Crisis intervention service, per 15 minutes) from all lines on the Prioritized List.
   a. Advise HSD to place H2011 on the Diagnostic Workup File.
4) Add ICD-10 F50.89 (Other specified eating disorder) to line 153 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD and line 635 PICA.
   a. Add a coding specification to lines 153 and 635 as follows:
      "ICD-10 F50.89 is included on lines 153 for avoidant/restrictive food intake disorder and on line 386 for psychogenic loss of appetite. ICD-10 F50.89 is included on line 635 for pica in adults and for all other diagnoses using this code."
5) Remove the following coding specification from line 386:
   ~~"ICD-10-CM F50.8 is included on this line only for binge eating disorder. All other diagnoses using this code (i.e. pica in adults) are included on line 664 PICA."~~

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

- **Topic: Straightforward/Consent Agenda**

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

Recommended Actions:

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

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

DISORDERS and remove from line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS~~545 DEFORMITIES OF FOOT~~

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

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

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

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

1) 58674 (Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency) was felt to not be experimental. However, the recommended placement on the Services Recommended for Non-Coverage was felt to be appropriate. The rationale for placement should be insufficient level of effectiveness.

2) 77065-77067 (Diagnostic and screening mammography with computer-aided-detection): The subcommittee determined that the computer aided detection guideline should be maintained, with wording altered to remove the CPT codes. This may allow value-based pricing by HSD, and serves as a statement of HERC's assessment of the evidence around CAD.

3) G9678 (Oncology care model (ocm) monthly enhanced oncology services (meos) payment for ocm enhanced services) was added to the Ancillary list rather than the chemotherapy/radiation therapy lines.

Recommended Actions:

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

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

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

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

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

- **Topic: Back Surgery Guideline**

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

  Recommended Actions:
  1) GN37 was modified as shown in Appendix A

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

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

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

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

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

- **Topic: SI Joint Fusion**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recommended Actions:

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

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

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

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

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

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

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

Recommended Actions:

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

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

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

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

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

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

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

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

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

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

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

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

Recommended Actions:

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

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

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**

  No items were carried forward to the next meeting

- **Next meeting:**

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

- **Adjournment:**

  The meeting adjourned at 1:10 PM.

Appendix A
Revised Guideline Notes

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

A) Genetic tests are covered as diagnostic, unless they are listed below in section F1 as excluded or have other restrictions listed in this guideline. To be covered, initial screening (e.g. physical exam, medical history, family history, laboratory studies, imaging studies) must indicate that the chance of genetic abnormality is > 10% and results would do at least one of the following:
   1) Change treatment,
   2) Change health monitoring,
   3) Provide prognosis, or
   4) Provide information needed for genetic counseling for patient; or patient's parents, siblings, or children

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

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

D) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history.
   1) Services are provided according to the Comprehensive Cancer Network Guidelines.
      a) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V2.2016 (9/26/16) ~~V.1.2015 (5/4/15).~~ www.nccn.org.
      b) Breast and ovarian cancer syndrome genetic testing services (CPT 81162, 81211-81217) for women without a personal history of breast, ovarian and other associated cancers should be provided to high risk women as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and ovarian. V1.2017 (9/19/16). ~~V2.2015 (6/25/15).~~ www.nccn.org.

c) Breast and ovarian cancer syndrome genetic testing services (CPT 81162, 81211-81217) for women with a personal history of breast, ovarian, and other associated cancers and for men with breast cancer should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V1.2017 (9/19/16). ~~V2.2015 (6/25/15).~~ www.nccn.org.

d) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Colorectal Screening. V2.2016 (9/26/16) ~~V.1.2015 (5/4/15).~~ www.nccn.org.

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

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

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

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

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

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

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

E) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:

1) CPT 81228, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.

2) CPT 81229, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities; plus cytogenetic constitutional microarray analysis for single nucleotide polymorphism (SNP) variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder; only if (a) consanguinity and recessive disease is suspected, or (b) uniparental disomy is suspected, or (c) another mechanism is suspected that is not detected by the copy number variant test alone.
3) CPT 81243, 81244, Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
4) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.

F) Related to other tests with specific CPT codes:
1) The following tests are not covered:
a) CPT 81225, CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
b) CPT 81226, CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN).
c) CPT 81227, CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
d) CPT 81287, MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme), methylation analysis
e) CPT 81291, MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
f) CPT 81330, SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal) (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)
g) CPT 81350, UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (eg, irinotecan metabolism), gene analysis, common variants (eg, *28, *36, *37)
h) CPT 81355, VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variants (eg, -1639/3673)
i) CPT 81417, re-evaluation of whole exome sequencing
j) CPT 81425-81427, Genome sequence analysis

k) CPT 81470, 81471, X-linked intellectual disability (XLID) genomic sequence panels
l) CPT 81504, Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores

2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
   a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
   b) Diagnostic testing for cystic fibrosis (CF)
      CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
   c) Carrier testing for cystic fibrosis
      i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered once in a lifetime.
   d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.
   e) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous 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 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.

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

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

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

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

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

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

DIAGNOSTIC GUIDELINE D15, COMPUTER-AIDED MAMMOGRAPHY

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

GUIDELINE NOTE 24, COMPLICATED HERNIAS

Lines 172,527

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

Appendix A
Revised Guideline Notes

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

Lines 351,532

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

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

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

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

1) MRI evidence of moderate to severe central or foraminal spinal stenosis AND
2) A history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
    a) Markedly abnormal reflexes
    b) Segmental muscle weakness
    c) Segmental sensory loss
    d) EMG or NCV evidence of nerve root impingement
    e) Cauda equina syndrome
    f) Neurogenic bowel or bladder
    g) Long tract abnormalities

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

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

Appendix A
Revised Guideline Notes

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

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

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 325

Medical treatment of overweight (with known cardiovascular risk factors) and obesity in adults is limited to ~~accepted~~ intensive~~,~~ counseling on nutrition and physical activity, provided by health care professionals. Intensive counseling is defined as face-to-face contact more than monthly. A multidisciplinary team is preferred, but a single clinician could also deliver intensive counseling in primary care or other settings.

~~Visits are not to exceed more than once per week.~~ Intensive counseling visits ~~(once every 1-2 weeks)~~ are included on this line for 6 months. Intensive counseling visits may continue for an additional 6 months (up to 12 months) as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention. Maintenance visits at the conclusion of the intensive treatment are included on this line no more than monthly after this intensive counseling period. The characteristics of effective behavioral interventions include: high intensity programs; multicomponent (including at a minimum diet and exercise), group-based commercial programs; Mediterranean diet; and the following sub-elements -- calorie counting, contact with a dietician, and comparison to peers.

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, prediabetes~~impaired fasting glucose~~, or the metabolic syndrome.

Medical treatment of obesity in children is limited to comprehensive, intensive behavioral interventions. For treatment of children up to 12 years old, interventions may be targeted only to parents, or to both parents and children.

Appendix A
Revised Guideline Notes

Pharmacological treatments and devices (e.g. gastric balloons, duodenal jejunal bypass liners, and vagus nerve blocking devices) for obesity are not intended to be included as services on this line or any other line on the Prioritized List.

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Line 3,625

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

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

USPSTF "D" recommendations are included on line 625

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

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

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

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

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

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

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

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

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

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

81414	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1	Diagnostic Workup File
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood	Services recommended for non-coverage
81439	Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN	Diagnostic Workup File
81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score	Services recommended for non-coverage
84410	Testosterone; bioavailable, direct measurement (eg, differential precipitation)	Diagnostic Procedures File
87483	Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (eg, Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, human parechovirus, herpes si	Diagnostic Procedures File
90674	Influenza virus vaccine, quadrivalent (ccIIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use	Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
90697	Diphtheria, tetanus toxoids, acellular pertussis vaccine, inactivated poliovirus vaccine, Haemophilus influenzae type b PRP-OMP conjugate vaccine, and hepatitis B vaccine (DTaP-IPV-Hib-HepB), for intramuscular use	Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

92242	Fluorescein angiography and indocyanine-green angiography (includes multiframe imaging) performed at the same patient encounter with interpretation and report, unilateral or bilateral	100,117,143,159,171, 175, 179, 248, 249, 252, 270, 274, 278,284,301, 302, 304, 313, 315, 323, 324, 340, 341, 342, 353, 356, 359, 365, 370, 372, 375, 379, 388, 399, 410, 441, 445, 453, 455, 456, 464, 475, 476, 488, 499, 505, 564, 567, 572, 597, 630, 636, 644
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
96160	Administration of patient-focused health risk assessment instrument (eg, health hazard appraisal) with scoring and documentation, per standardized instrument	Diagnostic Procedures File
96161	Administration of caregiver-focused health risk assessment instrument (eg, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument	Diagnostic Procedures File
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection	All lines with chemotherapy
96936	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion (List separately in addition to code for primary procedure)	Services recommended for non-coverage
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements f	All lines with 97001 currently 34,50,61,72,75,76,78,85,95, 96,135, 136, 140, 154, 157, 164, 182, 187, 188, 200, 201, 205, 206, 212, 259, 261, 276, 290, 297, 306, 314, 317, 322, 346, 350, 351, 353, 360, 361, 364, 366, 381, 382, 392, 406, 407, 413, 421, 423, 427, 428, 436, 447, 459, 467, 470, 471, 482, 490, 512, 532, 558, 561, 574, 592, 611

97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in	All lines with 97001 currently
97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures	All lines with 97001 currently
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment i	All lines with 97001 currently
97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An	All lines with 97003 currently 34,50,61,72,75,76,78,85,95,96, 135, 136, 140, 154, 157, 164, 182, 187, 188, 200, 201, 205, 206, 212, 259, 261, 276, 290, 297, 306, 314, 322, 346, 350, 351, 353, 360, 361, 364, 366, 381, 382, 392, 406, 407, 413, 421, 423, 427, 428, 436, 447, 467, 471, 482, 490, 512, 532, 558, 561, 574, 592, 611
97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or	All lines with 97003 currently
97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psych	All lines with 97003 currently

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

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

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

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

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

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

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

Appendix C
NEW GUIDELINES

GUIDELINE NOTE XXX PERCUTANEOUS REPAIR OF PARAVALVULAR LEAKS
Line 290
Percutaneous transcatheter closure of paravalvular leak (CPT 93590-93592) is included on this line only for patients with

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

GUIDELINE NOTE XXX DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE TREATMENT OF HEPATITIS C IN NON-CIRRHOTIC PATIENTS
Line 203

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

Imaging tests:

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

Blood tests (only if imaging tests are unavailable):

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

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

Imaging tests:

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

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

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

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

- Real time tissue elastography

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NEW GUIDELINES

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

The development of this guideline note was informed by a HERC Coverage Guidance. See http://www.oregon.gov/oha/herc/Pages/blog-liver-fibrosis.diagnosis.aspx

GUIDELINE XXX, SACROILIAC JOINT FUSION

Line 532

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

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

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

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

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

GUIDELINE NOTE XXX SKIN SUBSTITUTES FOR CHRONIC SKIN ULCERS
Line 384

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

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

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

MULTISECTOR INTERVENTIONS: PREVENTION AND TREATMENT OF OBESITY
Limited evidence supports the following interventions:

School and childcare settings

- School based interventions to reduce BMI (especially with physical activity focus)
- School nutrition policy and day care meal standards
- Family-based group education programs delivered in schools
- Obesity prevention interventions in childcare settings (nutrition education, healthy cooking classes for 2-6 year olds, physical activity and playful games)

Appendix C
NEW GUIDELINES

Community level interventions

- Environmental interventions (social marketing, cafeteria signs, farmers markets, walking groups, etc)
- Introduction of light rail
- Community-based group health education and counseling interventions, workplace education interventions
- Workplace and college interventions to improve physical activity

Multiple settings:

- Interventions to reduce sedentary screen time (in some studies, also to increase physical activity and nutrition).
- Multicomponent individual mentored health promotion programs to prevent childhood obesity
- Parental support interventions for diet and physical activity (group education, mental health counseling)

Policy changes

- Sugar sweetened beverage taxes
- Elimination of tax subsidy for advertising unhealthy food to children

This Multisector Interventions statement is based on the work of the HERC Obesity Task Force and the full summary of the evidence report is available here: http://www.oregon.gov/oha/herc/Pages/blog-obesityMSI.aspx

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

Line 6

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

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

Appendix D

APPENDIX D

DELETED GUIDELINE NOTES

~~GUIDELINE NOTE 76, LIVER ELASTOGRAPHY~~
~~Line 203~~
~~Liver elastography (CPT 91200) is included on this line only when the non-invasive test would replace liver biopsy for determination of eligibility for medications for chronic hepatitis C. Performance of liver elastography more than twice per year or within six months following a liver biopsy is not included on this line.~~

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
November 10, 2016

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

Members Absent: None.

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

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

*provided testimony

Call to Order

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

Minutes Approval Meeting materials page 4

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

Director's Report Meeting materials page 117

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

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

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

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

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

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

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

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

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

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

- Training for genetic counselors
- Licensing of genetic counselors

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

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

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

Recommended Code Movement:

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

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

Recommended Guideline Changes:

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

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

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

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

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

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

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

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

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

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

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

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

Key Questions

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

Contextual Questions

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

Evidence summary

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

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

Guidelines

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

Policies

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

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

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

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

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

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

Proposal

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

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

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

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

MOTION: To approve the letter from the HERC and EbGS chairs as drafted. Carries 12-0. *(Absent: Williams)*

Approved Coverage Guidance:

HERC Coverage Guidance

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

Changes for the Prioritized List of Health Services:

GUIDELINE NOTE 162 LONG-ACTING REVERSIBLE CONTRACEPTIVE (LARC) PLACEMENT
Line 6
Long-acting reversible contraceptives (implant or intrauterine device) are included on Line 6 in all settings, including (but not limited to) immediately postpartum and postabortion.

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

Review of Prioritization of Acute and Chronic Hepatitis C Meeting materials page 328

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

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

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

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

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

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

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

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

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

Public Testimony:

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

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

Public Comment

There was no other public comment at this time.

Adjournment

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

OFFICE FOR OREGON HEALTH POLICY & RESEARCH
Health Evidence Review Commission
Kate Brown, Governor

Oregon Health Authority

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November 10, 2016

Dear Medical Directors:

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

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

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

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

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

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

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

Sincerely,

Somnath Saha, MD, Chair, Health Evidence Review Commission

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

MINUTES

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

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

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

Members Absent: Mike Plunkett, DMD

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recommended Actions:

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

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

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

Recommended Actions:

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

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

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

Recommended Actions:

1) GN34 was modified as shown below:

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

Line 349

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

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

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

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

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

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

Recommended Actions:

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

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

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

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

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

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

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

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

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

Recommended Actions:

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

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

Approved with minimal discussion.

Recommended Actions:

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

- **Public Comment:**

No additional public comment was received.

- **Issues for Next Meeting:**

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

- **Next Meeting:**
  - TBD

Meeting was adjourned at 12:45 PM.

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE
February 2, 2017
8:00am - 1:00pm
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
A working lunch will be served at approximately 12:00 PM
All times are approximate

I. Call to Order, Roll Call, Approval of Minutes – Kevin Olson **8:00 AM**

II. Staff report – Ariel Smits, Cat Livingston, Darren Coffman **8:05 AM**
- **A.** Pain Commission letter on use of the pain scale
- **B.** Errata
- **C.** Sacroiliac joint surgery final changes

III. Advisory panel reports – Ariel Smits, Cat Livingston, Darren Coffman **8:15 AM**
- **A.** OHAP report

IV. Straightforward/Consent agenda – Ariel Smits **8:25 AM**
- **A.** Consent table
- **B.** Diaphragmatic hernia

V. 2018 Biennial Review **8:30 AM**
- **A.** Prioritization of pharmacologic treatments for Chronic Hepatitis C
- **B.** Injuries to major blood vessels
- **C.** Secondary and ill-defined malignancies

VI. Break **10:40 AM**

VII. Coverage guidances **10:50 AM**
- **A.** Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women

VIII. New discussion items **11:30 AM**
- **A.** Fecal microbiota transplant for recurrent C difficile infection
- **B.** Gallstones
- **C.** Meniscal injuries
- **D.** Chronic otitis media with hearing loss

IX.	**Previous discussion items** **A.** Preventive services guideline edits **B.** Bariatric surgery guideline	**12:30 PM**
X.	**Public comment**	**12:55 PM**
XI.	**Adjournment – Kevin Olson**	**1:00 PM**

Evidence-based Guidelines Subcommittee (EbGS)

Current Topics

Low Back Pain- Corticosteroid Injections

Next Topic

Low Back Pain – Minimally invasive and non-corticosteroid injections

EbGS topics being scoped

Urine drug testing

Colorectal cancer screening modalities

Multisector Intervention Report – Unintended pregnancy

Opportunistic Salpingectomy

CardioMEMs for heart failure monitoring (will be scoped in HTAS)

Health Technology Assessment Subcommittee (HTAS)

Current Topics

Breast cancer screening in women at above-average risk

Continuous Glucose Monitoring

Topics being scoped

Acellular dermal matrix for post-mastectomy breast reconstruction

Coverage Guidance on Biomarker Tests of Cancer Tissue for Prognosis and Potential Response to Treatment

- Prostate cancer (e.g. Prolaris)
- Breast cancer (e.g. EndoPredict)

Hepatic artery infusion pumps

Increasing the Use of Postpartum LARC Placement

Quality Health Outcomes Committee (QHOC)
February 9, 2017

Cat Livingston, MD, MPH, Associate Medical Director, HERC
Maria Rodriguez, MD, MPH, Department of Obstetrics and Gynecology, OHSU
Kim Wentz, MD, MPH, Medicaid Medical Director, OHA

Cat Livingston, MD, MPH
Associate Medical Director
Health Evidence Review Commission

HEALTH EVIDENCE REVIEW COMMISSION (HERC) COVERAGE GUIDANCE: TIMING OF LONG-ACTING REVERSIBLE CONTRACEPTIVE (LARC) PLACEMENT

Approved 11/10/2016

HERC Coverage Guidance

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

Oregon Health Authority

HERC approved guideline note, effective 1/1/2017

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

Line 6

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

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

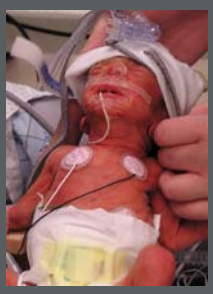
Oregon Health Authority

Immediate postpartum long acting reversible contraceptives

An important option for maternal and neonatal health

Maria I. Rodriguez, MD MPH

Benefits to planned pregnancy



Less preterm delivery

30%

53% costs
$4.6 billion

Trussell, et al Contraception, 2013.

Flower, et al BMC Pregnancy Childbirth, 2013. Wendt, et al. Paediatric and Perinatal Epidemiology, 2012.

Why is immediate postpartum LARC an important option?

- 40-57% of women report unprotected intercourse prior to standard postpartum visit
- Many women simply do not attend a postpartum visit
  - 41% attendance in a California Medicaid population
- Many women who want LARC don't get it
  - 63% attendance in an Oregon Medicaid population

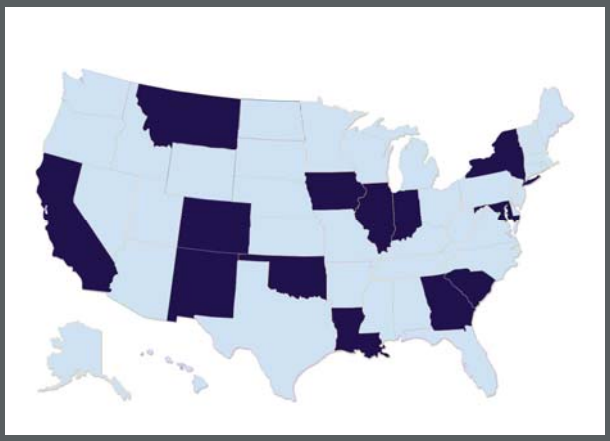
ACOG. Committee Opinion 670. August 2016
Thiel. Obstet Gynecol. August 2013

Postpartum IUD Safety

	LNG-IUS	Copper IUD
< 10 min	2	1
10 min to 4 weeks	2	2
> 4 weeks	1	1
Puerperal sepsis	4	4

World Health Organization. Medical Eligibility Criteria for Contraceptive Use. 2015

Policy barriers: advocating for access



States with reimbursement for immediate PP LARC

http://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception

Immediate postpartum LARC in Oregon

- OHSU offers postpartum LARC to a limited population (since 2008)
- OHSU Program (2014-2016 data)
- 423 devices placed
  - **Implant 66%,** Copper IUD 5%, LNG IUD 29%
- Payor distribution
  - **Medicaid 65%, C**AWEM 30%, Private 5%

OHSU Cohort Study

Postpartum LARC would save Oregon $2.94 for every dollar spent

N=1037	2003	2004	2005	2006
Pregnancies without PP IUD program	27	80	78	81
Costs without PP IUD program	$213,278	$637,126	$631,010	$636,210
Costs of IUD program	$106,000	$14,927	$16,931	$15,106
Costs of pregnancies expected with PP IUD program	$102,310	$297,970	$356,180	$395,320
Net Savings for Oregon	**$4,968**	**$324,229**	**$257,899**	**$225,784**

Rodriguez. Contraception. 2010

Hospital

- Whole site approach for training and implementation
  - Pharmacy
  - Nursing
  - Physicians & Midwives
  - Lactation
- Local champions
  - Didactics
- Evaluation & Monitoring

Quality and Reimbursement Strategies for Oregon FFS Medicaid

Kim Wentz, MD, MPH
Medicaid Medical Director
Oregon Health Authority

Barriers

- Billing bundled delivery Diagnosis Related Group (DRG) plus LARC insertion and device on the same day = FOF (Fear of Fraud)
- Supply and cost
- Awareness of providers and members
- Guidance: HERC, CMS Bulletins

Chief barrier: billing bundled inpatient delivery claim and LARC claim on same day

14 states are taking 3 primary approaches:

- Postpartum LARC as an add-on benefit to delivery DRG claim
  - IL, GA, LA, MA, SC
- "Unbundling," which enables reimbursement of both inpatient and outpatient claims on same day
  - AL, DE, IA, MD, MT, NM, NY, SC
- Enhanced DRG reimbursement
  - CO

Themes

- Commitment to reimburse full cost of device and insertion
- Mandated elimination of barriers: copays, prior authorization, step-therapy, coverage of removal
- Worked closely with hospital billing staff before, during and after
- Worked closely with internal claims staff
- Maintained federal family planning match
- Everything else was variable!

FFS approach

Approach #2: unbundling

- Hospital bills DRG as usual
- Hospital bills LARC device, CPT code for insertion, as separate outpatient claim
- FFS previously “kicks out” second claim if both inpatient and outpatient claims are received for same date
- Now second claim suspends, enters file marked for payment if LARC code “flag” is present on second or first claim
- Use J code for device, CPT code 58300 or 11981, and Family Planning Modifier V25.11

FFS work plan

QUALITY

- Collaborate with provider champions
- Work with hospitals
  - Compliance and Clinical Leadership
  - Ongoing technical assistance to Billing staff
- Work with Health Analytics and Public Health

COMMUNICATIONS

- Alert members and providers
- Present to Oregon Perinatal Collaborative and Oregon Professional Societies

Quality strategies to consider

- Determine adequacy of fee schedules
- Eliminate any barriers
- Collaborate with local provider champions, professional societies, neighbor CCOs, stakeholders
- Ongoing technical assistance/support to hospitals
- Provider and member education and awareness
- Ensure LARC placement counted in metric
- Provider training
- Labor and Delivery unit tool kits
- Assess baseline utilization and improvement
- Consider a Performance Improvement Project

Questions?

HEALTH EVIDENCE REVIEW COMMISSION (HERC) COVERAGE GUIDANCE: TIMING OF LONG-ACTING REVERSIBLE CONTRACEPTIVE (LARC) PLACEMENT

Approved 11/10/2016

HERC Coverage Guidance

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

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

RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

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

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

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

Our reports are based on a review of the relevant research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. For some conditions, the HERC has reviewed evidence and identified effective interventions, but has not made coverage recommendations, as many of these policies are implemented in settings beyond traditional healthcare delivery systems.

GRADE-INFORMED FRAMEWORK

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

Outcomes	**Estimate of Effect for Outcome/** ***Confidence in Estimate***
Unintended Pregnancy *(Critical outcome)*	Postabortion IUD (intention to treat at 6 months): 3/406 (0.74%) for immediate IUD vs. 11/472 (2.3%) for delayed IUD ARD 1.59% RR 0.37 (95% CI 0.12-1.14) ●●●○ *(Moderate confidence, based on 3 RCTs, N=878 women)* Postpartum IUD: 0/85 for immediate IUD vs. 0/85 for delayed IUD The identified systematic review of RCTs did not provide aggregate data on unintended pregnancy. No repeat pregnancies were reported in the 2 included RCTs providing pregnancy outcome data. ●●○○ *(Low confidence because no unintended pregnancies were observed, based on 2 RCTs, N=170)* Implants: No systematic reviews or RCTs were identified addressing immediate postpartum or postabortion implant use and unintended pregnancy.

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Abortion *(Critical outcome)*	IUDs: None of the identified systematic reviews reported on abortion rates in the follow-up period. Implants: No systematic reviews or RCTs were identified addressing implants and abortion rates.
Presence of LARC at one year *(Important outcome)*	None of the identified systematic reviews reported on LARC presence at one year but all reported on presence of an IUD at 6 months based on intention to treat analyses. Postabortion IUD (Presence at six months, including women who experienced an expulsion followed by reinsertion): 260/406 (64.0%) for immediate IUD vs. 219/472 (46.4%) for delayed IUD ARD=17.6% NNT=6: For 1000 patients treated, 167 more have an IUD in place at 6 months RR 1.4 (95% CI 1.24-1.58) ●●●○ *(Moderate confidence, based on 3 RCTs, N=878)* Postpartum IUD (Presence at six months, including women who experienced an expulsion followed by reinsertion): 97/120 (80.8%) for immediate IUD vs. 83/123 (67.4%) for delayed insertion ARD=13.3% NNT=8: For 1000 patients treated, 125 more continue to have an IUD in place at 6 months OR 2.04 (95% CI=1.01-4.09) ●●●○ *(Moderate confidence, based on 4 RCTs, N=243)*

Need for alternate or replacement contraception (e.g., expulsion of IUD, elective, indicated removal of device) *(Important outcome)*	<u>Postabortion IUD Expulsion at 6 months</u>: 18/406 (4.4%) for immediate IUD vs. 8/472 (1.7%) for delayed insertion ARD=2.74% NNH=37: For 1000 patients treated, 27 more experience expulsion RR 2.64 (95% CI 1.16-6.0) ●●●○ *(Moderate confidence, based on 3 RCTs, N=878)* <u>Postabortion IUD Removal</u>: 20/362 (5.5%) for immediate IUD vs. 12/428 (2.8%) for delayed IUD ARD 2.72% RR 2.01 (95% CI 0.99-4.06) ●●●○ *(Moderate confidence, based on 2 RCTs, N=790)* <u>Postpartum IUD Expulsion by 6 months</u>: 19/113 (16.8%) for immediate IUD vs. 3/97 (3.1%) for delayed insertion ARD=13.7% NNH=8: For 1000 patients treated, 125 more experience expulsion OR 4.89 (95% CI 1.47-16.32) ●●●○ *(Moderate confidence, based on 4 RCTs, N=210)* <u>Postpartum IUD Replacement</u>: When expulsion occurred after post-cesarean placement, replacement was more common for those undergoing immediate IUD placement (3 out of 4 expulsions in immediate group vs. 0 out of 1 in the delayed group, statistical analysis not reported). No data are available about IUDs placed after vaginal delivery. ●○○○ *(Very low confidence, based on one fair quality RCT, N=112)* <u>Implants</u>: No systematic reviews or RCTs were identified addressing implants and need for alternate/replacement contraception.

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Harms *(Important outcome)*	*Important harms specific to IUD insertion include uterine perforations and infections.* Postabortion IUD Perforation: 0/258 for immediate IUD vs. 0/317 for delayed IUD. No uterine perforations were observed in women randomized to immediate or delayed IUD insertion following first trimester abortion. ●○○○ *(Very low confidence, based on no observed perforations in 1 fair quality RCT, N=575)* Postabortion IUD infection: (Rates of upper genital tract infections). 5/406 (1.2%) for immediate IUD vs. 6/472 (1.3%) for delayed insertion ARD=0.04% OR 1.0 (95% CI 0.32-3.14) ●●●○ *(Moderate confidence, based on 3 RCTs, N=878)* Postpartum IUD infections: 2/120 (1.6%) for immediate IUD vs. 2/123 (1.6%) for delayed IUD. Reports of upper genital tract infections were rare in both groups (no statistical analysis provided). ●○○○ *(Very low confidence, based on 4 cases reported in 4 RCTs, N=243)* Implants: No systematic reviews or RCTs were identified addressing implants and harms.

Balance of benefits and harms:
Although there is insufficient data to show a reduced risk of unintended pregnancy from immediate placement, IUDs are among the most effective forms of contraception. The unintended pregnancies in the included intention-to-treat studies of IUD placement timing occurred almost exclusively in women who failed to return for their follow-up appointments and thus never received an IUD. The lack of statistical significance of the findings on postabortion IUD placement may be a result of differential loss to follow-up among the immediate and delayed study arms and the small study sizes relative to the rare occurrence of selected outcomes. The only "harm" shown by this evidence is an increased risk of IUD expulsion, which is easily remedied and usually without morbidity. Thus, the balance is in favor of immediate placement. Implants are also among the most effective forms of contraception, and there is no evidence of differential harm based on timing of placement.

Resource Allocation: The costs of unintended pregnancy are significant. Effective contraception is cost-saving (not just cost-effective). Economic modeling predicts high levels of cost savings from immediate placement of LARC.

Values and Preferences: Evidence shows most women of reproductive age desire to control their fertility and time their pregnancies. When women who desire contraception are presented with all contraceptive options, more than 70% select a LARC method, including teens. When women select their preferred contraceptive method, continuation rates across all methods are higher.
Evidence about women's preferences for timing of LARC placement is not available, but low dropout rates in the immediate placement arms of the trials examined here suggest it is an acceptable option for most women choosing an IUD.
For IUDs, women would need to balance the higher expulsion rate for immediate insertion against the observed higher perforation rate for actively breastfeeding women with routine (delayed) placement, as well as the convenience and immediate effectiveness of IUDs compared to alternative forms of birth control. For implants, there is no evidence about differential effectiveness or harms based on the timing of placement. Based on these factors, we expect low variability in values and preferences, with most women who have the option choosing immediate placement.

Other Considerations:
Missed opportunities for contraception are significant in the postpartum and postabortion periods: 30-40% of insured women do not attend a postpartum visit and 40-75% do not attend a postabortion visit, thus increasing the risk of unplanned pregnancy, abortion, or unmet contraceptive needs. Uninsured women, including those who are no longer covered under the Citizen Alien Waived Emergent Medical (CAWEM) program, may have additional access and financial barriers to obtaining contraception at a future visit. Uninsured women may also struggle to obtain important follow-up care including continued contraceptive management and/or device removal.

Ensuring that women are able to make a free, uncoerced, and informed choice about contraception is important.

Rationale: Although there is strong evidence that LARC use reduces unintended pregnancies and abortions, there is not direct randomized evidence comparing the timing of LARC placement (immediate postpartum or postabortion vs. delayed insertion) resulting in lowering rates of subsequent unintended pregnancy or abortion outcomes based on intention-to-treat analyses. However, 13 of the 14 unintended pregnancies in these studies occurred in the delayed placement arm to women without IUDs present. In addition, there is direct evidence that immediate postpartum and postabortion IUD insertion results in higher LARC use rates at 6 months. Based on evidence of the effectiveness of LARC, this would lead to lower rates of unintended pregnancy and abortion. Although there is an increased rate of IUD expulsion with immediate postpartum insertion, IUD use is still higher at 6 months, and economic analyses show the cost savings from immediate insertion. There is also observational evidence from a study of 61,000 women that a 6-fold risk of uterine perforation exists in actively breastfeeding women with delayed insertion compared to immediate insertion. Immediate postpartum LARC is a highly cost-saving strategy even considering IUD expulsion rates, and with the possibility of avoidance of uterine perforation. For implants, there is no RCT evidence about differences in pregnancy outcomes based on immediate versus delayed implant placement, but the CDC recommends the use of implants immediately postabortion and postpartum, and the disadvantages associated with an increased risk of an IUD expulsion do not exist for implants. The strong recommendation for coverage for either type of LARC (IUD or implant) is based on existing evidence and guidelines on the benefits of LARC, lack of significant harms for immediate placement, high cost-savings associated with immediate placement, and strong values and preferences.
Recommendation: Immediate postpartum and postabortion placement of LARC (implant or intrauterine device) is recommended for coverage *(strong recommendation*).

*The Quality of Evidence rating was assigned by the primary evidence sources, except where indicated, not the HERC Subcommittee.

Note: GRADE framework elements are described in Appendix A. The GRADE Evidence Profile for these outcomes is provided in Appendix B.

Prioritized List Guideline Note

January 1, 2017 Prioritized List

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

Line 6

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

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

OFFICE FOR OREGON HEALTH POLICY & RESEARCH
Health Evidence Review Commission
Kate Brown, Governor

Oregon Health Authority

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

November 15, 2016

Dear Medical Directors:

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

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

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

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

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

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

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

Sincerely,

Somnath Saha, MD, Chair, Health Evidence Review Commission

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

Postpartum LARC Update for QHOC 1-9-17, canceled

As presented in previous QHOC meetings, the HERC Coverage Guidance: Timing of Long-Acting Reversible Contraceptive (LARC) Placement, and Guideline Note 162: Long-Acting Reversible Contraceptive (LARC) Placement, were approved 11-10-16 and went into effect 1-1-17. Guideline Note 162 can be found at http://www.oregon.gov/oha/herc/Pages/Searchable-List.aspx and the guidance can be found at http://www.oregon.gov/oha/herc/CoverageGuidances/LARC-CG.pdf

Postpartum LARC placement is a covered benefit for Medicaid members in CCOs and FFS, both the device and the insertion, effective 1-1-17; however the payment strategies are up to each CCO. As noted in the letter from the HERC to Medical Directors, administrative barriers have been the major reason reimbursement for postpartum LARCs has been lacking; technically they were always covered by Medicaid regardless of setting or timing.
http://www.oregon.gov/oha/herc/Documents/LARC-Implementation.pdf

Please see the attached directive from CMS April 2016, which includes detailed information on the methods 14 states have used to optimize LARC utilization, in particular postpartum placement, and supply of outpatient clinics. Please see also the directive from CMS June 2016, with additional detail on strategies states can use to reimburse postpartum LARC.

These strategies fall into 3 general categories below with states using each specific strategy:

1. Postpartum LARC as an Add-on Benefit to Delivery Charges: IL, GA, LA, MA, SC
2. "Unbundling" approaches, enabling reimbursement of both an inpatient plus an outpatient claim on the same day: AL, DA, IA, MD, MT, NM, NY, SC
3. Enhanced DRG reimbursement: CO

Oregon FFS has chosen a strategy in the "unbundling" category. Strategies in categories 1 and 3 were not viable given the nature of FFS distribution across the entire state, and the billing and payment methodology available to FFS. However, a small, geographically limited CCO may find it easier to choose a strategy in category #1.

The FFS strategy is based on allowing hospitals to bill a normal delivery DRG claim on the same day as an outpatient claim. The outpatient claim must include the J code (HCPCS) for the device, and the CPT code 58300 for IUD insertion, or 11981 for implant insertion, together with the V25.11 modifier. We have removed an edit from our claims processing, which "kicked-out" the second claim received for the same day, when both an outpatient and an inpatient claim were submitted for the same day for the same member, and a LARC code is present.

FFS is working with hospitals statewide, through the Oregon Association of Hospitals and Health Systems (OAHHS) and their quality organization, Apprise HealthInsights on LARC billing strategy. OHA is also working with compliance specialists and billing staff to provide assurance that this billing methodology for postpartum LARC will not trigger auditing. Additionally, CMS is directing states to consider this strategy to optimize LARC utilization.

OHA is in the process of developing collaborative efforts around the use of LARCs including work with the Oregon Perinatal Collaborative, the Oregon chapter of ACOG, and other professional societies.

In addition to reimbursement of postpartum LARC placement, CCOs are recommended to consider:

1. Review fee schedules for devices and procedure codes to insure adequacy; fee schedules should not dis-incentivize hospitals or providers for either the device or insertion procedure.
2. Insure that no cost-sharing, step-therapy or prior authorization requirements exist for LARCs
3. Collaborate with local hospitals and provider champions
4. Consider provider education for insertion skills and advocacy
5. Alert members and providers to encourage LARC utilization
6. Insure that LARC placement is counted in the effective contraception CCO financial incentive metric
7. Make sure appropriate provider types are able to bill LARC insertion

8. Consider hospital Labor and Delivery toolkits to facilitate postpartum placement
9. Insure that removal of device is covered
10. Consider a performance improvement project

SHO # 16-008

Re: Medicaid Family Planning Services and Supplies

June 14, 2016

Dear State Health Official:

The purpose of this letter is to clarify previous guidance on the delivery of family planning services and supplies to all Medicaid beneficiaries, as well as to highlight approaches states may take to ensure timely access to this benefit. Specifically, this letter provides guidance on family planning services provided under both fee-for-service and managed care delivery systems; clarifies the purpose of the family planning visit; offers strategies to reduce barriers to receiving family planning services and supplies; and suggests ways to increase access to contraceptive methods. The guidance in this letter is effective immediately.

Background

Under section 1905(a)(4)(C) of the Social Security Act (the Act), family planning services and supplies must be included in the standard Medicaid benefit package and in alternative benefit plans (ABPs). The mandatory family planning benefit provides coverage for services and supplies to prevent or delay pregnancy and may include: education and counseling in the method of contraception desired or currently in use by the individual, a medical visit to change the method of contraception, and (at the state's option) infertility treatment. For expenditures for family planning services and supplies, states receive an enhanced Federal Financial Participation (FFP) of 90 percent.

In addition, section 1902(a)(10)(G) of the Act, as amended by section 2303(a)(3) of the Affordable Care Act, added an optional family planning eligibility group. While full benefit Medicaid eligible individuals receive a wide array of care under other Medicaid coverage categories, individuals in this optional eligibility group are covered only for family planning services and family planning *related* services. Family planning *related* services are medical, diagnostic, and treatment services provided pursuant to a family planning visit that address an individual's medical condition and may be provided for a variety of reasons including, but not limited to: treatment of medical conditions routinely diagnosed during a family planning visit, such as treatment for urinary tract infections or sexually transmitted infection; preventive services routinely provided during a family planning visit, such as the HPV vaccine; or treatment of a major medical complication resulting from a family planning visit. Expenditures for family planning *related* services are matched at the states' regular Federal Medical Assistance Percentage (FMAP). The clarifications in this letter supplement all earlier guidance.

The Centers for Medicare & Medicaid Services (CMS) issued a State Medicaid Directors letter on July 2, 2010 (SMDL #10-013), which provided guidance on the new optional family planning state plan eligibility group created by section 2303 of the Affordable Care Act. In a subsequent

letter issued on April 16, 2014 (SMDL #14-003), CMS provided additional clarification on coverage of family planning-related services provided to individuals eligible under the new optional family planning state plan group.

Applying Family Planning Policy to Fee-for-Service and Managed Care

In accordance with section 1902(a)(23)(B) of the Act, an individual has free choice of a family planning provider regardless of the state's delivery system (i.e., fee-for-service or managed care) and cannot be required to obtain a referral prior to choosing a provider for family planning services. In managed care, enrollees can select any qualified family planning provider from in-network or out-of-network without referral.

In addition to a beneficiary's free choice of provider, beneficiaries are free to choose the method of family planning as provided for in 42 C.F.R. § 441.20. States must provide that individuals are free from coercion or mental pressure and free to choose the method of family planning to be used. States cannot have requirements that would place an undue burden, coercion, or mental pressure that would impinge on access to family planning services.

While states and managed care plans have the ability to apply medical necessity or utilization control criteria for a beneficiary's request for family planning services, such processes cannot interfere with a beneficiary's freedom to choose the method of family planning or the services or counseling associated with choosing the method. For example, a state or managed care plan cannot require that a particular method be used first (e.g., step therapy) or have in place policies that restrict a change in method (which may involve removal of an implanted or inserted method). The only permissible prior authorization requirement would be the determination that the method is medically necessary and appropriate for the individual, using criteria that may include considerations such as severity of side effects, clinical effectiveness, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service. States and managed care plans should avoid practices that delay the provision of a preferred method or that impose medically inappropriate quantity limits, such as allowing only one long acting reversible contraceptive (LARC) insertion every five years, even when an earlier LARC was expelled or removed. To the extent that states elect to employ utilization practices, they should pursue only those practices that ensure beneficiaries choice in family planning providers and method of contraception.

Clarification of the Purpose of the Family Planning Visit

CMS is clarifying that, when family planning services and supplies are delivered during a medical visit in which family planning and non-family planning services are furnished, expenditures for such family planning services and supplies are eligible for 90 percent FFP. Therefore, if an individual presents at a medical visit for any reason, such as an annual physical exam, and obtains a family planning service or supply for a family planning purpose during that visit, an expenditure for the family planning service or supply, if properly identified on the claim, is eligible for the 90 percent FFP. The family planning purpose must be for the purpose of preventing or delaying pregnancy (or at the state's option, for treating infertility). In order for the state to claim the 90 percent FFP for that family planning service, states must ensure that

provider claims are appropriately documented to reflect the provision of family planning services and supplies.

Assuring Access to Family Planning Services and Supplies

Coverage of specific family planning services and supplies is one key to ensuring access to family planning for Medicaid beneficiaries. However, family planning benefit requirements differ depending on whether a beneficiary has coverage under the traditional state plan benefit package or under an Alternative Benefit Plan (ABP.)[1] In general, ABPs allow states flexibility in defining benefit packages that are different from the Medicaid state plan. ABPs must include all Essential Health Benefits (EHBs). Under the Preventive Services EHB category, coverage must include all U.S. Food and Drug Administration (FDA) approved methods of contraception prescribed for women by a health care practitioner. ABPs must cover at least one form of contraception within each method approved by the FDA. For a list of approved methods, see FDA Office of Women's Health Birth Control Guide available at http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM356451.pdf.

For Medicaid beneficiaries whose coverage is governed by the state plan rather than the ABP's, states may determine the specific services and supplies that will be covered as Medicaid family planning services and supplies so long as those services are sufficient in amount, duration, and scope to reasonably achieve the purpose of preventing or delaying pregnancy and permit beneficiary choice of the method of family planning. Although it is not required, CMS recommends that states cover all FDA-identified contraceptive methods for beneficiaries, including both prescription and non-prescription methods. Because not all forms of contraception are appropriate for all beneficiaries, in the absence of contraindications, patient choice and efficacy should be the principal factors used in choosing one method of contraception over another. One pathway for states to accomplish this would be to align ABP and state plan coverage for these services.

Under both ABP and state plan coverage, whether provided through a fee-for-service or a managed care delivery system, family planning services and supplies, including contraceptives and pharmaceuticals, must be provided without cost sharing pursuant to 42 C.F.R. §447.56(a)(2)(ii) and 42 C.F.R. §438.108. Additionally, existing timely claims payment provisions specified in 42 C.F.R. §447.45 and §447.46 apply to claims for family planning services and supplies. For managed care plans, these provisions apply to claims from in-network and out-of-network providers, unless a mutually agreed to alternative payment schedule is in place.

Other confidentiality requirements protect individuals seeking family planning services. State Medicaid programs and managed care plans are "covered entities" under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. Under 45 C.F.R. §164.522(b)(ii), the

[1] States are required to provide Medicaid benefits through an ABP for the Medicaid expansion population. The state has the option of providing benefits through an ABP for other populations, otherwise individuals receive traditional state plan benefits.

state Medicaid program and managed care plans must accommodate a beneficiary's reasonable request to receive communications, including explanation of benefits, by alternative means or at an alternative location when the individual clearly states that disclosure could endanger the individual. For example, a beneficiary may request that a plan communicate with her/him via cell phone instead of paper mail. States and managed care plans are responsible for ensuring that beneficiaries are informed of this option. In addition, under 45 C.F.R. §164.522(b)(i), health care providers must accommodate an individual's reasonable request for alternative means of communication in all circumstances. All states and Medicaid managed care plans (and health care providers) should already be ensuring confidentiality as part of their compliance with the HIPAA Privacy Rule.

Strategies for Improving Access to Long Acting Reversible Contraceptives (LARCs)

LARCs, including IUDs and contraceptive implants, are an extremely effective form of contraception. LARCs are administered by physicians and other providers who may administer them within their scope of practice. LARCs may also be cost effective (and when expenditures are federally matched at the 90 percent rate, the costs to states are extremely low). For Medicaid eligible individuals, reimbursement to providers for LARCs should be reasonable and must include not only the insertion and removal of the LARC, but also the LARC itself, even if the service and device are billed and paid separately. CMS issued an informational bulletin on April 8, 2016, highlighting emerging payment approaches that several state Medicaid agencies have used to optimize access to and use of LARCs.[2]

States may cover LARCs through their pharmacy benefit. Covering LARCs through the pharmacy benefit means that dispensing pharmacies bill the state for the LARCs and applicable dispensing fees, then deliver the LARCs to providers for insertion or administration. The provider then bills the state for the furnished insertion or implantation service. These steps may present barriers to access since this process requires the woman to see the provider twice: once to obtain the LARC prescription and then again for insertion or administration. Another challenge is that, absent permissible state policies or prior manufacturer arrangements, providers may not return un-inserted or un-administered LARCs, resulting in waste and financial loss for the state.

Issues have also arisen when states cover LARCs through the medical benefit. In these states, providers can stock the array of LARCs and implant or administer the most appropriate one during the patient's visit, which helps improve access by reducing the need for a second visit. It could also reduce the waste from unused LARCs. High upfront costs required to maintain a stock of LARCs, however, may deter providers from implementing this approach, resulting in barriers to access due to a potential unwillingness of providers to furnish LARCs.

CMS encourages states to explore and pursue the following models, some of which are already being used by states, to overcome administrative and logistical barriers to the provision of LARCs:

[2] State Medicaid Payment Approaches to Improve Access to Long-Acting Reversible Contraception. April 8, 2016. https://medicaid.gov/federal-policy-guidance/downloads/CIB040816.pdf

First, states are encouraged to implement measures that facilitate immediate postpartum LARC insertion, when a woman chooses this option. As a result of the global or bundled pregnancy and delivery payment arrangements, some states have established policies of not covering additional services provided immediately following delivery. These policies have the effect of deterring providers from inserting LARCs immediately after delivery. In addition, when multiple procedures are performed during a single hospital stay and submitted as a single inpatient claim, if those costs attributable to family planning services are separately identified, the state can receive federal matching funds at the 90 percent rate. To the extent that there are shared costs between family planning services and other services, the state should develop a methodology for allocating these costs. CMS strongly recommends that states establish payment policies that, when a woman chooses, permit and encourage insertion of LARCs immediately following a vaginal delivery or surgical procedure as a separately identified service that is eligible for the 90 percent FFP. CMS also recommends similar policies with respect to coverage of free standing birth center services, which are generally reimbursed at the state's regular FMAP unless the free standing birth center provides family planning services. These services would then be eligible for the 90 percent FFP.

Another approach to ensure same-day access, to the extent permissible, is for publicly funded providers of family planning services who also serve Medicaid patients to pre-purchase and stock their inventories with LARC methods and bill Medicaid or the pertinent third-party payer for the LARC when it is used.

Additionally, states are encouraged to direct pharmacies and providers to utilize programs already established by manufacturers that facilitate stocking providers with LARCs for medical benefit coverage, as well as those that facilitate the return of, and reimbursement by manufacturers to states for unused LARCs dispensed under the pharmacy benefit. Or states can seek to establish new arrangements with LARC manufacturers to increase Medicaid beneficiary access to their LARCs. In one such arrangement piloted in a number of states, the LARC manufacturer proactively furnishes providers with its LARCs without upfront costs. At a reasonable time post-implantation or administration, the manufacturer bills the provider for the cost of the LARC to ensure providers have had the time to be reimbursed by third party payers, including state Medicaid programs. With this approach, providers can be stocked with a supply of LARCs without incurring upfront costs. Providers' funds which would otherwise be invested in inventory could be used in other ways to improve the range and quality of services provided. Beneficiaries would also receive LARCs in a more timely and efficient manner. Lastly, providers may be able to focus more on the provision of healthcare and not the administrative duties related to stocking and being reimbursed for LARCs. This approach is consistent with existing Medicaid policy, including the availability of manufacturer rebates on the drugs.

CMS is also interested in exploring with states the use of section 1115(a) demonstration authority to make available administrative funding at the 90 percent federal matching (authorized by section 1903(a)(5) of the Social Security Act) for states to maintain an inventory of LARCs for providers who furnish covered medical assistance for eligible individuals. The 90 percent federal matching is available for costs related to the state's administration of family planning services and supplies. CMS envisions that, under a section 1115(a) demonstration, the state would incur an administrative expense to purchase a stock for a Medicaid provider for use by

Medicaid beneficiaries. Once the entire stock is used, the state Medicaid agency would re-stock the provider with the same number of LARCs. To be a reasonable administrative cost, the stock would be expected to be used in the course of a period of time, such as a month, and would be replenished as a stock consisting of the same number of items. To account for the costs, states would claim the cost of the stock as a family planning administrative cost, make the stock available without cost to providers, prohibit any further claim by the provider for the cost of LARCs taken from stock for Medicaid use (the provider would bill for insertion or removal of the LARC, but not for the LARC itself), and provide for replenishment of the stock when LARCs are used. CMS will consider other state ideas like this, related to all types of family planning services, subject to the regular process for review, approval, and evaluation of section 1115(a) demonstrations.

Clarifying Policies Regarding Sterilization and Delivery

Federal funds are available for sterilizations as a family planning service, including when the sterilization is provided immediately following delivery with the informed consent of the patient as an add-on procedure. When provided with the informed consent of the patient, postpartum sterilization is an effective form of contraception that provides convenience for the woman, reduces costs, and reduces unplanned pregnancies. All sterilization services require informed consent in accordance with 42 C.F.R., Part 441, Subpart F. The Federally required consent form, without alteration, must be used and consent must be obtained at least 30 days before the sterilization, but not more than 180 days before the date of the sterilization. The only exception is in the case of procedures performed post-premature delivery or following emergency abdominal surgery. Under those exceptions, the informed consent must be given no less than 72 hours prior to the sterilization and, in the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

CMS encourages states to develop appropriate policies and procedures that eliminate barriers to requested postpartum sterilization while ensuring informed consent. Providers should be encouraged to discuss postpartum sterilization with interested patients early in the course of treatment to ensure that the requirements for informed consent and for completion of the consent form are met pursuant to 42 C.F.R., Part 441, Subpart F, to avoid payment disallowances. When a postpartum sterilization is performed that does not comply with the requirements for informed consent described in 42 C.F.R., Part 441, Subpart F, FFP is not available for costs related to the sterilization.

CMS is committed to assuring that all Medicaid beneficiaries have access to and receive vital family planning services and supplies without limitations on their choice of provider or their choice of contraception method. CMS hopes that states find the information and clarifications provided within this letter useful in administering the Medicaid family planning benefit. If you have any questions regarding this information, please contact, Kirsten Jensen, Director, Division of Benefits and Coverage, at 410-786-8146.

Sincerely,
/s/

Vikki Wachino
Director

cc:

National Association of Medicaid Directors

National Academy for State Health Policy

National Governors Association

American Public Human Services Association

Association of State Territorial Health Officials

Council of State Governments

National Conference of State Legislatures

AcademyHealth

CMCS Informational Bulletin

DATE: April 08, 2016

FROM: Vikki Wachino, Director
Center for Medicaid and CHIP Services

SUBJECT: **State Medicaid Payment Approaches to Improve Access to Long-Acting Reversible Contraception**

In July 2014, the Center for Medicaid and CHIP Services (CMCS) launched the Maternal and Infant Health Initiative to improve maternal and infant health outcomes. The initiative has two primary goals: 1) increasing the rate and improving the content of postpartum visits; and 2) increasing access and use of effective methods of contraception. Medicaid provides coverage for more than 70 percent of family planning services for low-income Americans. Given this important role, CMCS sought to identify approaches to Medicaid reimbursement that promote the availability of effective contraception.[1] This Informational Bulletin describes emerging payment approaches several state Medicaid agencies have used to optimize access and use of long-acting reversible contraception (LARC).

Background

Beyond preventing unplanned pregnancies, research indicates that effective contraception helps prevent poor birth spacing, thereby reducing the risk of low-weight and/or premature birth.[2] It can also be essential to a woman's long-term physical and emotional well-being. LARCs—intrauterine devices (IUDs) and contraceptive implants—are highly effective methods of birth control that last between 3 and 10 years (depending on the method) without requiring daily, weekly, or monthly user effort.[3] The Centers for Disease Control and Prevention has identified LARCs as among the most effective family planning methods with a pregnancy rate of less than 1 pregnancy per 100 women in the first year. For comparison, the contraceptive pill has a rate of 9 pregnancies per 100 women in the first year, while the male condom has rate of 18 pregnancies per 100 women in the first year.[4] While Medicaid agencies typically reimburse for multiple types of contraception, LARCs possess a number of advantages: they are cost-effective, have

[1] Sonfield A and Gold RB. (2012). Public Funding for Family Planning, Sterilization and Abortion Services, FY 1980–2010, New York: Guttmacher Institute, <http://www.guttmacher.org/pubs/Public-Funding-FP-2010.pdf>.
[2] Agustin Conde-Agudelo, MD, MPH; Anyeli Rosas-Bermúdez, MPH; Ana Cecilia Kafury-Goeta, MD (2006). Birth Spacing and Risk of Adverse Perinatal Outcomes: A Meta-analysis. *JAMA* 295 (15): 1809-1823.
[3] Trussell J. Contraceptive efficacy. In: Hatcher R, Trussell J, Nelson A, Cates W, Kowal D, Policar M, eds. Contraceptive Technology. 20th ed. New York, NY: Ardent Media; 2011:779–863.
[4] U.S. Centers for Disease Control. Effectiveness of Family Planning Methods. http://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/contraceptive_methods_508.pdf. Accessed March 28, 2016.

high efficacy and continuation rates, require minimal maintenance, and are rated highest in patient satisfaction.[5]

Despite these known advantages, LARC utilization in the U.S. remains relatively low when compared to rates in other countries. As of 2009, LARC utilization rates among contraception users in the U.S. are higher for women covered by Medicaid (11.5 percent) than the national rate (8.5 percent).[6] But more can be done to increase the use of this form of contraception. Two reasons cited for the low utilization of LARCs in the U.S. are (1) administrative and reimbursement barriers that result in high upfront costs for devices and (2) payment policies that reduce (or do not provide) reimbursement for devices or placement.[7,8] States have flexibility in how they reimburse for LARC, and by promoting access to contraceptive methods of choice—and the support necessary to use chosen methods effectively—states can support not only the health of women and their children, but also reduce the number of unintended pregnancies.

LARC Utilization and Medicaid Reimbursement

Payment challenges related to LARC utilization exist in both fee-for-service (FFS) and managed care environments, as well as in inpatient and outpatient settings (primary, specialty, or other ambulatory care).

In the inpatient setting, for example, the use of a single prospective payment for labor and delivery services may not sufficiently address the additional costs associated with the provision of LARC. There are significant advantages to providing LARC immediately after delivery while the woman is still under hospital care.[9] But many states do not provide additional payment for the cost of LARC, and do not provide additional payment to either the hospital or the practitioner for placement or insertion services.

In outpatient settings, payment rates may be insufficient for LARC devices and/or for placement services. LARC placement may require significant up-front costs to providers, primarily costs to obtain devices prior to placement. For devices covered through a patient's pharmacy benefit, and in the absence of prior arrangements (or state policy), providers may not be able to return a dispensed device if it is not used for the specific patient for whom it was dispensed; these devices must then be discarded at a financial loss to the provider.

If states limit provider payment to an initial LARC placement, but do not provide payment for replacement or reinsertion when necessary, providers may face further disincentives.

[5] Peipert JF, Zhao Q, Allsworth JE, Petrosky E, Madden T, Eisenberg D, Secura G.(2011) Continuation and satisfaction of reversible contraception. *Obstet Gynecol*. 117(5):1105-13.
[6] Finer LB, Jerman J, Kavanaugh ML. (2012). Changes in use of long-acting contraceptive methods in the United States, 2007-2009. Fertility and Sterility 98(4), 893-89
[7] Committee Opinion No. 615. American College of Obstetricians and Gynecologists. 2015. Access to contraception. Obstet Gynecol: 125: 250-5.
[8] Rodriguez, MI, Evans, M, Espey, E. (2014). Advocating for immediate postpartum LARC: increasing access, improving outcomes, and decreasing cost. *Contraception*. 90, 468-471.
[9] Long-acting reversible contraception: implants and intrauterine devices. Practice Bulletin No. 121. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011; 118:184–96.

Additionally, providers may be hesitant to insert LARC devices for women when continued coverage for individuals is uncertain in the event there is later need for removal of the LARC.

Finally, some states or Managed Care Organizations (MCOs) require prior authorization and, as part of the prior authorization, may question medical necessity absent failure using another birth control method (sometimes called step therapy).

State Medicaid Payment Strategies to Optimize LARC Utilization

To assist states in optimizing the existing statutory flexibilities in this area, this Informational Bulletin identifies LARC reimbursement strategies implemented by states. Information on challenges and opportunities were obtained through several sources, including a September 2014 Technical Review Panel on Contraceptive Services in Medicaid and the Children's Health Insurance Program (CHIP) and a scan of state policies and interviews with several state Medicaid officials. Emerging approaches to mitigate challenges in fourteen states, identified as of March 2015, involve a combination of contractual, payment strategies, and policy guidance. Additional states may also use similar strategies which fall into five broad categories:

1. Provide timely, patient centered comprehensive coverage for the provision of contraceptive services (e.g., contraception counseling; insertion, removal, replacement, or reinsertion of LARC or other contraceptive devices) for women of child-bearing age.
2. Raising payment rates to providers for LARC or other contraceptive devices in order to ensure that providers offer the full range of contraceptive methods.
3. Reimbursing for immediate postpartum insertion of LARC by unbundling payment for LARC from other labor and delivery services.
4. Removing logistical barriers for supply management of LARC devices (e.g., addressing supply chain, acquisition, stocking cost and disposal cost issues).
5. Removing administrative barriers for provision of LARC (e.g., allowing for billing office visits and LARC procedures on the same day; removing preauthorization requirements).

The following table summarizes state efforts to optimize LARC utilization, followed by a detailed summary of the approaches three states use. CMS is available to provide technical assistance to states who are interested in reviewing options for modifying LARC policies. For additional information on this Informational Bulletin, please contact Karen Matsuoka at karen.matsuoka@cms.hhs.gov or 410-786-9726.

Table 1. State Medicaid Payment Strategies to Optimize Long-Acting Reversible Contraception (LARC) Utilization in 14 States

A scan of state reimbursement policies on LARC was conducted in 2014, resulting in the identification of payment practices in 14 states. This table describes the payment strategies that these 14 states used to optimize LARC utilization. The payment strategy noted for each state is intended to be a short title, while the policy description provides an overview of the key components of the state Medicaid policy that supports the strategy. The implementation considerations are specific details about how the state implements the payment strategy while maintaining compliance with the state policy.

State Effective Date	Payment Strategy	Policy Description	Implementation
Alabama April 2014	Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting or outpatient practice setting.	1. Covers the cost of the LARC device/drug implant as part of the hospital's cost, and the insertion of the device/drug implant is billable to Medicaid when the insertion occurs immediately after a delivery before discharge from an inpatient setting. 2. Covers the cost of the LARC device/drug implant as part of the hospital's cost, and insertion is billable to Medicaid when the insertion is provided in an outpatient setting after delivery and immediately after discharge from an inpatient setting.	1. Inpatient: the hospital must use an International Classification of Diseases (ICD-9) delivery diagnosis code within the range 630 – 67914 and must use the ICD-9 surgical code 69.7 (insertion contraceptive device) to document LARC services provided after the Delivery. 2. Postpartum LARC in the outpatient hospital setting immediately after discharge from inpatient settings, should be billed on a UB-04 claim form using one code from each of the following with family planning modifier (FP): • 58300 Insertion of IUD • 11981-FP Insertion, non-biodegradable drug delivery implant • 11983-FP Removal with reinsertion ICD-9 diagnosis codes: • V255 Encounter for contraceptive management, insertion of implantable

State Effective Date	Payment Strategy	Policy Description	Implementation
			subdermal contraceptive • V2511 Insertion of intrauterine contraceptive device • V2502 Initiate contraceptive NEC • V251 Insertion of IUD Physician bill on CMS 1500 form using the same coding as above and also indicate Place of Service: • 21 Inpatient hospital setting • 22 Outpatient hospital setting
California **July 1, 2015**	Reimbursement of LARC	General acute care hospitals may submit claims for the long-acting reversible contraceptive methods on an outpatient claim, even when treatment is provided on an inpatient basis	Hospital LARC claims should be billed using the following Healthcare Common Procedure Coding System (HCPCS) codes: • J7300 • J7301 • J7302 • J7307
Colorado **October 2013**	Temporary system work-around for reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.	Medicaid Management Information System (MMIS) was scheduled for an update to the APR DRG[1], in January 2014 to automatically report if a claim includes LARC insertion. For a temporary system work around: • The insertion will be reimbursed and paid separately from the global	1. To receive a LARC payment in addition to the APR DRG, the hospital must include the ICD-9 and Current Procedural Terminology (CPT) codes that are included in the Colorado Medical Assistance Program Revenue Codes UB04/institutional billing form on the same claim as the hospital stay. 2. The "trigger" for LARC payment will be the inclusion of these codes:

[1] 3M™ All Patient Refined Diagnosis-Related Group (APR DRG) Classification System for adjusting data for severity of illness (SOI) and risk of mortality (ROM).

State Effective Date	Payment Strategy	Policy Description	Implementation
		obstetric fee code. • State will cover two LARC devices every five years.	• V25.11 – encounter for insertion of intrauterine contraceptive device; and/or • V25.13 – encounter for removal and reinsertion of intrauterine contraceptive device.
	Reimbursements for LARCs outside of the normal encounter (per visit) rate for Rural Health Centers (RHCs)	RHCs may receive reimbursement for IUDs and implants used for contraceptive purposes in addition to their normal encounter rate reimbursements. Federally Qualified Health Centers (FQHC) do not receive an additional payment for LARCs since the FQHC encounter payment rates are based on "full-cost" reimbursement calculations.	1. For devices purchased under the 340B Program, individual providers and RHCs must bill the actual acquisition cost for the device. 2. Reimbursement will be based on the actual 340B acquisition cost. For devices not purchased through the 340B program, reimbursements are the lower of the provider's charges or the rate on the Department's practitioner fee schedule, whichever is applicable. 3. Reimbursement is separate from any encounter payment the RHC may receive for implanting the device. 4. When a LARC is inserted, removed, or reinserted during a visit, the practitioner must use the appropriate diagnostic code, such as, V25.11 or V25.5, and use the family planning modifier (FP) on the claim form.

State Effective Date	Payment Strategy	Policy Description	Implementation
Georgia **April 2014 for practitioner reimbursement;** **Hospital reimbursement to begin in 2016**	Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.	1. Reimburses hospitals and practitioners the cost of the LARC device outside of the global obstetric fee for delivery. 2. Georgia policy, regardless of delivery system (FFS or Managed Care Organization (MCO)) defines "immediate postpartum" as within ten minutes of birth. 3. Devices should be available in the birthing suite to ensure timely insertion.	1. LARC insertion is considered an add-on benefit and is not included in the DRG reimbursement process. 2. Practitioners receive additional reimbursement when one of the following four devices, indicated by their respective J code, is inserted within ten minutes of birth: • J7300 • J7301 • J7302 • J7307
Illinois **October 2012** **July 2014**	Contraceptive Devices in FQHCs and RHCs Dispensing Fee Incentive	FQHCs and RHCs may receive reimbursement for LARC devices (IUDs and single rod implantable devices) for contraceptive purposes. 340B providers may receive a dispensing fee add-on when dispensing highly-effective contraceptives	1. For devices purchased under the 340B Program, the FQHC or RHC must bill the actual acquisition cost for the device. 2. Reimbursement will be based on the actual 340B acquisition costs and must include modifier "UD" in conjunction with the appropriate procedure code. For devices not purchased through the 340B program, reimbursements are the lower of the provider's charges or the rate on the Department's practitioner fee schedule, whichever is applicable.

State Effective Date	Payment Strategy	Policy Description	Implementation
			3. Reimbursement is separate from any encounter payment the FQHC or RHC may receive for implanting the device.
October 2014	Increased reimbursement for insertion and removal of LARC in the outpatient setting. Allowed reimbursement for office visit along with LARC insertion/removal procedure on the same day. Outpatient provider office stocking.	1. Increased reimbursement rate for insertion/removal procedures of LARC. 2. Provide reimbursement for evaluation/management (E/M) visits, where a practitioner and beneficiary discuss contraceptive options, in addition to same day LARC insertion or removal procedures. 3. Pilot program to ensure practitioners have sufficient devices stocked, with automatic re-supply as needed.	1. When a LARC is inserted, removed, or reinserted during a visit, the practitioner uses a modifier V25 on the claim along with the type of visit: • Postpartum visit (CPT 59430) • Initial or annual preventive visit (CPT 99381-99397) 2. A practitioner must order the device and document the insertion procedure in both the hospital's and the practitioner's medical record:
July 1, 2015	Reimbursement of LARC insertion immediately postpartum in the inpatient setting.	Medicaid allows hospitals separate reimbursement for the LARC device provided immediately postpartum in the inpatient hospital setting.	3. The hospital must use its fee-for-service National Provider Identifier (NPI) to bill the appropriate device or implant (by specific National Drug Code (NDC) on the claim. The hospital must use the appropriate family planning ICD-9-CM diagnosis code (or upon implementation, ICD-10-CM) on the claim.
Iowa **March 2014**	Reimbursement of LARC insertion immediately	1. Medicaid allows the insertion of IUDs and other LARC devices	1. Practitioners may bill for the professional service associated with insertion of the

State Effective Date	Payment Strategy	Policy Description	Implementation
	postpartum in the hospital setting.	before the beneficiary leaves the hospital following delivery. 2. Payment for these services is allowed for both practitioners and hospitals.	LARC with the appropriate CPT code. 2. If a practitioner supplies the LARC, the practitioner may also bill for the device(s). 3. When hospitals provide the LARC services, the claim must be submitted as an outpatient claim, separate from the inpatient DRG claim for the delivery. The outpatient claim will be based on the fee schedule for the HCPCS Level II procedure code billed.
Louisiana **June 2014**	Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.	1. Hospitals and practitioners are reimbursed for LARCs as an add-on service in addition to their daily per diem rate for the inpatient hospital stay (DRG rate) or professional services rate, respectively. 2. Reimbursement amount is determined by: • LARC service provided (insertion or reinsertion) • IUD or non-biodegradable drug delivery implant • The beneficiary's age (0 – 15 years or 16+ years) 3. Medical management, including prior authorization and step	1. In FFS: Hospitals use the appropriate LARC J-code on their hospital stay claim. • On a paper claim (CMS 1500) "DME" must be written in bold, black print on the top of the form. • If the hospital bills electronically, the 837P must be used with the Durable Medical Equipment (DME) file extension. 2. Payment for the LARC is equal to the DME fee schedule, and added to the amount of the hospital's per diem payment. 3. If a LARC device is expelled after insertion, the state applies a pre- determined cost of reinsertion and replacement device to the standard DRG or professional services rates. 4. MCO contracts with the state prohibit

State Effective Date	Payment Strategy	Policy Description	Implementation
		therapy, are prohibited for LARC devices and procedures.	prior authorization for LARC devices or procedures. Further, MCO contracts require hospital and practitioner reimbursement for LARC devices and procedures at a minimum of the FFS fee schedules for the same DME or CPT codes, respectively.
Maryland **July 2013** **September 2014**	Contraceptive Devices in FQHCs Reimbursement of LARC insertion immediately postpartum in the inpatient setting	FQHCs are reimbursed for an office visit and the acquisition cost for one (1) of the three (3) covered LARC ~~procedures~~ devices. LARC devices and insertion procedures are reimbursable and are separate from the delivery fee (Maryland Medicaid does not reimburse physicians for "global" maternity care services; deliveries are billed separately from prenatal care).	Practitioners receive reimbursement for one of the three devices, as indicated by their respective J code: • J7300 • J7302 • J7307 1. Maryland Medicaid reimburses for all LARCs, including those placed immediately postpartum without preauthorization. 2. Hospitals include the LARC invoice separately from the inpatient labor and delivery claim using the appropriate claims using the appropriate codes and modifiers.
Massachusetts **October 2014**	Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting. Comprehensive LARC coverage for outpatient practice settings such as hospital outpatient	1. Hospitals are reimbursed for the provision of the LARC device. The insertion procedure is reimbursed directly through the claim payment, while the device is reimbursed indirectly as part of the hospital's base rate. The device is reported on the annual cost report as a supply, and those costs are incorporated	1. MassHealth payment methodology recently adopted the APR DRG model by 3M Health Information Systems, which weights every service that is entered on the claim. The device is accounted for on the annual hospital cost report, and these costs are incorporated into the hospital's overall provider base rate.

State Effective Date	Payment Strategy	Policy Description	Implementation
	departments or family planning agencies.	into the hospital's provider base rate calculation. 2. Hospital-based practitioners bill the professional claim for surgical procedure through the hospital. The professional claim for hospital-based providers does not include the device. 3. Community-based practitioners are reimbursed separately for the professional service of inserting the device as well as the device itself (if supplied by the physician) on the claim.	2. Family planning agencies that participate in MassHealth are reimbursed for the LARC device and insertion when billed with the appropriate code: 11981 - Insertion, non-biodegradable drug delivery implant 11983 - Removal with reinsertion, nonbiodegradable drug delivery implant 58300 - Insertion of intrauterine device (IUD) J7301 Levonorgestrel-releasing intrauterine contraceptive system, 13.5 mg J7302 Levonorgestrel-releasing intrauterine contraceptive system, 52 mg S4989 Contraceptive intrauterine device, including implants and supplies 3. The community based practitioner is reimbursed separately for the professional service of inserting the device as well as for the device itself if supplied by the physician. Billing is done on a professional claim and paid according to a fee schedule. 4. Regular HCPCS updates to capture new device availability
Montana January 2015	Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.	LARCs inserted at the time of delivery are excluded from the PPS inpatient APR-DRG group. Montana Medicaid is allowing PPS hospitals to unbundle the LARC device and the insertion from the inpatient delivery claim.	These services can now be billed as an outpatient service on a 13X type of bill, and will be paid at the OPPS rates. The following HCPCS/CPT codes are allowed: • J7300 • J7301 • J7302

State Effective Date	Payment Strategy	Policy Description	Implementation
			• J7307 • 11981 • 58300
New Mexico 2014	Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.	1. Practitioners receive reimbursement for insertion in the hospital and for the device if the practitioner supplied it. 2. Hospitals are reimbursed for the device as a medical supply company. 3. Insertion within the same surgery as a Cesarean section is considered incidental to the surgery, and therefore not reimbursed. However, the practitioner will still be reimbursed for the device.	1. Hospitals are reimbursed for the device if: • The facility is enrolled in the New Mexico Medicaid program as a medical supplier (provider type 414); a separate NPI is not required. • Date of service is the same as the DRG date of service. • Hospital's professional claim (837P electronic claim or CMS-1500 form) is submitted as a medical supply company. • Claim includes the appropriate HCPCS procedure code and NDC number for the device. • Place of service (POS) code is 21 (inpatient hospital). • The billing taxonomy number for a medical supplier appears on the claim (typically 332BOOOOOX). 2. Practitioners are reimbursed for the device and insertion if: • Billed on the same professional claim (837P electronic or CMS-1500 paper) as the delivery procedure. • Claim indicates the device HCPCS code and NDC number.

State Effective Date	Payment Strategy	Policy Description	Implementation
			• Claim indicates procedure CPT codes (most likely 58300 or 11981). • Claim indicates the POS as 21 (inpatient hospital).
New York April 2014	Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.	1. Reimbursement provided for the LARC device and insertion during postpartum inpatient hospital stay. 2. Medicaid will reimburse for the replacement of IUDs once every five years (Skyla every three years) per manufacturer recommendations. Reimbursement will be provided for an IUD sooner than five years if medically necessary.	1. Hospitals include the LARC invoice separately from the inpatient labor and delivery claim. 2. Physicians, midwives, and nurse practitioners may submit a separate claim to FFS Medicaid for their professional services.

State Effective Date	Payment Strategy	Policy Description	Implementation
South Carolina **March 2012**	Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting. Outpatient procedure using specialty pharmacy.	1. Allows reimbursement to the practitioner and hospital for delivery and all costs associated with LARC. 2. In the outpatient setting, practitioners may order a LARC device for delivery to the practitioner's office by a specialty pharmacy. 3. Increased LARC reimbursement rate to cover slightly more than the practitioner's cost to purchase LARC devices to stock in their office.	1. Inpatient reimbursement guidelines for the cost of the LARC in addition to the DRG for labor and delivery: • Using the HCPCS code. • Using device J-codes. • Using a family planning modifier on the physician claim when billing for insertion 2. Hospitals are reimbursed for the device by submitting: • The ICD-9 Surgical Code • The ICD-9 Diagnosis Codes • A UB-04 or Institutional Claim so that a gross-level credit adjustment can be generated. 3. Payments to hospitals through FFS: • DRG portion of the claim will be paid in the regular weekly claims payment cycle. • The LARC reimbursement will process as a gross level credit adjustment and will appear on a future remittance advice on a monthly quarterly basis. 4. Outpatient reimbursement guidelines for the cost of the device: • Device can be shipped for a specific patient overnight from specialty

State Effective Date	Payment Strategy	Policy Description	Implementation
			pharmacy. • Device billed directly to Medicaid FFS or the MCO. • The practitioner's office has 30 days to return the unopened device to the specialty pharmacy if the device is not used for the specific patient for which it was ordered. The cost of the device is then credited back to Medicaid FFS or the MCO. 5. Reimbursement for LARC through MCO's: The LARC policy is a FFS benefit; however, provision of LARC is estimated and included in the MCO's per member per month (PMPM) rate. Reimbursement methodology may differ between FFS and MCO's. The state currently includes coverage for the provision of LARCs in both its contractual language and its rate setting methodology with the MCO's. MCOs in the state individually contract with providers and negotiate their rates; claim filing procedures differ based on the MCO.
Texas	Pharmacy reimbursement	1. Texas Health and Human	1. State currently contracts with two

State Effective Date	Payment Strategy	Policy Description	Implementation
August 2014	for LARC devices.	Services (HHS) allows providers the option to prescribe and obtain a limited number of LARC products from specialty pharmacies and to return unused and unopened LARC products through a "abandoned unit return" program. 2. Practitioners may continue to obtain LARC products, then bill for them when they are used under the medical benefit.	specialty pharmacies to deliver Mirena and Skyla to practitioners (Walgreens Specialty Pharmacy, LLC and CVS Caremark Specialty Pharmacy). 2. Practitioners continue to bill for the insertion of the LARC product. 3. If the patient was eligible for Medicaid on the date of service when the LARC product was prescribed and ordered, but the patient is no longer eligible for Medicaid, when the LARC product is inserted, Medicaid will cover the device but will not reimburse for the insertion procedure claim.

Detailed Payment and Policy Approaches of Three Selected States

Below is a more detailed description of the strategies used by three states (Illinois, Louisiana and South Carolina) to optimize LARC utilization and illustrate the range of approaches they have employed within existing state authorities.

The states were selected based on the range of changes they have implemented and the length of experience they have had implementing these innovative approaches. For example, the state of South Carolina was the first state to implement an immediate postpartum payment for LARC separate from the labor and delivery Diagnosis-Related Group (DRG) payment. Since establishing the policy, the state has addressed implementation challenges and seen improvement in its rates. These more detailed state examples provide greater insight for states considering which options may be most viable to address payment barriers for their Medicaid enrollees.

Illinois

Long-Acting Reversible Contraception (LARC) Optimization Strategies

SUMMARY

This document describes payment strategies the Illinois Department of Healthcare and Family Services (HFS) incorporated into its Family Planning Action Plan to increase access to safe and effective LARC.

BACKGROUND

In 2014, HFS implemented the Family Planning Action Plan to increase access to family planning services for Medicaid beneficiaries by: 1) providing comprehensive and continuous coverage for family planning services; and 2) aligning policies and reimbursement to providers to promote provision of highly effective contraception.[1]

- In 2010, 52 percent of all pregnancies (128,000) in Illinois were unintended.[2]
- Its unintended birth rate was 57 per 1,000 women aged 15-44.
- This same year, the reported public expenditures for family planning client services in Illinois totaled $57 million, of which $40.7 million was paid by Medicaid.[3]
- Illinois has the 21st highest pregnancy rate in the nation among adolescents between ages 15 and 19.

To address the rate of unintended pregnancies, the state Medicaid agency implemented several payment strategies to increase access to safe and effective LARC, such as IUDs, in an effort to reduce the number of unintended pregnancies. These strategies are: 1) increased provider reimbursement for insertion and removal of LARC in the outpatient practice setting; 2) provide reimbursement for an evaluation/management (E/M) visit on the same day as LARC insertion or removal procedures; 3) provision for reimbursement of actual LARC acquisition costs under the 340B program to Federally Qualified Health Centers and Rural Health Centers; provision for hospital reimbursement of LARC in addition to the DRG reimbursement for labor and delivery; 5) increased providers' 340B federal drug pricing program dispensing fee to encourage providers to supply LARC and other highly effective methods; and 6) established statewide Medicaid policy for family planning and reproductive health services to improve access to LARC methods.

ILLINOIS MEDICAID REIMBURSEMENT FOR LARC

Effective July 1, 2015, HFS implemented a policy to allow hospitals to receive separate reimbursement for LARC devices provided immediately postpartum in the inpatient setting, in

[1] Illinois Department of Healthcare and Family Services (2014). Important family planning policy change and payment increases. Retrieved from http://hfs.illinois.gov/assets/101014n1.pdf.
[2] Guttmacher Institute (2014). State facts about unintended pregnancy: Illinois. Retrieved from http://www.guttmacher.org/statecenter/unintended-pregnancy/pdf/IL.pdf .
[3] Sonfield A and Gold RB, Public Funding for Family Planning Sterilization and Abortion Services, FY 1980–2010, New York: Guttmacher Institute, 2012, < https://www.guttmacher.org/pubs/Public-Funding-FP-2010.pdf >.

addition to the DRG reimbursement for labor and delivery. Providers not employed by the hospital may bill the respective Current Procedural Terminology (CPT) code for LARC insertion in addition to the labor and delivery fee.[4]

Illinois also implemented several other payment strategies that are intended to increase access to LARC placement in the outpatient practice setting.

Reimbursement of LARC Procedures in the Outpatient Practice Setting

In October 2014, HFS increased the reimbursement rate for the insertion, removal, and reinsertion of IUDs and implants in the outpatient practice setting.[5] HFS increased the reimbursement rate for implant insertions by 20 percent and doubled the reimbursement rate for IUD insertions. LARC insertion and removal procedures may be reimbursed on the same day as evaluation and management visits. Physicians can receive the increased reimbursement for LARC insertion by including the LARC insertion CPT code on their billing form. Physicians can also use the relevant CPT codes to bill for the removal and reinsertion of implants, and removal of IUDS.

Federally Qualified Health Centers (FQHC) and Rural Health Center (RHC)

Effective October 13, 2012, FQHCs and RHCs may elect to receive reimbursement for implantable contraceptive devices. To the extent that the implantable contraceptive device was purchased under the 340B Drug Pricing Program, the FQHC or RHC must bill the actual acquisition cost for the device. Reimbursement is made at the FQHC or RHC's actual 340B acquisition cost for implantable contraceptive devices purchased through the 340B program. For implantable contraceptive devices not purchased through the 340B program, reimbursement is based on the lower of the provider's charges or the rate on the Department's practitioner fee schedule, whichever is applicable. Reimbursement for the device is separate from encounter payment for related procedures.

Additional Dispensing Fees to Providers

Effective July 2014, HFS increased the dispensing fee add-on payment to $35 for providers who dispense highly-effective contraceptives through the 340B federal drug pricing program. In order to receive the additional fee, providers must identify 340B purchased drugs by reporting modifier "UD" in conjunction with the appropriate procedure code and actual acquisition cost for the birth control method on the claim form.

[4] Illinois Department of Healthcare and Family Services (2015). Informational Notice: Hospital Billing and Reimbursement for Immediate Postpartum Long-Acting Reversible Contraceptives. Retrieved from http://www.hfs.illinois.gov/html/063015n.html .
[5] Illinois Department of Healthcare and Family Services (2014). Important family planning policy change and payment increases. Retrieved from http://hfs.illinois.gov/assets/101014n1.pdf.

Approaches for Managed Care Entities

The state's actuarially sound rates include reimbursement for LARC devices and clinical insertion. The state's external quality review organization (EQRO) has developed a family planning readiness review tool and reviews the plans' family planning policies and procedures. Additionally, the MCO contract was revised to include language that provider policies/protocols shall not present barriers that delay or prevent access, such as prior authorizations or step-therapy failure requirements; and that clients should receive education and counseling on all FDA-approved birth control methods from most effective to least effective, and have the option to choose the preferred birth control method that is most appropriate for them.[6]

Pharmaceutical Pilot Programs in Outpatient Settings

HFS is piloting a new program with Bayer HealthCare (Mirena and Skyla) and Teva Pharmaceuticals (Paragard) to make these products available in physician offices without upfront physician costs. This will allow for an inventory of these LARC devices so that they are available when a patient returns for a postpartum visit, or at their annual reproductive health visit. If the patient decides she wants to use this type of contraception, it can be inserted immediately and the patient will not have to return for a second visit. This will improve the efficiency of this program and should lead to increased use of these devices. If deemed successful, the pharmaceutical companies plan to scale the program to a national level.[7]

OUTCOMES

While the impact of these payment strategies have not yet been assessed, Illinois expects that improved access to contraceptive care for low-income women will result in savings due to a decrease in unintended pregnancies and the associated costs.

[6] Wheal, L. (2015). Interview with Illinois Medicaid.
[7] Illinois Department of Healthcare and Family Services (2014). Family Planning and Reproductive Health Services. Retrieved from http://www.hfs.illinois.gov/assets/062614n1.pdf .

Louisiana

Long-Acting Reversible Contraception (LARC) Optimization Strategies

SUMMARY

This document describes a payment strategy the Louisiana Medicaid agency implemented to increase access to safe and effective LARC.

BACKGROUND

Prior to June 2014, Louisiana covered LARC devices under the pharmacy benefit. In the clinical setting, the pharmacy reimbursement rate for LARC devices was approximately $300 less than what the LARC devices cost; hence, physicians who provided LARC devices in the hospital setting suffered financial loss.[8] Furthermore, physicians were not reimbursed for 30 percent of the LARC devices ordered at the time of consent in the hospital, due to the failure of the patients for whom the device was ordered to return for subsequent insertion in the office practice setting.[9]

- In 2010, 60 percent of all pregnancies (53,000) in Louisiana were unintended.
- That same year, the reported public expenditures for family planning client services in Louisiana totaled $39.3 million; this includes $34.5 million through Medicaid.[10]

To address the high rate of unintended pregnancies, Louisiana Medicaid initiated a process to increase LARC utilization that included: 1) LARC reimbursement for insertion immediately after delivery in the inpatient hospital setting; 2) provider education; 3) adjustments in its State Plan Amendment (SPA) to allow more flexibility in inpatient and outpatient LARC reimbursement; and 4) the inclusion of LARC reimbursement requirements in its MCO contracts.

LOUISIANA MEDICAID REIMBURSEMENT FOR LARC

Effective June 2014, the Louisiana Department of Health and Hospitals implemented a LARC reimbursement policy as a central component to reducing the number of unintended pregnancies among low-income women. This policy increases access to LARC placement in the inpatient hospital setting immediately after delivery and before the patient is discharged from the facility by:

- Allowing hospitals to receive reimbursement for the full cost of five LARC devices (Skyla, ParaGard, Nexplanon, Merina, and Norplant) in addition to the DRG that is normally paid to hospital.[11] Manufacturer wholesale prices are re-evaluated and re-adjusted annually.

[8] Gee, R. (2014). Interview with Louisiana Medicaid Medical Director.
[9] Gee, R. (2015). Interview with Louisiana Medicaid Medical Director.
[10] Guttmacher Institute (2014). State facts about unintended pregnancy: Louisiana. Retrieved from http://www.guttmacher.org/statecenter/unintended-pregnancy/pdf/LA.pdf.
[11] Louisiana Medicaid Management Information System (2015). Louisiana Medicaid professional services fee schedule. Retrieved from http://www.lamedicaid.com/provweb1/fee_schedules/FEESCHED.pdf.

- Allowing hospitals or physicians receive additional fees for LARC insertion.
- Eliminating the use of medical management activities, such as prior authorization or step therapy, for LARC devices or procedures.[12]

Hospital Reimbursement of LARC Insertion Immediately Postpartum

The recent changes in Louisiana Medicaid payment policies provide reimbursement to acute care hospitals for LARC devices inserted immediately postpartum and prior to discharge.[13,14] The state is separately reimbursing the hospital both for the cost of the LARC device as well as its insertion procedure in order to clearly demonstrate to hospitals that they are fully reimbursed for LARC costs according to the Louisiana Medicaid fee schedule for durable medical equipment (DME).[15]

Louisiana MCOs have also supported and willingly adopted coverage and the reimbursement policy for postpartum LARC insertion. The hospital and the provider must submit their claims to the MCO for payment. The reimbursement rates are established by the MCO.[16]

Practitioner Reimbursement of LARC Insertion

Practitioners who insert a LARC device immediately post-delivery receive separate reimbursement for this service as defined in the Professional Services Program.[17] In the event that a LARC device is expelled after insertion, Louisiana factors the cost of the expulsion into the reimbursement and also pays for reinsertion of a new LARC. Adding the LARC devices to the physician schedule rather than just the pharmacy schedule allows the physician to store the device in office and not have to provide it to a specific individual.[18]

Capitated Managed Care Implementation

Louisiana Medicaid is completing a three year transition from a FFS reimbursement model to mandatory managed care, which will account for 95 percent of all Medicaid enrollees by December 2015. Based on retrospective data, Louisiana Medicaid negotiates blended capitated

[12] Gee, R. (2015). Interview with Louisiana Medicaid Medical Director.
[13] Hospitals record the appropriate LARC J-code on the paper CMS1500 claim form with "DME" written in bold, black print on the top of the form when submitting their claim to the Fiscal Intermediary (FI). When the hospital bills electronically, the 837P must be used with the DME file extension. The Louisiana Medicaid DME fee Schedule J codes are only intended for use on Inpatient Claims.
[14] Foubister, V. (2013). Case study: Louisiana's poor rankings make improving birth outcomes a state imperative. Quality Matters. Retrieved from http://www.commonwealthfund.org/publications/newsletters/quality-matters/2013/february-march/case-study.
[15] Louisiana Department of Health and Hospitals (2014). Long acting reversible contraceptives (LARCs) for inpatient hospitals. Retrieved from http://dhh.louisiana.gov/assets/docs/BayouHealth/HealthPlanAdvisories/2014/HPA14-9.pdf.
[16] Gee, R. (2014). Interview with Louisiana Medicaid Medical Director.
[17] Practitioners include the LARC insertion code with the family planning modifier on their billing form (CMS 1500 or electronic equivalent). The reimbursement is dependent on the LARC service provided and the patient's age. The global CPT codes include: 11981 - Insertion, non-biodegradable drug delivery implant; and 58300 - Insertion of intrauterine device (IUD).
[18] Gee, R. (2015). Interview with Louisiana Medicaid Medical Director.

per member per month (PMPM) fees to account for projected LARC insertions. MCO contracts require hospital and practitioner reimbursement for LARC devices and procedures at a minimum of the FFS fee schedules for the same DME or CPT codes, respectively. In addition, the MCOs are not permitted to require prior authorization for LARC devices or procedures.

All five Louisiana Medicaid MCOs voluntarily adopted the LARC reimbursement strategy. The MCO contracts contain a requirement for developing birth outcomes quality improvement programs that align with the state's goals, and a one percent withhold of MCO administrative fees to fund shared savings-based pay for performance (P4P) incentives. These provide clear boundaries and predictable revenues that allow MCOs maximum flexibility in their interactions with their network providers and the incentives they offer providers and/or patients.

The Louisiana Medicaid agency achieved the legal authority to require MCOs to fully participate in LARC quality improvement efforts in four phases:

1. Applied non-payment strategies such as provider and MCO education and outreach to establish expectations for MCO performance;
2. Presented a compelling case for the political support needed to establish birth outcomes as the state's highest health priority;
3. Submitted a SPA to include LARC utilization payment policies as a strategy to improve birth outcomes; and
4. Aligned MCO contractual requirements with state Medicaid FFS payment strategies to increase LARC utilization.[19]

ANTICIPATED OUTCOMES

Changes to reimbursement of LARC devices and procedures in the hospital were initiated in 2014. The Louisiana Medicaid Medical Director reports that due to these payment policy changes, voluntary election of LARC insertions increased from nine percent (7,000) of all child-bearing aged enrollees in 2013 to 11 percent (10,000) in 2014.

[19] Gee, R. (2015). Interview with Louisiana Medicaid Medical Director.

South Carolina

Long-Acting Reversible Contraception (LARC) Optimization Strategies

SUMMARY

The South Carolina Birth Outcomes Initiative (SCBOI) launched in July 2011 to improve maternal and infant health outcomes and to reduce Medicaid costs. The SCBOI has supported the development and implementation of a LARC payment policy, which is a central component of South Carolina's effort to reduce the number of unintended pregnancies among low-income women and at-risk adolescents.

BACKGROUND

Low-income women of childbearing age who are sexually active with limited access to effective contraception and family planning services are likely to have unintended pregnancies and increase Medicaid spending.[30]

- In 2010, public expenditures for family planning services in South Carolina totaled $33.7 million, including $25 million paid by Medicaid.[31]
- In 2011, South Carolina ranked as the 12th highest state in teen pregnancy.[32]
- Only 50% of Medicaid-covered postpartum women in South Carolina attend the postpartum visit.

To address this problem, South Carolina Department of Health and Human Services (SCDHHS) leveraged their Birth Outcome Initiative (BOI), an active collaborative of hospitals, providers, and policymakers, to increase LARC placements through changes to existing payment policies. Payment policy changes included 1) increased reimbursement for LARC devices; 2) reimbursement of LARC insertion immediately postpartum; and 3) supply management through the pharmacy benefit.

SOUTH CAROLINA MEDICAID REIMBURSEMENT FOR LARC

The selected payment strategies are intended to increase access to LARC placement in both the inpatient hospital setting as well as the outpatient practice setting. Key elements of the reimbursement strategy include:

- Funding the full costs of four LARC devices (Skyla, ParaGard, Nexplanon, and Mirena).

[30] Guttmacher Institute (2014). State facts about unintended pregnancy: South Carolina. Retrieved from http://www.guttmacher.org/statecenter/unintended-pregnancy/SC.html.
[31] Sonfield A and Kost K, Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010, New York: Guttmacher Institute, 2015, <http://www.guttmacher.org/pubs/public-costs-of-UP-2010.pdf>,
[32] U.S. Department of Health and Human Services Office of Adolescent Health (2014). South Carolina adolescent reproductive health facts. Retrieved from http://www.hhs.gov/ash/oah/adolescent-health-topics/reproductive-health/states/sc.html#.

- Providing additional fees for insertion, device, and removal (if medically necessary) in addition to the DRG fee that is paid to hospital.
- Eliminating prior-authorization or step therapy requirements for LARC procedures.

Reimbursement of LARC Insertion Immediately Postpartum in the Hospital

In March 2012, the South Carolina became the first state in the country to change its reimbursement policy in order to increase LARC placement immediately after delivery and prior to hospital discharge.[33] Prior to that time, hospitals were not incentivized to perform this procedure due to the lack of payment for this activity (beyond the existing DRG payment). South Carolina's Medicaid program now reimburses hospitals the cost of the LARC device as well as payment to the physician for its insertion immediately post-delivery. This LARC reimbursement is provided in addition to any other payments for maternity related services.

Hospitals receive this increased payment through a quarterly adjustment for prior month's claims (credit adjustment). To receive reimbursement for the LARC device itself, hospitals must include on each Uniform Billing (UB-04) claim for delivery services the Healthcare Common Procedure Coding System (HCPCS) code that represents the device. As well as the International Classification of Diseases (ICD-9) Surgical and Diagnosis Codes that best describe the service delivered.

Physicians may also receive reimbursement for immediate post-delivery LARC insertion by including on their billing form (CMS 1500 or electronic equivalent) the LARC insertion code with the family planning modifier.

After the first year of implementation, South Carolina Medicaid learned that hospitals were not receiving the additional LARC payments; further implementation guidance and system changes were needed. In the second year of implementation, all Medicaid providers received specific billing instructions identifying how to capture appropriate reimbursement for all fees covered by the payment policy. By the third year of implementation, providers were receiving appropriate reimbursement, including retrospective payments that previously had not been billed or processed accurately.[34]

These new payments reimburse all costs and clinical efforts associated with LARC placement and promote a highly cost-effective, preventive health practice. However, payment alone is not sufficient to ensure LARC placements. This strategy also requires continued collaboration with MCOs, hospitals, and physicians to ensure that all stakeholders understand the purpose of these increased payments and the impact LARC will have on reducing unintended pregnancies and Medicaid costs.

Reimbursement of LARC Insertion in the Outpatient Practice Setting

[33] Health Management Associates (2013). Medicaid reimbursement for immediate post-partum LARC. Retrieved from https://www.acog.org/~/media/Departments/LARC/HMAPostpartumReimbursmentResource.pdf.
[34] Giese, M. (2015). Interview with SCDHHS Director of Birth Outcomes Initiative.

SCDHHS also addressed the initial costs to providers for stocking LARC devices in its SCBOI "specialty benefit" in the spring of 2014. The new payment policy allows a physician to order a LARC device for a specific Medicaid recipient which is shipped to the physician's office by a specialty pharmacy which is designated by either the state Medicaid agency's Pharmacy Benefit Manager or by the individual MCO's. The device can be shipped overnight and is billed directly to Medicaid FFS or the MCO so that the physician does not incur the initial cost of the device. The physician's office has 30 days to insert the LARC for the specific patient for which it was ordered and bill Medicaid the insertion fee only, or to return the unopened device to the specialty pharmacy if the device is not used. The cost of the device is then credited back to Medicaid or the MCO.

Capitated Managed Care Implementation

Managed care enrollment is mandatory in South Carolina. As a result, approximately 90 percent of all Medicaid births are covered by the six fully capitated MCOs. Although the Medicaid agency did not require its capitated MCOs to adopt this payment policy, all six of them did so voluntarily.

In the first year of implementation of the policy, South Carolina did not develop a payment mechanism specifically for the MCOs to provide this service. Instead, the additional fees associated with LARC payments were prospectively estimated and included in the actuarially sound MCO per member per month (PMPM) rate. The MCO then provides the additional payments to the clinicians in the MCO's network through their negotiated contractual rates. It is not possible to compare the differences in LARC utilization between the MCO and FFS populations (90 percent and 10 percent, respectively).

The MCOs use their regular claims processing cycles to pay for these LARC services and don't have a special process like FFS Medicaid, which was described earlier.

OUTCOMES

As noted above, South Carolina initiated changes to the reimbursement of LARC devices and procedures in the hospital setting in March 2012 and issued a clarification bulletin for billing in 2013 which allowed for appropriate claims payment dating back to the inception of the policy. Although the impact of both of these policy changes has not yet been fully evaluated, South Carolina has documented that their rate of voluntary election of inpatient insertions has gone from approximately 0% to 16%. South Carolina also has seen a 110% increase in inpatient LARC utilization between FY2013 through FY 2015.

Statewide CCO Learning Collaborative: Applied Behavioral Analysis

Quality and Health Outcomes Committee Meeting
Human Services Building, 500 Summer St NE, Salem, OR, Rm 137A-D
February 9, 2017
11:00 a.m. – 12:30 p.m.

Toll-free conference line: 888-278-0296
Participant code: 310477

Applied Behavioral Analysis (ABA)

Session Objectives
Participants will:

- Understand ABA resources across the state.
- Identify best practices in assessment and diagnosis for autism.
- Discuss challenges and barriers for services/treatment.

1. **Introductions and reflection**

2. **ABA resources across the state**
    - Current coverage guidelines
    - Current OAR
    - Statewide directory of providers

3. **Panel: Best Practices in assessment and diagnosis for autism**
    - Evidence Based Best Practice: *Dr. Eric Frombonne, Oregon Health Sciences University*
    - Community approaches: *Marilyn Berardinelli, Oregon Health Sciences University*
    - CCO implementation: *Dr. Tracy Muday, Western Oregon Advanced Health*
    - Practice-level approaches: *Dr. Sondra Marshall, St. Charles Bend*
    - Panel Q & A

4. **Discussion on challenges, barriers and solutions for delivery of ABA services**

5. **Next steps**
    - Closing
    - Evaluation
    - Next QHOC Learning Collaborative: EDIE / PreManage

410-172-0650

Prior Authorization

(4)(h) For Applied Behavioral Analysis (ABA) services, the Division requires submission of:

(A) An evaluation as described in OAR 410-172-0770(1) from a physician or psychologist experienced in the diagnosis and treatment of autism;

(B) A referral for treatment as described in OAR 410-172-0770(1)(e) from a physician and/or psychologist experienced in the diagnosis and treatment of autism;

(C) A functional analysis and a behavior treatment plan from a licensed health care professional as defined in section 1 of 2015 Oregon Laws Chapter 674; or by a behavior analyst or assistant behavior analyst licensed by the Oregon Behavior Analysis Regulatory Board; or by an individual actively pursuing or holding a declaration of practice through the Oregon Behavior Analysis Regulatory Board as described in OAR 824-035-0005.

410-172-0760

Applied Behavior Analysis

(1) Applied Behavior Analysis (ABA) services shall be recommended by a licensed physician or licensed psychologist who has experience or training in the diagnosis of autism spectrum disorder and holds at least one of the following educational degrees and valid licensure:

(a) Physician licensed to practice in the State of Oregon;

(b) Psychologist licensed to practice in the State of Oregon;

(2) Paid providers of ABA services shall hold the following license, registration, or declaration of practice:

(a) Licensed Behavior Analyst as described in OAR 824-030-0010;

(b) Licensed health care professional who is registered with the Oregon Behavior Analyst Certification Board as described in OAR 824-030-0030;

(c) Individual actively pursuing or holding a declaration of practice through the Oregon Behavior Analysis Regulatory Board as described in OAR 824-035-0005.

(3) Non-paid providers of ABA services shall hold the following license or registration:

(a) Assistant Behavior Analyst licensed by the Oregon Behavior Analysis Regulatory Board as described in OAR 824-030-0020;

(b) Behavior Analysis Interventionists registered by the Oregon Behavior Analysis Regulatory Board as described in OAR 824-030-0040.

Stat. Auth.: ORS 413.042, 430.640
Stats. Implemented: ORS 413.042, 414.025, 414.065, 430.640, 430.705, 430.715
Hist.: DMAP 85-2014(Temp), f. 12-24-14, cert. ef. 1-1-15 thru 6-29-15; DMAP 32-2015, f. 6-24-15, cert. ef. 6-26-15; DMAP 60-2016(Temp), f. & cert. ef. 10-7-16 thru 4-4-17

410-172-0770

Individual Eligibility for Applied Behavioral Analysis Treatment

(1) Prior to receiving services, individuals receiving ABA shall have an evaluation by a physician or psychologist experienced in the diagnosis and treatment of autism using the current DSM criteria that includes:

(a) A Diagnosis of an Autism spectrum disorder or stereotypy with self-abusive behavior due to neurological dysfunction;

(b) Documentation of and results from a standardized tool that has been used to substantiate the autism disorder or questionnaires or observation that have been used to substantiate a diagnosis of stereotypy with self-abusive behavior due to neurological dysfunction;

(c) Documentation of behaviors that are considered to have an adverse impact on the individual's development or communication;

(d) Documentation of behavior that is injurious to themselves or others or that interferes with everyday functions or activities;

(e) Documentation that less intensive treatment or other therapy has been considered or found insufficient;

(f) Any other documentation that would substantiate the diagnosis of autism or stereotypy with self-abusive behavior due to a neurological dysfunction including but not limited to:

(A) Notes from well-child visits or other medical professionals;

(B) Results from any additional assessments such as IQ tests, speech and language tests, or tests of auditory function.

(g) A referral for ABA treatment shall include:

(A) A diagnosis of autism or stereotypy with self-abusive behavior due to a neurological dysfunction;

(B) A copy of the evaluation described above;

(C) A referral for ABA treatment without specifying hours or intensity.

(2) Refer to the Health Evidence Review Commission's Prioritized List for guideline notes related to ABA therapy.

GUIDELINE NOTE 75, APPLIED BEHAVIOR ANALYSIS FOR AUTISM SPECTRUM DISORDER

Line 197

Applied behavioral analysis (ABA), including early intensive behavioral intervention (EIBI), represented by CPT codes 0359T-0374T, is included on Line 197 AUTISM SPECTRUM DISORDERS for the treatment of autism spectrum disorders.

ABA services are provided in addition to any rehabilitative services (e.g. physical therapy, occupational therapy, speech therapy) included in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES that are indicated for other acute qualifying conditions.

Individuals ages 1-12

Intensive interventions
Specifically, EIBI (for example, UCLA/Lovaas or Early Start Denver Model), is included on this line.

For a child initiating EIBI therapy, EIBI is included for up to six months. Ongoing coverage is based on demonstrated progress towards meaningful predefined objectives (objectives should be achieved as a result of the EIBI, over and beyond gains that would be expected to arise from maturation alone) using a standardized, multimodal assessment, no more frequently than every six months. Examples of such assessments include Vineland, IQ tests (Mullen, WPPSI, WISC-R), language measures, behavior checklists (CBCL, ABC), and autistic symptoms measures (SRS).

The evidence does not lead to a direct determination of optimal intensity. Studies of EIBI ranged from 15-40 hours per week. Through Oregon's Senate Bill 365, other payers are mandated to cover a minimum of 25 hours per week of ABA. There is no evidence that increasing intensity of therapy yields improves outcomes. Studies for these interventions had a duration from less than one year up to 3 years.

Less intensive ABA-based interventions

If EIBI is not indicated, has been completed, or there is not sufficient progress toward multidimensional goals, then less intensive ABA-based interventions (such as parent training, play/interaction based interventions, and joint attention interventions) are included on this line to address core symptoms of autism and/or specific problem areas. Initial coverage is provided for six months. Ongoing coverage is based on demonstrated progress towards meaningful predefined objectives, with demonstration of medical appropriateness and/or emergence of new problem behaviors.

Effective interventions from the research literature had lower intensity than EIBI, usually a few hours per week to a maximum of 16 hours per week, divided into daily, twice-daily or weekly sessions, over a period of several months.

Parent/caregiver involvement

Parent/caregiver involvement and training is recommended as a component of treatment.

Individuals ages 13 and older

Intensive ABA is not included on this line.

Targeted ABA-based behavioral interventions to address problem behaviors, are included on this line. The quality of evidence is insufficient to support these interventions in this population. However, due to strong caregiver values and preferences and the potential for avoiding suffering and expense in dealing with unmanageable behaviors, targeted interventions may be reasonable. Behaviors eligible for coverage include those which place the member at risk for harm or create significant daily issues related to care, education,
or other important functions. Ongoing coverage is based on demonstrated progress towards meaningful predefined objectives, with demonstration of medical appropriateness and/or emergence of new problem behaviors.

Very low quality evidence is available to illustrate needed intensity and duration of intervention. In the single-subject research design literature, frequency and duration of interventions were highly variable, with session duration ranging from 30 seconds to 3 hours, number of sessions ranging from a total of three to 8 times a day, and duration ranging from 1 to 20 weeks. These interventions were often conducted in inpatient or residential settings and studies often included patients with intellectual disabilities, some of which were not diagnosed with autism.

Parent/caregiver involvement and training is encouraged.

Additional ABA Provider Resources

These databases contain ABA providers and not necessarily those who are enrolled as Oregon Medicaid providers.

National Behavior Analyst Certification Board (BACB)

BACB has a database of all its members; that includes licensed as well as unlicensed providers. Info provided includes the provider's name, city, state, country, their certification and whether they are certified to supervise lower level providers. Search by the person's name, zip code or state. Providers can also be contacted by clicking on their name and sending them an email.

Click here for the BACB link

State of Oregon Behavior Analysis Regulatory Board (BARB)

In order to obtain a list of current practitioners, a public records request must be filled out. The link to the form is below.

Click here for the public records request form

Click here for the Behavior Analysis Regulatory Board Webpage

Type 33, Specialty 374	= Board certified Behavior Analysts (BCBA)
Type 33, Specialty 377	= Other licensed providers with ABA in their scope of practice
Type 33, specialty 379	= ABA organizations

Provider Type	Name	Provider Medicaid ID	Specialty Code	Specialty Code Description	Complete Street Address	City/State/ Zip
	BARKLEY, JESSICA B	500680338	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 3415 SE POWELL BLVD	PORTLAND,OR 97202-3371
	BARTON, HANNAH	500717527	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O ENCOUNTER ONLY 5305 RIVER RD N STE B1	KEIZER,OR 97303-5324
	BROUGHTON, AMANDA J	500693767	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	339 W BROADWAY APT 3	EUGENE,OR 97401-2883
	BRUNER, SHELBY	500691710	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 6400 ROSEWOOD ST	LAKE OSWEGO,OR 97035-5392
	CAMPBELL, EAMON S	500716824	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	19800 VILLAGE OFFICE CT STE 104	BEND,OR 97702-1813
	CHIRHART, KATIE M	500698308	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 129 NE 102ND AVE STE E	PORTLAND,OR 97220-4102
	CLARK, ERIN K	500693451	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 4724 SW MACADAM AVE	PORTLAND,OR 97239-9701
	COGLE, WHITNEY D	500710723	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	COOPER, SARAH	500708179	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 12155 SW TOOZE RD	SHERWOOD,OR 97140-8441
	COX, BETH-ANN J	500685397	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	756 HAWTHORNE AVE NE	SALEM,OR 97304-4674
	CRAIGHEAD, ROBERT B	500705311	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	DACOSTA, KELLY	500706797	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	5305 RIVER RD N STE B1	KEIZER,OR 97303-5324
	DO, THANG	500690770	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 3415 SE POWELL BLVD	PORTLAND,OR 97202-3371
	DWYER, MOLLY A	500700977	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 4724 SW MACADAM AVE	PORTLAND,OR 97239-9701
	ERB JR, JOHN P	500696406	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	2105 LIBERTY ST NE	SALEM,OR 97301-8353
	FISCHER, JENNY L	500675942	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 19800 VILLAGE OFFICE CT STE104	BEND,OR 97702-4883
	FITZPATRICK, JENNIFER	500711651	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O ENCOUNTER ONLY 401 E 3RD ST STE 101	THE DALLES,OR 97058-2563

	GARRIDO, NATALIA N	500713628	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	GEAN, EMILY G	500715033	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	GREEN, KAREN B	500709587	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	HAWS, SARAH B	500690463	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 1950 KEENE RD, BLDG L	RICHLAND,WA 99352-7752
	HELMS, NATALIE	500696876	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 6200 SW ARTIC DRIVE	BEAVERTON,OR 97005-9447
	HOSIE, KRISTEN M	500707671	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	2260 JUDSON ST SE	SALEM,OR 97302-1273
	HOYT, EMILY J	500687014	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	4724 SW MACADAM AVE	PORTLAND,OR 97239-9701
	JAQUES, DAVID W	500694331	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	339 W BROADWAY APT 3	EUGENE,OR 97401-2883
	JOHNS, MEGHAN	500691708	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 3415 SE POWELL BLVD	PORTLAND,OR 97202-
	KHAWAJA, FARZEEN O	500690571	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 1950 KEENE RD	RICHLAND,WA 99352-7751
	LIKE, ALICIA	500709701	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 756 HAWTHORNE AVE NE	SALEM,OR 97304-4675
	LINDEN, JULIA A	500692391	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 2648 SW HAMILTON CT	PORTLAND,OR 97239-1216
	LOUKUS, AMY K	500712562	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	1181 SW RAMSEY AVE	GRANTS PASS,OR 97527-5835
	LUEHRING, MATTHEW C	500709662	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O ENCOUNTER ONLY 5305 RIVER RD N STE B1	KEIZER,OR 97303-5324
	MAEPA HORN, SHAWN L	500696347	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 2120 SW JEFFERSON ST STE B200	PORTLAND,OR 97201-7727
	MARIN, CASEY L	500685400	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 129 NE 102ND AVE STE E	PORTLAND,OR 97220-4102
	MISHLER, ELIZABETH E	500693757	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 4724 SW MACADAM AVE	PORTLAND,OR 97239-9701
	MONCLUS, BRITTANY A	500714512	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 21600 OXNARD ST STE 1800	WOODLAND HILLS,CA 91367-
	MONTGOMERY, KRISTINA V	500690459	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 27960 SW CANYON CREEK RD N	WILSONVILLE,OR 97070-6717

	MORETTO, AMANDA L	500710176	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	MYERS, CARLAMARIE C	500697512	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 30 E BROADWAY STE 100	EUGENE,OR 97401-3175
	NGUYEN, QUYNH	500690767	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 3415 SE POWELL BLVD	PORTLAND,OR 97202-3371
	OROZCO BARAJAS, PERLA	500685403	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 236 SE D STREET	MADRAS,OR 97741-
	POGGE, CANDICE	500686811	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	6400 ROSEWOOD ST	LAKE OSWEGO,OR 97035-5392
	POLANI, SUNNI	500708751	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	ROACH, MOLLY E	500689699	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	3415 SE POWELL BLVD	PORTLAND,OR 97202-3371
	ROSSI, DENISE	500685638	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 129 NE 102ND AVE STE E	PORTLAND,OR 97220-4102
	RUIZ, KAYLEE C	500693677	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 4724 SW MACADAM AVE	PORTLAND,OR 97239-9701
	SANT WING, JENNA F	500713955	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 3995 MARCOLA RD	SPRINGFIELD,OR 97477-7948
	SAUCEDO, DESIREE N	500693908	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 2120 SW JEFFERSON ST STE 200B	PORTLAND,OR 97201-7727
	SCHWARTZ, HEATHER A	500685485	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 129 NE 102ND AVE STE E	PORTLAND,OR 97220-4102
	SMITH, WHITNEY D	500695996	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 756 HAWTHORNE AVE NE	SALEM,OR 97301-4675
	STUMP, COREY T	500688948	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 3415 SE POWELL BLVD	PORTLAND,OR 97202-3371
	TOWNSEND, KELSEY	500691619	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	4660 NE BELKNAP CT STE 123	HILLSBORO,OR 97124-8402
	URIBIO, GABRIELA M	500713202	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	VAN DER GENUGTEN, JULIE	500704522	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 3415 SE POWELL BLVD	PORTLAND,OR 97202-3371
	WARD, STEPHANIE M	500709202	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP NUMBER 6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447

	WHITE, JENNIFER M	500710270	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	C/O GROUP MEMBER 2120 SW JEFFERSON ST STE 200B	PORTLAND,OR 97201-7727
	WILSON, CAITLIN A	500706664	374	374 - ABA Board Certified Behavioral Analyst (BCBA)	6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	BASS, JENNIFER L	500693092	377	377 - ABA BARB Reg Licensed Health Care Professional	C/O LIFE TOOLS 5829 SE CENTER ST	PORTLAND,OR 97206-3721
	CHAN, JESSICA R	500693023	377	377 - ABA BARB Reg Licensed Health Care Professional	C/O GROUP MEMBER 4724 SW MACADAM AVE	PORTLAND,OR 97239-9701
	GARDER, DAVID L	500698229	377	377 - ABA BARB Reg Licensed Health Care Professional	C/O GROUP MEMBER 2648 SW HAMILTON CT	PORTLAND,OR 97239-1216
	GATTEN, LAUREN A	500693036	377	377 - ABA BARB Reg Licensed Health Care Professional	C/O GROUP MEMBER 4724 SW MACADAM AVE	PORTLAND,OR 97239-9701
	GULSETH, JOY M	500713073	377	377 - ABA BARB Reg Licensed Health Care Professional	18765 SW BOONES FERRY RD #100	TUALATIN,OR 97062-8607
	TOWNSEND, KELSEY	500691619	377	377 - ABA BARB Reg Licensed Health Care Professional	4660 NE BELKNAP CT STE 123	HILLSBORO,OR 97124-8402
	A HOPE FOR AUTISM FOUNDATION	500689591	379	379 - ABA Organization	2120 SW JEFFERSON ST STE 200B	PORTLAND,OR 97201-7727
	AUTISM BEHAVIORAL CONSULTING	500685320	379	379 - ABA Organization	129 NE 102ND AVE STE E	PORTLAND,OR 97220-4102
	BUILDING BRIDGES BEHAVIORAL INTERVENTION FOR YOUNG	500688221	379	379 - ABA Organization	4724 SW MACADAM AVE	PORTLAND,OR 97239-9701
	CENTER FOR AUTISM AND RELATED DISORDERS	500685180	379	379 - ABA Organization	6200 SW ARCTIC DR	BEAVERTON,OR 97005-9447
	CENTER FOR AUTISM AND RELATED DISORDERS LLC	500706999	379	379 - ABA Organization	129 NE 102ND AVE STE E	PORTLAND,OR 97220-4102
	CENTER FOR AUTISM AND RELATED DISORDERS LLC	500707015	379	379 - ABA Organization	756 HAWTHORNE AVE NE	SALEM,OR 97301-4675
	CENTER FOR AUTISM AND RELATED DISORDERS, LLC	500704527	379	379 - ABA Organization	2105 LIBERTY ST NE	SALEM,OR 97301-8353
	CENTER FOR AUTISM AND RELATED DISORDERS, LLC	500704534	379	379 - ABA Organization	134 E 13TH AVE STE 2B	EUGENE,OR 97401-3572
	CENTRIA HEALTHCARE	500702330	379	379 - ABA Organization	5305 RIVER RD N STE B1	KEIZER,OR 97303-5324
	CHILD ENRICHMENT CENTER LLC	500690458	379	379 - ABA Organization	1950 KEENE RD BLDG L	RICHLAND,WA 99352-7752
	JENNY LEE FISCHER CASCADE BEHAVIORAL INTERVENTION	500687351	379	379 - ABA Organization	19800 VILLAGE OFFICE CT STE104	BEND,OR 97702-4883

	MARIN, CASEY L	500685400	379	379 - ABA Organization	C/O GROUP MEMBER 129 NE 102ND AVE STE E	PORTLAND,OR 97220-4102
	TRILLIUM FAMILY SERVICES	312072	379	379 - ABA Organization	SECURE ADOLESC INPATIENT 4455 NE HIGHWAY 20	CORVALLIS,OR 97330-9695
	TRILLIUM FAMILY SVCS	312008	379	379 - ABA Organization	C/O PARRY CTR FOR CHILDREN 3415 SE POWELL BLVD	PORTLAND,OR 97202-3371
	TRILLIUM FAMILY SVCS, INC	312089	379	379 - ABA Organization	STABILIZATION AND TRANSITION 4455 NE HIGHWAY 20	CORVALLIS,OR 97330-9695
	VICTORY ACADEMY	500691508	379	379 - ABA Organization	12155 SW TOOZE RD	SHERWOOD,OR 97140-
	VISIONS LLC	500695471	379	379 - ABA Organization	339 W BROADWAY APT 3	EUGENE,OR 97401-2883

BIOGRAPHICAL SKETCH - ERIC FOMBONNE

Dr. Eric Fombonne trained in child psychiatry in France. He held appointments as clinical scientist at the National Institute of Health and Medical Research (INSERM, France), as Senior Lecturer and Reader at the Institute of Psychiatry and Maudsley Hospital, King's College London, UK (1993-2001), as tenured Professor of Psychiatry at McGill University (Canada), Head of the Division of Child Psychiatry and Canada Research Chair in Child Psychiatry (2001-2012). In September 2012, he joined the Department of Psychiatry at Oregon Health & Science University in Portland, Oregon (USA), and is now Director of Autism Research at the Institute for Developmental Disabilities. He has a long experience of clinical work with children with autism and their families, over the lifespan, and has been also directing clinical services for teenagers with depression. His research activities on developmental disorders and child and adolescent psychiatric disorders encompass genetic, longitudinal, epidemiological studies and clinical trials. He has published over 300 articles in peer-reviewed journals, 40 chapters in books. He is past Associate Editor of the *Journal of Autism and Developmental Disorders* (1994-2004); he is currently Joint Editor of *Journal of Child Psychology and Psychiatry* (JCPP) and is on the editorial board of several other journals in the field of autism and child psychiatry.

Publication list:

http://www.ncbi.nlm.nih.gov/sites/myncbi/eric.fombonne.1/bibliography/48417593/public/?sort=date&direction=ascending

Assessment and Diagnosis of ASD: Best practices

Statewide CCO Learning Collaborative

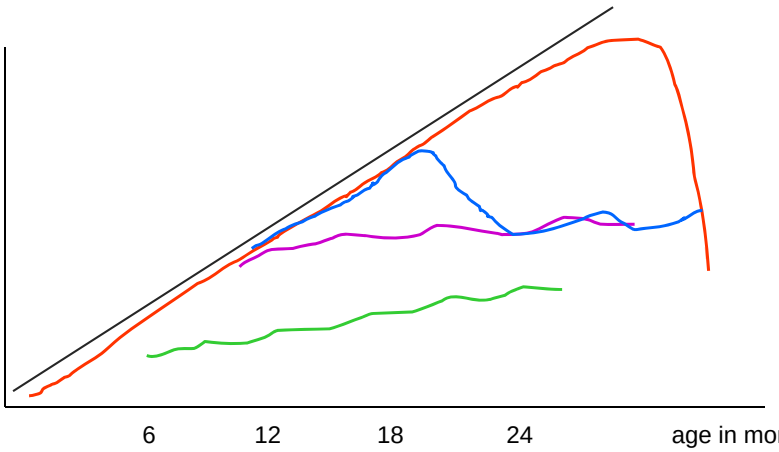
Applied Behavioral Analysis

January 9 2017

Pr. Eric Fombonne

Professor of Psychiatry
Director of Autism Research, Institute for Development & Disability
Oregon Health & Science University

Early markers: Developmental trajectories in ASD



normal | early 'onset' | fluctuating skill acquisition | 'regression' | childhood disintegrative disorder

DSM 5 criteria for Autism Spectrum Disorder

A. Persistent deficits in social communication and social interaction across contexts, not accounted for by general developmental delays, and manifest by all 3 of the following:

1. Deficits in socio-emotional reciprocity
2. Deficits in nonverbal communicative behaviours used for social interaction
3. Deficit in developing and maintaining relationships

B. Restricted, repetitive patterns of behaviour, interests, or activities as manifested by at least 2 of the following:

1. Stereotyped or repetitive speech, motor movements, or use of objects
2. Excessive adherence to routines, ritualized patterns of verbal or nonverbal behaviour, or excessive resistance to change
3. Highly restricted, fixated interests that are abnormal in intensity or focus
4. Hyper- or hypo-reactivity to sensory input or unusual interests in sensory aspects of environment

C. Symptoms must be present in early childhood (but may not become fully manifest until social demands exceed limited capacities

D. Symptoms together limit and impair everyday functioning

Must meet A, B, C and D, currently or by history

Language/communication abnormalities

- No babbling, language delay
- No compensation by alternate modes of communication
- No pointing *(protodeclarative vs protoimperative)*
- No gestures *(nodding, shaking, waving bye-bye, etc..)*
- Receptive language
- Pronominal reversal
- Neologisms, idiosyncratic sentences
- Conversation abnormalities
- Alteration of the pragmatic aspects
- Literal understanding

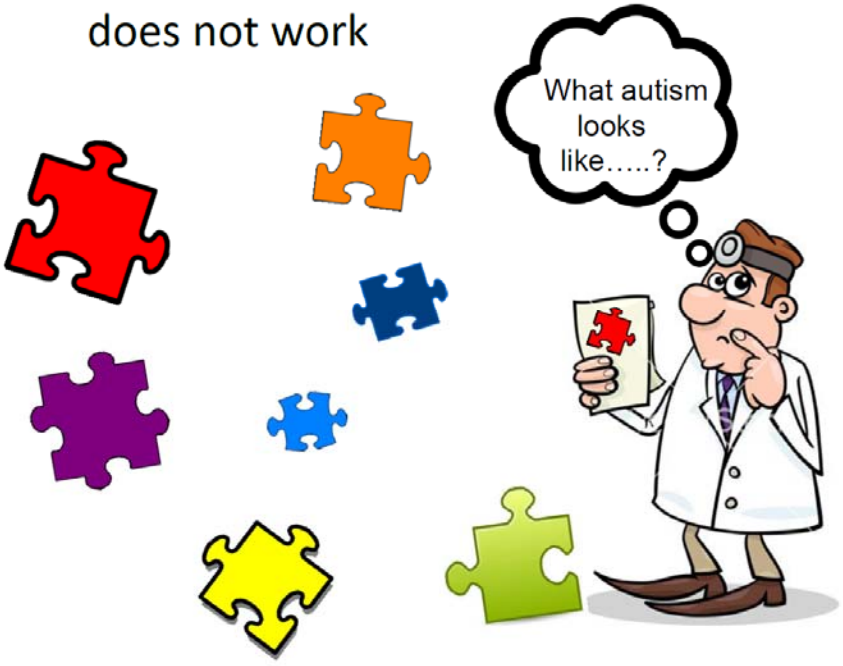
Social interaction abnormalities

- Poor eye gaze and social smiling
- No social orientation, does not respond to name
- Atypical greeting behaviors
- No or infrequent affectionate behaviors
- No social play
- No offering/seeking comfort
- Reduced shared enjoyement
- Reduced facial and affect expressions
- Difficulty in emotional recognition
- Inappropriate behaviors/remarks with strangers
- Lack of friendships, loner

Repetitive behaviors/Unusual interests

- Hand and finger mannerisms
- Unusual sensory reactions
- Unusual attachment to objects *(metal objects,…)*
- Non functional use of objects/toys *(lining up,…)*
- Lack of imagination
- Obsessive behaviors, rituals
- Resistance to change
- Insistance on sameness
- Rigid, inflexible routines
- Odd pursuits
- Circumscribed interests

Pattern recognition approach to diagnosis does not work



Challenges in the diagnostic process

- Phenotypic heterogeneity:
  - Same age children with the same diagnosis look very different
  - Child with ASD looks very different at different ages
- Global development level may or not be delayed
- Language may or not be delayed
- Parents caregivers may or not be " good" informants
  - Variable knowledge of typical normal development
  - Spontaneous compensatory behaviors masking child deficits
  - Familial/cultural dynamics and interpretations
- Oversimplistic explanations: child is misbehaving, or anxious/timid, parenting seems the problem, other detrimental 'interpretations',…

Rationale for using standardized diagnostic interviews

- Clinicians use idiosyncratic and inconsistent approaches
  - in coverage
  - in weighing each symptom
  - in combining symptoms in diagnoses
- Reliability (agreement between clinicians) is low unless they use standardized diagnostic techniques
- Need for structure and standardization
  - to avoid 'illusory correlations', confirmatory bias,…
  - to organize coverage, ways of evaluating symptoms, combining symptoms into diagnoses, resolving discrepancies
- Can be achieved by existing interviews or standardization of the clinical approach

ASD evaluation tools

- Diagnostic check-lists: Childhood Autism rating Scale (CARS), etc..
- Standardized diagnostic tools:
  - ADI-R: Autism Diagnostic Interview-Revised (parent/caregiver interview; ~ 2 hours)
  - ADOS-G: Autism Diagnostic Observational Schedule-Generic, ADOS-2 (direct child observation; 30-45 minutes)
  - Others tools: DISCO, 3Di, STAT, ASI…
  - Administration requires clinical background and specific *ad hoc* training
- Symptom check-lists
  - Social Reciprocity Scale (SRS; parent- or teacher-completed)
  - Autism Screening Questionnaire (ASQ), GARS,..
  - Screening tools for toddlers: ESAT, M-CHAT
  - Other screening tools: SCQ, etc..

Diagnostic evaluation - 1

- There is no biological test or marker for ASD
- Diagnostic principles:
  - Require multidisciplinary team: Peds/Psychiatry/Neuro + OT, Audiology, SLT, Psychology
  - Specific diagnostic tools are preferred (ADOS, ADI)
  - Combination of multi-informant/data sources is necessary
- Usual steps are:
  - Parent/caregiver interview (ADI)
  - Direct observation of child (ADOS)
  - Review of medical records and of day care/teacher reports
  - Medical history and examination
- Other assessments are required to evaluate functional impairment and treatment needs:
  - OT, SLP, audiology
  - intellectual assessment and adaptive behavior (psychology)

Diagnostic evaluation - 2

- Integration of data from different sources is necessary, including resolving discrepancies
  - Mechanical reliance on scores ("above the cut-off") is discouraged
- Differential diagnosis:
  - Mental retardation & developmental delays
  - Anxiety disorder , OCD
  - Severe ADHD
  - Language disorders *including* Semantic pragmatic disorder
  - Schizoid disorder & Sx spectrum
- Subspecialty referrals must be considered when appropriate
- Feed-back to parents is a crucial piece

ASD Medical Assessment
Audiology

- All children with developmental delays, especially social and language
- Requires modifications of traditional test techniques and environments *(e.g., operant test procedures)*
  - Electrophysiologic procedures are useful for estimating hearing sensitivity and for examining middle ear, cochlear, and VIIIth nerve or auditory brainstem pathway integrity
  - Evoked otoacoustic emissions are useful for examining cochlear (sensory) function, and is a frequency-specific, as well as a time- and cost-efficient procedure
  - Frequency-specific auditory brainstem response (ABR) is the single most useful electrophysiologic procedure for use in estimating hearing thresholds, and has been demonstrated to be highly correlated with behavioral hearing thresholds in children who hear normally and in children who have sensorineural hearing loss.

Committee on Infant Hearing of the American Speech–Language–Hearing Association

ASD Medical Assessment
Genetic Testing

For all patients

- Chromosomal microarray: oligonucleotide array-comparative genomic hybridization (CGH) or single-nucleotide polymorphism array

Conditional on findings

- Deoxyribonucleic acid (DNA) testing for fragile X:
  - In males: to be performed routinely
  - In females: if indicators present *(e.g., family history and phenotype)*
- *Methyl-CPG-binding protein 2 (MECP2)* sequencing to be performed:
  - for all females with autism spectrum disorders (ASDs)
  - *MECP2* duplication testing in males, if phenotype is suggestive
- *Phosphatase and tensin homolog (PTEN)* testing only if the head circumference is >2.5 standard deviation (SD) above the mean

American College of Medical Genetics and Genomics 2013

ASD Medical Assessment

Other laboratory tests

- Metabolic disorders in ASDs represent “low incidence yet high impact.”
  - No consensus on what level of testing should be recommended
  - Consider if: lethargy, cyclic vomiting, early onset seizures, dysmorphic features, newborn screening not done

American College of Medical Genetics and the Society for Inherited Metabolic Disorders in 2009

- Mitochondrial testing
  - Electrolyte disturbances, anemia, lethargy, multisystem perturbations, regression, cyclic vomiting, dermatologic changes, poor growth, seizures, hypo-/dystonia, gastrointestinal dysfunction, microcephaly
- Lead testing
  - Children with developmental delays, including Autism, even without frank pica, should be screened for lead poisoning

National Center for Environmental Health of CDC, 1997

- <u>No evidence</u>:
  - hair analysis, celiac antibodies, allergy testing *(food allergies for gluten, casein, candida, and other molds)*, immunologic or neurochemical abnormalities, micronutrients such as vitamin levels, intestinal permeability studies, stool analysis, urinary peptides, mitochondrial disorders *(including lactate and pyruvate)*, thyroid function tests, or erythrocyte glutathione peroxidase studies

ASD Medical Assessment

Brain Imaging & EEG

- Neuroimaging: <u>not</u> recommended routinely

American Academy of Neurology Practice Parameter,Filipek 2000

- More recently, brain MRI recommended when:
  - Abnormal neurologic examination/pre-existing or known Neurologic Disorder (26%)
  - Headaches (26%)
  - Seizures (22%)

Cooper et al., 2016

- EEG:
  - <u>not</u> recommended routinely
  - adequate sleep-deprived EEG with appropriate sampling of slow wave sleep recommended if:
    - clinical seizures or suspicion of subclinical seizures
    - history of regression (clinically significant loss of social and communicative function) at any age, but especially in toddlers and preschoolers

American Academy of Neurology Practice Parameter,Filipek 2000

Co-occurring medical conditions

- Common childhood diseases
  - occur in child with ASD as in any other child
- Medical issues more frequently occurring in ASD
  - Seizures: early or late (puberty) onset
  - Gastro-intestinal problems: constipation 20% , chronic diarrhea 19%
  - Selective eaters
  - Obesity
  - Sleep disturbances: 40-80%
- Risk of overshadowing

Psychiatric disorders occurring more frequently in ASD

Disorder	Prevalence %
Any disorder	**70**
>= 2 disorders	**41**
Social anxiety	29
ADHD	28
Oppositional Defiant Disorder	28
Obsessive Compulsive Disorder	17

In addition:

- Disruptive problems: SIB, aggression, property destruction
- Tics, Tourette Syndrome: increased
- Gender Dysphoria: increased
- Schizophrenia and bipolar disorder can occur in ASD individuals but the risk is not raised (except in some forms of syndromic autism such as 22q, 16q)

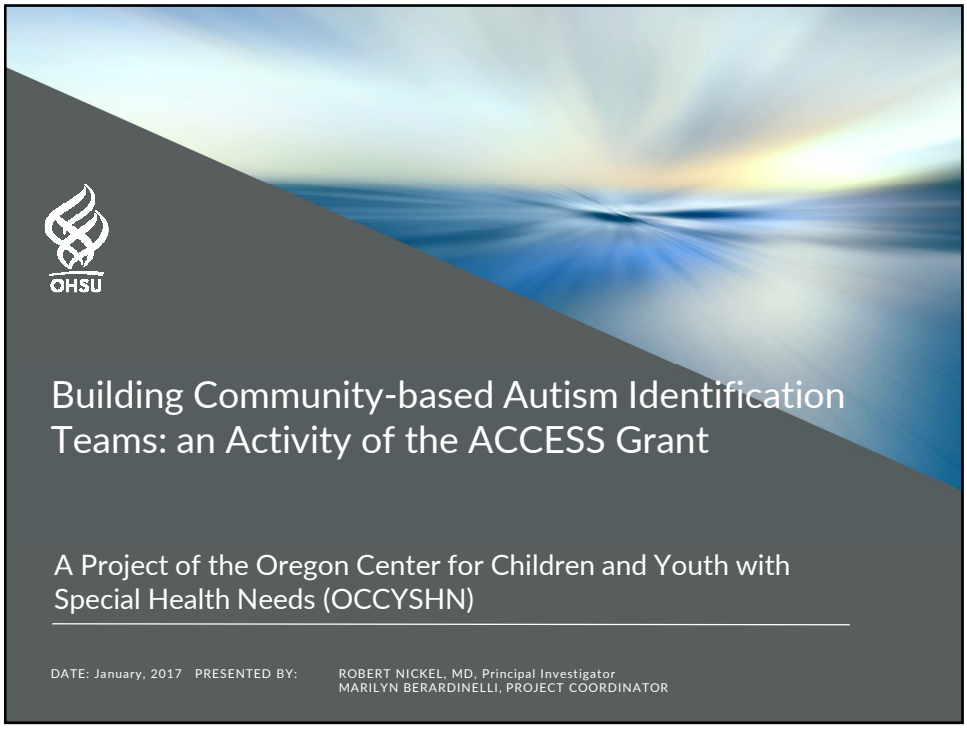
Source: SNAP study, London – Simonoff et al. 2008

Common misconceptions

- Diagnosis cannot be done before age 3.
- Diagnosis requires the full battery ADI+ADOS+ other assessments.
- An ADOS test is sufficient to the diagnosis.
- When a child has Fragile X (or Down´s or TS or any known genetic disorder), he cannot be diagnosed with ASD.

Common misconceptions *cont'd*

- Because of its early onset, ASD cannot be newly diagnosed in adult life.
- An autistic syndrome in a child who is adopted, in foster care, or raised in a context of maternal deprivation, means his diagnosis should be 'Reactive attachment disorder'.
- If parent endorses descriptions read aloud from the DSM, the child has surely an ASD.
- If 2 siblings are affected with ASD, they will show the same degree of severity.



The ACCESS Project

- State autism implementation grant funded by the US Maternal Child Health Bureau
- Administered by the Oregon Center for Children and Youth with Special Health Needs (OCCYSHN)
- Follow-up to project funded by the Oregon Commission on Autism Spectrum Disorder (OCASD)and the Centers for Disease Control

Five Components

- Assure project fidelity with existing OCASD State Plan (**Advisory Group**)
- Increase state and local community capacity for the identification for young children with ASDs/other DDs (**Autism Identification Teams**)
- Improve screening, referral and management of children with ASD and other DDs in a medical home (**Enhancing the Medical Home**)
- Support family-professional partnership in all levels of the project (**Parent Partners**)
- Develop effective coordination of complex services and systems (**Care coordination within the Medical Home**)

ASD Identification Teams

- Goal: Establish a single, valid and timely process in the local community that establishes both a medical diagnosis and educational eligibility for autism services for children up to 5 years of age

- Anticipated Outcomes: improved family and provider satisfaction, decreased age at entry to ASD services, decreased cost to health plans/CCO's

Background

- Currently in Oregon, children may receive a medical diagnosis but not educational eligibility for ASD services and vice versa
- Certain agencies do not accept educational eligibility as a diagnosis, e.g., Developmental Disability services, Social Security Administration
- Different process in medical vs. educational settings: *for example,*
  - prescribed timeline to complete evaluation in education and long wait lists for a medically-based team evaluation
  - use of DSM criteria by medical teams and not by educational teams

OCASD Screening Identification and Assessment Committee's Recommendations for Identification

- Consistent process across medical and educational settings
- Interdisciplinary Team evaluation based on DSM criteria
- Specific Components for the evaluation
- Specific Competencies for team members

http://www.orcommissionasd.org

Recommended Components of the Identification Team Evaluation

- Diagnostic interview based on DSM
- Standard observation using research-based, autism-specific tool (e.g. ADOS 2)
- Observation of individual in unstructured activity
- Developmental assessment
- Hearing testing
- Once identified, reports to caregivers and "starter pack" on next steps and resources to families

Developmental Assessment

- A developmental assessment, using the best available standardized tools for:
  - Cognition: thinking and reasoning
  - Adaptive functioning
  - Functional communication, including speech and language skills
  - Sensory processing
  - Social and emotional skills

Recommended Competencies to be Possessed by the Identification Team

- Ability to assess and/or conduct:
- Typical and atypical child development
- Differential diagnosis (what looks like ASD but isn't)
- Formal and informal assessment practices
- Specific assessment tools and methods for accurate identification of ASD and other disorders
- Characteristics of ASD
- Family and environmental dynamics/systems
- Knowledge re common co-occurring medical and mental health conditions and resources

Who is On the ACCESS ASD Identification Team?

- Health care professional
- Mental health provider (regular participant or consultant)
- Educational staff (ESD staff)
  - Autism specialist
  - Speech pathologist
  - School psychologist or Special Educator
  - Other staff as needed, e.g., Occupational Therapist
- Parent of child with ASD (Parent Partner)
  - Connects with parent before and 1 month after evaluation, present at team and family conferences

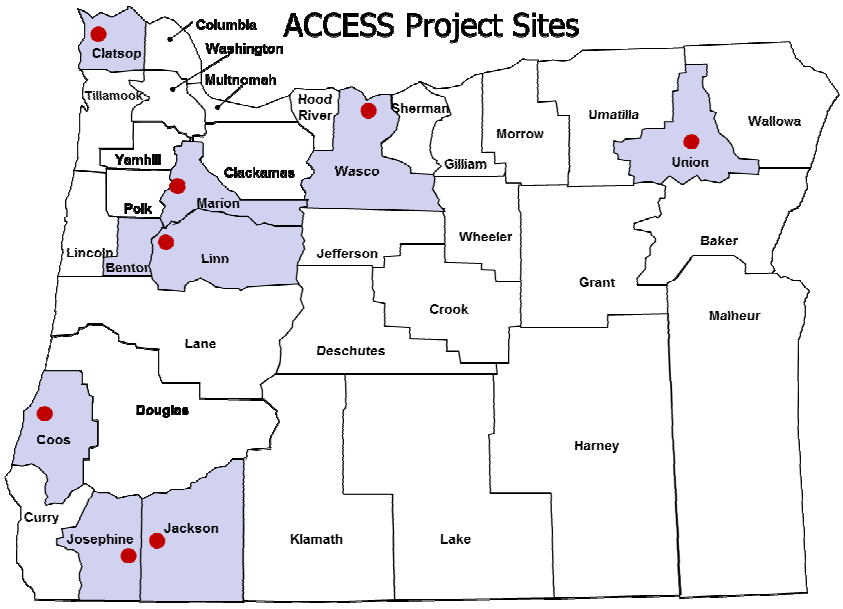
Family-Professional Partnerships: the Parent Partners

Parent-Professional partnerships are supported at every level of the grant. Advisory Committee

- Parent partners participate on:
  - Advisory Committee
  - Autism Identification Teams
  - Practice-based Quality Improvement (QI) Teams
  - OCCYSHN Internal Project Team
- All are members of OCCYSHN's Family Involvement Network and participate in monthly conference calls and annual meeting
- All are paid for their service

Where We Are Now

- 8 Communities (the cities represent regions covered by an Educational Service District):
  - Coos Bay, Salem, the Dalles, Seaside/Astoria, Medford, Grants Pass, La Grande and Albany
  - Four are rural, 2 sites on the coast, 2 in Eastern Oregon
- Teams meet regularly and evaluate children at least monthly.



Team Process

- Referral initially primarily from EI/ECSE, now also local medical providers
- Concurrent or sequential medical and educational evaluations
  (all teams do initial evaluations together)
- Team conference to review results and complete DSM 5 checklist
- Joint review of results with families
- If disagreement, referral to the Child Development & Rehabilitation Center for further evaluation (to top of waiting list)

Training, TA and Support Available to the Autism Identification Teams (AITs) through OCCYSHN

- Initial training for all team members
  - Characteristics of high performing teams
  - Intro to team roles and responsibilities, DSM 5 criteria
  - Characteristic behaviors of young children with ASD (online videos from National Professional Development Center, Autism Navigator, CDC, Diagnose First)
  - Differential Diagnosis
  - Using a diagnostic interview, parent-completed questionnaires
  - Medical/Mental Health issues of children with ASD
  - Interpreting information to families ("Breaking the News")
  - All day training on use of the STAT (Screening Test for Autism in Toddlers and Young Children, W Stone) for health care members

Ongoing Technical Assistance & Supports

- Site visits (initial and at least one follow-up by Medical Director)
- Every other month webinars/conference calls
  - Team updates, what's new (research/policy) and special topic
  - Special webinars, e.g., ADOS scoring reliability, STAT scoring reliability, case study ADHD vs ASD
- Information, Materials (including materials developed by AAP/CDC) and Resources
  - DSM 5 Family Interview, "Getting Started" hand out, Resources for Families, Tip sheets (e.g., Nutrition, Picky Eaters, CAM treatments)
- Sakai Learning Management System
- Online discussion group

Experience to Date

- Total # of children evaluated: 107
- Average age at evaluation: 3.8 years
- Total # with ASD identification: 82 (75%)
- Total # of disagreements: 7
- # other referrals to CDRC: 12
- Referral source to AITs: primarily from Early Intervention/Early Childhood special Education (EI/ECSE)

Program Evaluation

Family Satisfaction Survey – 15 responses

- **18 months,** average age families were first concerned about their child's development
- **20%** reported being on waitlist at OHSU, CDRC, or other clinic to get an Autism evaluation prior to the AIT evaluation
  - **3.7 months,** average time one waitlist
- **How well did the AIT explain their findings to you?**
  - 60% Extremely Well
  - 33% Very Well
  - 7% Somewhat Well

Program Evaluation
Family Satisfaction Survey

- **How well did the AIT make you feel like an equal member of the team?**
  - 60% Extremely Well
  - 27% Very Well
  - 13% Somewhat Well
- **How well did the AIT explain their recommendations to you?**
  - 33% Extremely Well
  - 53% Very Well
  - 13% Somewhat Well
- **93%** would recommend the AIT evaluation process to other families

Program Evaluation
End of Grant AIT Member Satisfaction

All established AIT members surveyed: **30 responses**

- **92% reported that they dedicate time to discuss team process and issues.**
  - 52% report meeting "Often" to discuss team process and issues
- **What percentage of time does your team meet the educational timeline to complete the ASD evaluation and conference?**
  - 80% reported 76 – 100%
  - 12% reported 52 – 75%
  - 4% reported 26-51%
  - 0% reported 1 – 25%
  - 4% reported 0%
- **Overall, how satisfied are you with the AIT process?**
  - 36% Very Satisfied
  - 40% Satisfied
  - 20% Neutral
  - 4% Unsatisfied
  - 0% Very Unsatisfied

Program Evaluation

End of Grant AIT Member Satisfaction

- **How could the AIT process be improved for families?**
  - More timely evaluations. *"Quicker process with less waiting time."*
  - More materials in Spanish.
- **How could the AIT process be improved for team members?**
  - Increased time available for team members to meet.
  - Professional pay rate for Parent Partners.
- **If OCCYSHN does not get funded for the new grant, what are the areas for which you would need additional support or would appreciate more resources?**
  - Continued training and technical assistance (e.g. webinars, in person trainings).
  - Payment for the Parent Partners to keep them on the AIT.
    - *"Other creative ways to continue to compensate team members for their time. Pediatrician and Parent Partner. Educational Staff already get paid to do what we do."*

Teams: What Worked Well

- Value of working together as team to evaluate for autism
- Participation of Parent Partner highly valued: "Each member has something to offer and we continue to learn from each other."
- Good collaboration and communication amongst team members
- Multidisciplinary, strong knowledge base
- Compassionate: "We have a team of people that are really compassionate about others. Our team is excellent with children and good at talking with parents in a way that shows we care. We get along well and work well together."

Teams: What are the Challenges

- Team member turnover/absences
- Difficulty changing usual practice, i.e., sharing diagnosis or educational eligibility with family before discussing as team
- Difficulty taking family perspective, e.g., reason for comprehensive evaluation, value of second opinion if disagreement
- Scheduling and meeting the educational timelines
- Working through disagreements amongst the team about a diagnosis
- Capacity and sustainability

South Coast AIT Project

- 1 year contract with WOAH (Western Oregon Advanced Health) to be paid a case rate for each evaluation
- Project approved February 15, 2016
- Funded by CCO Quality Innovation funds related to screening metric
  - $ per evaluation to cover MD, Parent Partner and extra educational time
- (data pending for the year)

For more information…

Contact Robert Nickel, MD at nickelr@ohsu.edu
or Marilyn Berardinelli at berardin@ohsu.edu

Visit the OCCYSHN webpage at www.occyshn.org , click on Programs & Project, click on Community-based ASD Identification

Thank You

Programs of Evaluation, Development And Learning or PEDAL

A story of moving ASD assessments from a specialty setting to a primary care setting

30,000 Foot View

St. Charles PEDAL CLINIC BEND

OHSU

- 2010-NICU Follow up clinic
- 2011-Multidisciplinary Clinic for children and youth with complex health conditions (wait list 9-12 months)
- 2012-2015-Added Behavior Clinic, Feeding Clinic, Concussion Clinic
- 2016-Lost space so lost clinics

Needed to get Creative!

- 2016 Reduced multidisciplinary team to DVP, Psychology, Speech and Social Work.
- In April began our Birth to Five Clinic with DVP/Psychology in Primary Care Setting
  - Patients are primarily under 5 with complex special health care needs. Approximately 50-70% have ASD as referral diagnosis.
  - Rate of false positives for this clinic is very high. Of the children who are referred for ASD, I estimate only about 30% have ASD.
  - Wait list quickly grows to 8 months.

Needed to Get Creative!

- 2013 St. Charles and Central Oregon Pediatrics Associates forged a partnership to embed Psychologists as integrated behavioral health providers.
- 2016-worked with Pacific Source to provide developmental screening/evaluation as an integrated provider in Primary Care allowing us to practice at the highest end of our license, reduce PEDAL wait time, and offer early identification for children with developmental concerns including ASD.

DATA for our Embedded Testing

- Between October-December 2016 we (2 psychologists; 2 days/week dedicated to evaluation) have seen approximately:
  - 23 patients
  - 16 were referred due to ASD concerns
  - Approximately 5 were diagnosed with ASD
  - Referrals made to ABA, Speech, OT, DD and 4 patients were recommended to return for a more comprehensive evaluation in a year due to complex presentation. Parents provided support and parenting guidance.

Questions from the Workgroup to the CCO's regarding quarterly data reporting to OHA

Specific to the grievance reporting on the quarterly template:

1. Are you open to changes in the quarterly reporting logs?
2. Would you agree to these changes/feel they would be helpful for your data analyses:
    a. A locked template? [This standardizes the responses and allows us to combine and report the data more quickly and with fewer errors]
    b. A drop down menu for category options? [This standardizes the responses and makes combining and reporting the data with less errors]
    c. Removal of column "H", "I" and "J" from the grievance log. ["H" unnecessary as days to resolution tells if resolved same day. "I" and "J" are duplications of service type]
    d. Auto calculations where possible (e.g. days to resolution for grievances)
    e. Auto feed data into the summary tabs for grievances, NOAs, Hearings
    f. Grievance summary: remove service type column and add rows for each service type for each sub-category
    g. Add member name to both the grievance and appeal logs [CCOs are required to have logs that include member name for all grievances and appeals. Current logs only have member ID so they do not meet this requirement for CCOs specified in OAR 410-141-3260.
3. How do you currently log grievances resolved in the current reporting quarter that were flagged as 'pending' in the previous quarter?
    a. Resubmit the grievance in the quarter the resolution occurs?
    b. Don't enter the grievance data but submit the resolution data?
    c. Only submit grievance data for grievances resolved in reporting quarter?
    d. If none of these fit, please explain how you enter these data
4. Would you agree to a process change where we would only report grievances once they are resolved? [Plans that report to Medicare report their grievances by the quarter in which they were resolved, entering all the information requested about the grievance at that time.]
5. Do you have additional changes to suggest?
    a. Please list your requested changes and help us understand why this might be beneficial

Quality Assessment and Performance Improvement

2017 OHA Quality Assessment and Performance Improvement
QHOC
January 9, 2017

HEALTH SYSTEMS DIVISION
Quality Management Team

Quality Assessment and Performance Improvement (QAPI)

Quality Assurance (QA)

- QA is a process of meeting quality standards and assuring that care reaches an acceptable level. QA is a reactive, retrospective effort to examine if certain standards were met.

Performance Improvement (PI)

- PI (also called Quality Improvement - QI) is a pro-active and continuous study of processes with the intent to prevent or decrease the likelihood of problems by identifying areas of opportunity and testing new approaches to fix underlying causes of persistent/systemic problems.

Adapted from CMS.gov

2017 OHA CCO QAPI Review Team

- OHA cross functional review team
  - Health Policy and Analytics
    - Quality Improvement
    - Behavioral Health
  - Health Systems Division
    - Quality Assurance
    - Fraud, Waste, Abuse Compliance
  - Office of Equity and Inclusion
  - Public Health

2017 Timeline for Quality Strategy Review

- March 16–QAPI submitted to OHA
  - Goals: Distribute to OHA review team
- April 3–Check in meeting
  - Goal: Status check on review of CCO QAPIs
- April 10—QHOC update
- April 21–OHA Review Team completion
  - Goal: Completed review and documentation of evaluation due back to QM team
- April 28–Send completed review to HealthInsight for final analysis
- May 8—Update CCOs at QHOC
  - Goal: Begin to send QAPI feedback to CCOs
- June 10– Final CCO QAPI due to OHA

Why we do this work…

QAPI Federal Requirements

CFR guidelines 438.240

State must require at a minimum:

- Conduct Performance Improvement Projects
- Submit performance measurement data
- Have in effect mechanisms to detect both underutilization and overutilization of services.
- Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.
- The State must review, at least annually, the impact and effectiveness of each MCO's and PIHP's quality assessment and performance improvement program. The review must include—

CCO Contractual QAPI requirements

- Develop a QAPI program under an annual quality strategy and work plan.
- Quality strategy identifies the goals, objectives and intended outcomes for the annual QAPI program
- Work plan flows from strategic plan and identifies each project with goals and details about project (who, what, when)
- CCO shall have in effect process for its own evaluation of impact and effectiveness
- CCO shall have, at minimum, the following nine items as identified in the CCO contract (Exhibit B, Part 9, Section 2d); however, these are not intended to be the only QAPI activities reported. Contractor shall include in its annual QAPI program evaluation all system activities utilized to implement and ensure quality coordinated health care, including behavioral health and dental care.
-

CCO Contract QAPI Activities

1. An internal Quality Improvement Committee that monitors the annual quality strategy and work plan;
2. An internal Utilization Review oversight committee that monitors utilization against practice guidelines and treatment planning protocols and policies. Contractor shall have in effect mechanisms to detect both under-utilization and over-utilization of services, to document the findings, to report aggregate data indicating the number of enrollees identified, and to describe follow-up actions for both findings;
3. An assessment of the quality and appropriateness of care furnished to all Members, availability of services, second opinions, timely access and cultural considerations, with a report of aggregate data indicating methods used to monitor compliance;
4. An assessment of the quality and appropriateness of care furnished to Members with special health care needs, with a report of aggregate data indicating the number of enrollees identified and methods used to evaluate the need for direct access to specialists;

CCO Contract QAPI Activities

5. A demonstration of improvement in an area of poor performance in care coordination for Members with serious and persistent mental illness, with a report of aggregate data indicating the number of Members identified and methods used;
6. **A report on the grievance system inclusive of complaints, notice of actions, appeals and hearings, and a**
7. **Monitoring and enforcement of consumer rights and protections** within the Oregon Integrated and Coordinated Health Care Delivery System that ensures consistent response to complaints of violations of consumer rights and protections;

CCO Contract QAPI Activities

8. Assessment of the quality of the fraud, waste and abuse program, including the number of preliminary investigations, and the number of referrals to OPAR or MFCU, training and education for employees, CCO Compliance Officer, other CCOs, and Subcontractors; and
9. Participation as a member of the OHA Quality and Health Outcomes Committee (QHOC).

Questions and Answers??

CCO Quality Strategy Development
Health Transformation 2.0

February 13, 2017
QHOC Quality and Performance Improvement Session

Lisa Bui
Quality Improvement Director
Health Policy and Analytics Division

Where is Quality and Transformation going?

- Directed by OHA leadership to "merge" the CCO Transformation Plan and the CCO Quality Assessment and Performance Improvement (QAPI).
- Convene a broad OHA group to advise leadership on the future framework for CCO Quality and Transformation monitoring.
- Using the collective expertise of this group (health equity, measurement, quality monitoring, program development, community engagement, public health) the team will develop the areas of focus, topics and format for the CCO Quality and Transformation strategy.
- Regular updates on progress at QHOC QPI session and via innovator agents

Purpose

To support the safe and high quality care for all members under CCOs by ensuring the quality and transformation plan adequately covers federal requirements, pushes health transformation forward, and continues the path towards the Triple Aim (better care, better health, lower cost).

Key Functions: 2017 Schedule

January	April	June	August	October
• Kick off meeting • Identify gaps in participants • CCO deliverable schedule reviewed	• Focus areas agreed upon • Included topics brainstorm list generated	• Draft template for "new plan" • Leadership review	• Draft FAQ • Finalize template • OHA Leadership approval	• "New Plan" template distributed to CCOs • Posted to OHA website

Current State

Quality

- Annual submission
- CFR requirement
- QAPI includes:
  - Retrospective analysis of key quality items
  - Prospective work plan
  - CCO QI Committee minutes

Transformation Plans

- 2 year plan
  - Progress report every 6 months
- CCO Contract requirement
  - Submission is a contract amendment
- T Plans includes:
  - 8 Areas of Transformation

Transformation Plan

Areas of Transformation

- Integration of Care
- PCPCH
- Alternative Payment Methodologies
- Activities from the CCO Community Health Assessment and Community Health Improvement Plan
- EHR, HIT, Meaningful Use
- Communications, Outreach and Member Engagement
- Meeting the culturally diverse needs of members
- Eliminating racial, ethnic, and linguistic disparities

*areas in green are across T Plans / Quality

QAPI

Six Levers of Quality

- Improve Care Coordination; including PCPCH
- Implementing alternative payment methodologies
- Integrating physical, behavioral, and oral health care structurally and in the model of care
- Increased efficiency in providing care through administrative simplification and a more effective model of care that incorporates community-based and public health resources
- Implementation of health-related flexible services aimed at improving care delivery, enrollee health, and lowering costs
- Testing, accelerating and spread of best practices and innovation

*areas in green are across Tplans / Quality

QAPI continued

Seven Focus Areas of Performance Improvement Projects

- Reducing preventable re-hospitalizations;
- Population health issues (such as diabetes, hypertension and asthma);
- Deploying care teams to improve care and reduce preventable or unnecessarily costly utilization by super-utilizers;
- Integrating primary care and behavioral health;
- Ensuring appropriate care is delivered in appropriate settings;
- Improving perinatal and maternity care; and
- PCPCH

*areas in green are across T Plans / Quality

Proposed Assumptions for New Plan

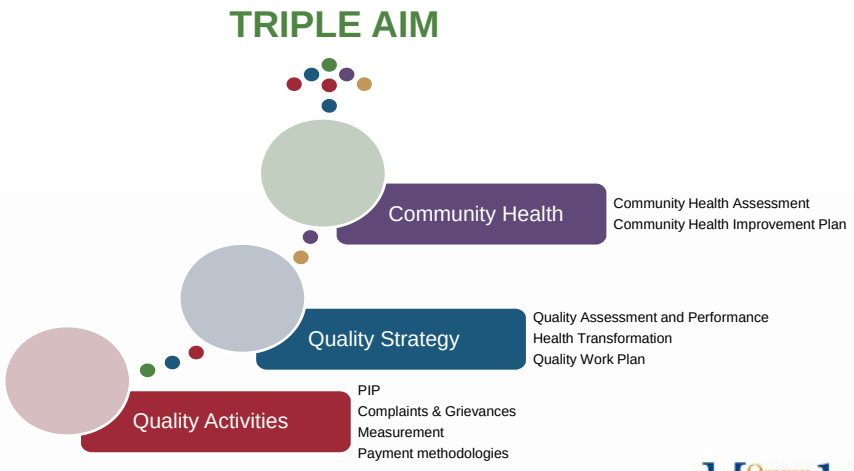
CCO "New Plan"

- Contract Amendment
- Annual Plan
- Calendar Year Plan
- Progress report every 6 months
- Yes OHA to provide a template for plan and progress report

Proposed Deliverables Schedule

- 2015 – 2017 Transformation Plan Benchmark report (closing report) due January 30, 2018
- "New Plan" due March 16, 2018
  - Effective January 2018
- "New Plan" due annually thereafter in January
  - One progress report due mid-year

Summary



Confused yet…Questions