

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

For specific coding recommendations and guideline wording, please see the text of the 3/10/2016 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 10/1/16)

- Move several newborn diagnoses to more appropriate covered lines.
- Add diagnosis codes for esophageal hernias with obstruction or gangrene to the covered hernia line with the appropriate treatment codes and delete from the covered GERD/esophagitis line.
- Delete the treatment code for intracranial vascular balloon dilation for atherosclerosis from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Delete the treatment code for intracranial vascular balloon dilation for vasospasm from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Add procedure codes for perioperative pelvic physical therapy and laser hair removal for surgical site preparation to the gender dysphoria line.
- Add various straightforward codes to appropriate lines.

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Several newborn lines with hematologic conditions were considered for merging but not approved.
- Waiving the requirement to live as the desired gender for 1 year prior to breast or chest surgery for gender dysphoria was not approved.

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

- Modify the gender dysphoria guideline to remove the requirement for hormone therapy prior to breast or chest surgery, to add laser hair removal for surgical site preparation in the same way as restricted for electrolysis, to clarify when revision surgeries are covered, and to specify that pelvic PT procedures codes are only covered for peri-operative therapy.

BIENNIAL REVIEW CHANGES (effective 1/1/18)

- Merge the two premature baby lines and prioritize to the upper line position. Move the diagnosis codes for intraventricular hemorrhages to another line to pair with required treatments.
- Merge the congenital infections line and congenital syphilis lines and prioritize at their current position.
- Merge three lines containing endocrine conditions of the newborn and prioritize to approximately the mid position of the lines.
- Add diagnosis codes and change the line title for the line containing omphalitis and newborn mastitis codes, reprioritizing to a slightly lower position.

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
March 10, 2016
8:30 AM – 1:00 PM

Members Present: Susan Williams, MD, Chair Pro Tempore; David Pollack, MD; Irene Crosswell, RPh; Holly Jo Hodges, MD; Vern Saboe, DC; Gary Allen, DMD.

Members Absent: Kevin Olson, MD; Mark Gibson.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Denise Taray, RN; Daphne Peck (by phone).

Also Attending: Kim Wentz, MD, MPH, and Jim Rickards, MD (Oregon Health Authority); Valerie King, MD, MPH, and Adam Obley, MD, MPH (OHSU Center for Evidence-based Policy); Megan Bird, MD, and Valerie Halpin, MD (Legacy); Amy Penkin (OHSU); Maura Roche and Andrea Zekis (Basic Rights Oregon); Casey Parks (Oregonian); Kimberly Ruscher, MD, and Garret Zallen, MD (via phone) (PeaceHealth); Brenna Legaard; Tobi Rates (Autism Speaks Oregon); Rebekah Brewis (PDX TransPride); Dan Unumb, Esq. (via phone) (Autism Speaks).

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

The meeting was called to order at 8:45 am and roll was called. Minutes from the January 14, 2016 VbBS meeting were reviewed and approved.

Staff reviewed errata published since the January meeting. There were no questions about these items.

Smits introduced the idea of having the October 1 Prioritized List changes only include those without significant fiscal impact. Those changes expected to have significant fiscal impact would be included in January 1 Prioritized List changes to coincide with the next CCO contract period. The subcommittee was generally in favor of this change. Hodges felt that this change would be very helpful for the health plans.

Vern Saboe, DC was introduced as a new member of VBBS. He comes from the HERC and EGBS and has a long history with the Health Services Commission as well. Dr. Saboe spoke to his background in both policy and clinical expertise.

Livingston announced that the Obesity Task Force has started to meet and will give recommendations for biennial review changes for coverage of obesity later in the year.

➤ **Topic: Straightforward/Consent Agenda**

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

Recommended Actions:

- 1) Add 20924 (Tendon graft, from a distance (eg, palmaris, toe extensor, plantaris)) to line 436 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
- 2) Add D62 (Acute posthemorrhagic anemia) to line 152 ACQUIRED HEMOLYTIC ANEMIAS and remove from line 122 NUTRITIONAL DEFICIENCIES
- 3) Add 96150-96155 (Health and behavior assessment) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
- 4) Remove 64505, 64508, 64510, 64517, 64520, and 64530 (Injection, anesthetic agent) from line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
- 5) Add L66.2 (Folliculitis decalvans), L66.8 (Other cicatricial alopecia) and L66.9 (Cicatricial alopecia, unspecified) to line 517 HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP
- 6) Remove L66.2, L66.3 (Perifolliculitis capitis abscedens), L66.8 and L66.9 from line 588 DISEASE OF NAILS, HAIR AND HAIR FOLLICLES
- 7) Remove 92507-92508, 92526, 92607-92609, and 92633 (Speech therapy services) and all CPT codes for inpatient and ICU care from line 501 CALCIUM PYROPHOSPHATE DEPOSITION DISEASE (CPPD) AND HYDROXYAPETITE DEPOSITION DISEASE
- 8) Add E11.49 (Type 2 diabetes mellitus with other diabetic neurological complication) and E11.59 (Type 2 diabetes mellitus with other circulatory complications) and E11.628 (Type 2 diabetes mellitus with other skin complications) to line 169 PREVENTIVE FOOT CARE IN HIGH RISK PATIENTS
- 9) Remove 27175-27185 (Treatment of slipped femoral epiphysis) from lines 431 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY and 508 PERIPHERAL ENTHESOPATHIES
- 10) Add 96904 (Whole body integumentary photography, for monitoring of high risk patients with dysplastic nevus syndrome or a history of dysplastic nevi, or patients with a personal or familial history of melanoma) to lines 234 MALIGNANT MELANOMA OF SKIN, 280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA and 631 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
- 11) Remove 96904 from lines 60, 217, 363, 378, 413, 430, 493, 525, 535, 536, 544 and 548
- 12) Add roseacea ICD-10 diagnosis codes to line 525 ROSACEA; ACNE and remove from line 507 ERYTHEMATOUS CONDITIONS
 - a. L71.1 Rhinophyma
 - b. L71.8 Other rosacea
 - c. L71.9 Rosacea, unspecified
- 13) Remove CPT 11450-11471 (Excision of skin and subcutaneous tissue for hidradenitis) from lines 378 ACNE CONGLOBATA (SEVERE CYSTIC ACNE), 525 ROSACEA; ACNE and 631 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES

- 14) Add E50.0-E50.3 (Vitamin A deficiency with conjunctival or corneal xerosis) to line 122 NUTRITIONAL DEFICIENCIES and remove from line 456 EXOPHTHALMOS AND CYSTS OF THE EYE AND ORBIT
- 15) Add E50.3 (Vitamin A deficiency with corneal ulceration and xerosis) to line 249 CORNEAL ULCER; SUPERFICIAL INJURY OF EYE AND ADNEXA
- 16) Remove E50.5 (Vitamin A deficiency with night blindness) from line 455 DISORDERS OF REFRACTION AND ACCOMMODATION

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 6-0.

➤ **Topic: 2018 Biennial Review—Newborn Line Merging**

Discussion: Smits reviewed the meeting handout with updated staff recommendations for merging various newborn condition lines. The subcommittee generally agreed with all the staff recommendations. The merging of various hematologic conditions was deemed too complicated and liable to have unintended consequences. The changes were accepted as recommended by staff, but the suggested hematologic line changes were not accepted and staff was directed to not pursue this question further.

Recommended Actions:

- 1) Effective October 1, 2016
 - a. Remove P54.0 (Neonatal hematemesis) from the dysfunction lines (lines 75, 297, 350 and 382) and keep only on line 296 ADRENAL OR CUTANEOUS HEMORRHAGE OF FETUS OR NEONATE
 - b. Remove P55 (Hemolytic disease of newborn) from the dysfunction lines (lines 75, 297, 350 and 382) and keep only on line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE
 - c. Add the following codes found only on the dysfunction lines to line 2 BIRTH OF INFANT and remove from the dysfunction lines (lines 75, 297, 350 and 382)
 - i. P05.01-P05.08, P05.11-P05.2 Newborn light for gestational age
 - d. Remove E80.4-E80.8 from line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE and add to line 64 METABOLIC DISORDERS to match similar diagnoses.
 - i. E80.4 Gilbert syndrome
 - ii. E80.5 Crigler-Najjar syndrome
 - iii. E80.6 Other disorders of bilirubin metabolism
 - iv. E80.7 Disorders of bilirubin metabolism, unspecified
 - e. Remove P54.1-P54.3 from line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND

FETAL AND NEONATAL JAUNDICE and add to line 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE

- i. P54.1 Neonatal melena
 - ii. P54.2 Neonatal rectal hemorrhage
 - iii. P54.3 Other neonatal gastrointestinal hemorrhage
 - iv. Line 60 contains all endoscopy and other treatment codes as well as NICU codes
- 2) Make the biennial review changes to lines effective January 1, 2018 as noted in Appendix B.

MOTION: To approve the recommendations in the meeting handout material as amended. CARRIES 6-0.

➤ **Topic: Diaphragmatic hernia**

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

Recommended Actions:

- 1) Add ICD-10 K44.0 (Diaphragmatic hernia with obstruction, without gangrene) and K44.1 (Diaphragmatic hernia with gangrene) to line 172 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE and remove from line 385 ESOPHAGITIS; ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS
- 2) Add the CPT codes for repair of complicated diaphragmatic hernia to line 172 and remove from line 385
 - a. 39503 Repair, neonatal diaphragmatic hernia, with or without chest tube insertion and with or without creation of ventral hernia
 - b. 39540 Repair, diaphragmatic hernia (other than neonatal), traumatic; acute
 - c. 39541 Repair, diaphragmatic hernia (other than neonatal), traumatic; chronic
 - d. 39560 Resection, diaphragm; with simple repair (eg, primary suture)
 - e. 39561 Resection, diaphragm; with complex repair (eg, prosthetic material, local muscle flap)
- 3) Change the line title for line 385
 - a. Condition: ESOPHAGITIS; GERD; ~~ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS~~

MOTION: To approve the code change recommendations. CARRIES 6-0.

➤ **Topic: Intracranial stenting and angioplasty for atherosclerosis**

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

Recommended Actions:

- 1) Remove 61630 (Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous) from line 200 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN and place on the Services Recommended for Non-Coverage Table
- 2) Affirm placement of 61635 (Transcatheter placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed) on the Services Recommended for Non-Coverage Table

MOTION: To recommend the code changes as presented. CARRIES 6-0.

➤ **Topic: Balloon dilation of intracranial vasospasm**

Discussion: Smits reviewed the summary document. There was discussion about the HERC policy for removing a service from the Prioritized List. The current algorithm does not include evidence of harm as a criterion. The subcommittee recommended that harm be taken into account and that HERC staff formulate a new policy for the website. The subcommittee determined that balloon dilation of intracranial vasospasm should be removed from the List due to evidence of harm and placed on the Services Recommended for Non-Coverage Table.

Recommended Actions:

- 1) Remove CPT 61640-61642 Balloon dilation of intracranial vasospasm, percutaneous) from line 200 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN and place on the Services Recommended for Non-Coverage Table

MOTION: To approve the coding changes listed as “option 1” in the meeting materials. CARRIES 6-0.

➤ **Topic: Hormone requirements for chest surgery in the gender dysphoria guideline/other gender dysphoria issues**

Discussion: Smits reviewed the summary of the topic in the meeting materials. Testimony was heard from Dr. Megan Bird, MD and Amy Penkin, MSW regarding their support for removing hormone therapy as a prerequisite for breast/chest surgery. Williams raised a question about what would constitute a non-medical contraindication to hormone prior to breast/chest surgery. Bird responded that patients have various reasons not to take hormones such as nausea, emotional problems, exacerbation of mental illness, or identification as gender neutral and therefore not wanting to take hormones at all. The subcommittee later debated the hormone requirement prior to breast or chest surgery. Hodges argued that breast augmentation needs estrogens for optimal outcomes, and stated

she was uncomfortable with the idea of allowing patients to opt out of hormone therapy on the basis of preference without contraindication or intolerance. Wentz was concerned about the equity of requiring trials of drugs prior to procedures for other conditions (such as requiring a trial of OCPs prior to hysterectomy for menorrhagia) but not requiring a trial of a drug prior to a chest/breast procedure for this condition. Bird argued that there was an ethical issue with not allowing patients to access a needed therapy based on refusal of one particular therapy. The final decision was that patients should be allowed to opt out of hormone therapy prior to breast or chest surgery, and additional wording was added to the requirement for estrogen prior to mammoplasty which allowed "intolerance or patient refusal" as allowable indications for not requiring hormones. Smits pointed out that this basically made the estrogen before mammoplasty clause have the only binding effect of disallowing surgery if a patient reaches Tanner stage 5 with estrogens alone; this was felt to be fine as such a patient would have, by definition, adequate adult female breast tissue and any issues with size will then be cosmetic only.

There was minimal discussion about the staff proposal to remove the requirement for living as the desired gender for 1 year prior to chest surgery. The experts advocated for removing this requirement as a safety issue. It was pointed out that there was already a clause that would exempt a patient from this requirement if two providers documented that it was a safety issue. The staff proposed change was not accepted.

Bird testified regarding the use of laser for hair removal. She stated that laser treatment can permanently eliminate dark hair and therefore reduce the need for electrolysis and the amount of time for treatment. A typical treatment regimen is 4-6 months of laser (separate by 4-6 weeks due to hair growth cycles for each area), then followed up with electrolysis for any non-responding hair. Hodges raised concerns that laser hair removal may not be permanent and asked the experts whether electrolysis would be sufficient for the Prioritized List coverage. The experts responded that electrolysis coverage would be enough to allow surgical site preparation, but that laser allows faster treatment and is less painful. The subcommittee asked the experts for guidance regarding what is a standard need for a hair removal regimen, but the experts felt that hair removal was very individualized and could not recommend guidelines. The decision was made to add laser hair removal as an option.

Williams asked if the experts were seeing requests for revisions which were being denied, and the reasons for the denials. Bird replied that standard types of surgical complications such as fistulas have the repair of the fistula covered, but not subsequent reconstruction that might be required (new donor sites not covered, larger procedures not covered). The experts have also seen denials for chronic pain, revisions of older procedures like silicone injections that need removal, etc. Williams asked about what constitutes chronic pain. Bird replied pain can result from scarring, pulling, or other wound/healing issues. The clause regarding revisions to surgeries was accepted, with additional wording that the complication must be directly related to the surgery.

Bird had concerns about requiring tobacco cessation prior to genital surgery. Vaginoplasty has a high rate of failure with smoking, higher than other types of gender conforming surgeries like hysterectomy. The subcommittee debated including a requirement for smoking cessation in the gender dysphoria guideline, or referring to gender dysphoria procedures in the more general tobacco cessation for elective surgery guideline yet to be established. The decision was to have the restrictions in the elective surgery guideline. There was discussion about whether the restriction should be for cessation at 4 weeks, 6 weeks, or 8 weeks prior to surgery. Bird noted that the best outcomes for hysterectomy were with 8 weeks of cessation, but that the abstinent period required for best outcomes was different with different genital surgeries.

The recommended addition of pelvic physical therapy to the gender dysphoria guideline was discussed. There was a discussion about adding the PT included in this guideline to the totals referenced in GN 6 REHABILITATIVE THERAPIES. The subcommittee agreed with this change and wording was added to reference GN6 in the gender dysphoria guideline. It was noted that urinary incontinence has PT in its treatment guideline that is not referenced in GN6, and staff was instructed to propose adding this line/guideline to GN6.

Recommended Actions:

- 1) Modify GN 127, GENDER DYSPHORIA as shown in Appendix A
- 2) Add laser hair removal for surgical site preparation (CPT 17110, 17111) to line 317 GENDER DYSPHORIA
 - a. 17110: Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
 - b. 17111: 15 or more lesions
- 3) Add pelvic physical therapy to line 317 GENDER DYSPHORIA
 - a. 97001 Physical therapy evaluation
 - b. 97002 Physical therapy re-evaluation
 - c. 97110 Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
 - d. 97140 Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
 - e. 97530 Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
- 4) Staff to review a tobacco cessation requirement for vaginoplasty as part of the larger tobacco smoking and elective procedures guideline still under discussion

MOTION: To approve the recommendations as amended. CARRIES 6-0.

➤ **Topic: Acupuncture for tobacco cessation**

This topic was tabled until the May, 2016 VBBS meeting.

➤ **Topic: Hyperbaric oxygen**

This topic was tabled until the May, 2016 VBBS meeting.

➤ **Topic: Pectus excavatum and pectus caravatum**

Discussion: Smits reviewed the summary document and staff recommendations.

Dr. Ruscher testified that pectus excavatum (PE) results in cardiac impairment and exercise impairment in many children. She requested addition of coverage of treatment of PE for patients meeting certain criteria. She has gotten denials from health plans, which delays surgery to the point where the chest wall is not as elastic and will not respond to surgery as well and results in a more difficult repair. Pectus caravatum (PC) does not have major physiologic effects, but has major physical appearance issues. The treatment of PC is the use of braces, which is not invasive. For bracing, a patient needs a surgery consult, and PT consult and brace fitting. She requested coverage for moderate to severe PC (no accepted scoring system to differentiate severity of the condition exists), and PT coverage including an initial consult and 3 follow-up visits.

Dr. Zellen testified that PE is the single condition where he hears dramatic thanks from families for the ability of the child to exercise and interact with peers. He noted that brace might need to be altered with breast development in girls, or for breakage, etc for both sexes.

Wentz asked whether adults with PC have any cardiovascular impacts. Ruscher responded that some adults may have issues if they also have connective tissue disorders. Zellen replied that surgery is very invasive and painful for PE after adolescence, and corrective surgery for PC is a severe surgery not normally done. Therefore the focus is on treatment of adolescents.

Wentz asked what the efficacy rate is for the use of PC bracing. Ruscher responded that studies show 90% + success rates, which agrees with her clinical experience. Zellen agreed with Ruscher's response.

Zellen responded to the staff proposed guideline, which required PE to be severe based on the Haller index. This index requires 3D imaging. He and Ruscher do not get this imaging just to confirm clinical findings of severity. This saves money and resources. Both surgeons

recommend allowing expert opinion as an option rather than simply requiring all patients to have an imaging-derived Haller index.

Both Zellen and Ruscher recommended coverage for both PE and PC when there is severe body image disturbance, even with no other cardiac or pulmonary impediments. Pollack felt that severe body disturbance can be a real issue in adolescents.

Williams asked about the harms/complications of PE surgery. Ruscher responded that there has been death reported from bar placed through heart, but that newer surgical techniques elevate the sternum and make other changes to minimize this risk. Other complications include infection (1%), allergic reaction to implant, and bar displaced backwards into the chest. On bar removal, one death has been reported which led to technique change. Recurrence of PE after bar removal is also a risk. Patients might need to limit contact sports while the bar is in place.

The experts recommended not including exercise intolerance as a criteria in the guideline, as many of these kids are not active and cannot get a history and actual testing is expensive (metabolic exercise test) and not a good use of resources.

Williams had issues with including atypical chest pain, exercise limitation, and paradoxical chest movement (without cardiac dysfunction as a result) as criteria for allowing PE surgery.

Coverage for PC was not discussed fully at this meeting; further discussion on coverage of treatment for PC was delayed until the May, 2016 VBBS meeting.

HERC staff was directed to work with the OHP medical directors and Dr. Ruscher and Zellen to rework the proposed guideline for treatment of PE and PC. The VBBS generally felt that PE should be included on a covered line, and also left on an uncovered line, with a guideline to distinguish when it is intended to be covered.

Recommended Actions:

- 1) Staff will work with experts and CCO Medical Directors to refine guideline wording and bring back for review at the May, 2016 VBBS meeting

➤ **Topic: Retractable testicles**

This topic was tabled until the May, 2016 VBBS meeting.

➤ **Topic: Remote imaging for screening and management of retinopathy of prematurity**

This topic was tabled until the May, 2016 VBBS meeting.

➤ **Topic: Implantable cardiac loop recorders**

This topic was tabled until the May, 2016 VBBS meeting.

➤ **Topic: Electric tumor treatment fields for initial treatment of glioblastoma**

This topic was tabled until the May, 2016 VBBS meeting.

➤ **Topic: Introduction to issues regarding services for autism and dementia**

Discussion: Smits reviewed the summary document issues, including the possible removal of autism and dementia diagnosis codes from the dysfunction lines and adding certain procedural codes to the autism and dementia specific lines as the Commission deems fit. Coffman reviewed various legal issues around limiting physical therapy (PT) and occupational therapy (OT) and speech services in GN6 REHABILITATIVE SERVICES, including a recent brief on the topic from the Oregon Department of Justice (DOJ).

Testimony was heard from Brenna Legaard regarding her successful lawsuit against Providence Health Plan for violation of the Mental Health Parity Act in terms of that plan's limitations to PT/OT/speech services for her autistic child. She disagrees with the Department of Justice brief that PT/OT are physical health benefits. She stated that the law determines that a medical service is a mental health benefit based on the nature of the disorder you are treating. Autism is a mental health disorder and therefore PT/OT are mental health treatments and subject to parity. The Oregon Insurance Division has published guidance on this topic that applies to private insurers but not to OHP, which she provided to the subcommittee for review. She feels that OHP cannot cap therapies intended to treat mental health conditions. Furthermore, she said EPSDT requires all medical necessary PT/OT to treat medical and mental health conditions to children.

Tobi Rates, the Executive Director of the Autism Society of Oregon and parent of 2 children with autism spectrum disorder, provided testimony. She stated that the current limit of PT/OT/speech of 30 visits per year is not sufficient to meet many children's needs. She feels that this is not morally or legally right, and not good long term fiscal policy because of the long-term costs of treating children who are not given adequate services.

Dan Unumb, an attorney from Autism Speaks, testified that mental health parity does apply to PT/OT services for mental health conditions and requested the removal of limits on these services when treating mental health conditions. He also feels that age limits for ABA violates mental health parity. EPSDT mandates all medically necessary care to ameliorate developmental physical or mental deficits for children under 21. He read the DOJ judgment

as saying that OHP can limit services by not pairing them on the Prioritized List, but once a service is paired to a mental health condition, OHP cannot put a numerical cap on services. He stated that Oregon is the only state that has limits on PT/OT/speech for medically necessary services.

Pollack raised questions about the definition/meaning of mental health parity.

Wentz asked the experts what the amount of unmet need they estimated existed among Medicaid children. The experts could not put a numerical number on the unmet need, but felt that for some children, the numerical cap did create unmet need. Not all children need more than 30 or 60 PT/OT/speech visits in a year.

This topic was informational only and no significant discussion by the subcommittee occurred and no decisions were made.

Recommended Actions:

- 1) Staff will continue to work with the Department of Justice and with OHA leadership for guidance on this topic and will bring back to the May, 2016 VBBS meeting.

➤ **Topic: Coverage Guidance— Skin substitutes for chronic skin ulcers**

Discussion: Obley reviewed the evidence summary and public comment. Livingston highlighted the key discussion points at EbGS (quality of evidence, late breaking studies, reimbursement issues, prerequisites for surgery). She addressed the challenges with estimating average costs of the use of skin substitutes. Livingston reviewed the proposed changes to the Prioritized List based on the draft Coverage Guidance box language. The subcommittee decided to include the full table of those skin substitutes that were recommended/not recommended and including information about a maximum number of applications. Pollack asked why the additional skin substitutes available in the US were not reviewed and Obley clarified that these were included based on the AHRQ systematic review. Livingston discussed that Washington has made a different decision about coverage that may have been influenced by the cost, to which Obley clarified that Washington is rereviewing this topic currently. Williams questioned whether the low evidence was sufficient to justify coverage on the Prioritized List. Livingston and Obley clarified that very low evidence lead to noncoverage recommendations, and that even with low quality evidence it is possible to derive a strong recommendation for coverage. Hodges clarified that those skin substitutes that are recommended by EbGS have at least low quality evidence.

Recommended Actions:

- 1) Approve proposed guideline note language edits. Include within the guideline note the list of included/not included skin substitutes and the maximum application language (for those skin substitutes that will be included on the Prioritized List).

MOTION: To approve the recommended changes to the Prioritized List based on the Draft Skin Substitutes for Chronic Skin Ulcers Coverage Guidance scheduled for review by HERC. CARRIES 6-0.

➤ **Topic: Coverage Guidance— Metabolic and bariatric surgery**

Discussion: Staff discussed that no decision needed to be made about the draft Coverage Guidance at this meeting; rather, the intent was to understand subcommittee concerns prior to revisiting this topic with the Obesity Task Force. Obley presented the evidence and public comment. Livingston highlighted key discussion points of the HTAS and Obesity Task Force Phase 1 meeting. Specifically the recommended language on reoperations was discussed in detail. Hodges raised the concern about possible decreased success rates in subsequent operations if the first one was a failure. Additionally, concerns were raised about covering reoperations when there are significant capacity concerns for the OHP population. Obley clarified that the evidence is low quality, and most comes from case series.

The subcommittee raised the question about whether to cover gastric banding at all. Dr. Valerie Halpin clarified that it would be very rare to offer gastric banding, and only after a lot of counseling that a bariatric surgeon would recommend it.

Recommended Actions:

- 1) The Obesity Task Force to continue discussions, but consider the concerns about reoperation and banding in their deliberations.

➤ **Public Comment:**

Public comment was received from Rebekah Brewis, Executive Director of PDX TransPride. She requested coverage for facial feminization surgery, which is an access barrier and is a safety issue. She testified to her own difficulties in accessing these services. She noted that New York covers these services due to a legal decision that is was discriminatory based on gender and sexual orientation.

➤ **Issues for next meeting:**

- Pectus excavatum and pectus carnitatum
- Rehabilitative services for autism and dementia
- Tobacco cessation and elective surgery
- Acupuncture for tobacco cessation
- Hyperbaric oxygen
- Ventral hernias
- Hypospadias
- Retractable testicles
- Remote imaging for screening and management of retinopathy of prematurity
- Implantable cardiac loop recorders
- Electric tumor treatment fields for initial treatment of glioblastoma

➤ **Next meeting:**

May 19, 2016 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

➤ **Adjournment:**

The meeting adjourned at 1:25 PM.

Appendix A

Revised Guideline Notes

GUIDELINE NOTE 127, GENDER DYSPHORIA

Line 317

Hormone treatment with GnRH analogues for delaying the onset of puberty and/or continued pubertal development is included on this line for gender questioning children and adolescents. This therapy should be initiated at the first physical changes of puberty, confirmed by pubertal levels of estradiol or testosterone, but no earlier than Tanner stages 2-3. Prior to initiation of puberty suppression therapy, adolescents must fulfill eligibility and readiness criteria and must have a comprehensive mental health evaluation. Ongoing psychological care is strongly encouraged for continued puberty suppression therapy.

Cross-sex hormone therapy is included on this line for treatment of adolescents and adults with gender dysphoria who meet appropriate eligibility and readiness criteria. To qualify for cross-sex hormone therapy, the patient must:

1. have persistent, well-documented gender dysphoria
2. have the capacity to make a fully informed decision and to give consent for treatment
3. have any significant medical or mental health concerns reasonably well controlled
4. have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care (www.wpath.org).

Sex reassignment surgery is included for patients who are sufficiently physically fit and meet eligibility criteria. To qualify for surgery, the patient must:

1. have persistent, well documented gender dysphoria
2. [for genital surgeries](#), have completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless hormones are not clinically indicated for the individual
3. have completed twelve months of living in a gender role that is congruent with their gender identity unless a medical and a mental health professional both determine that this requirement is not safe for the patient
4. have the capacity to make a fully informed decision and to give consent for treatment
5. have any significant medical or mental health concerns reasonably well controlled
6. for breast/chest surgeries, have one referral from a mental health professional provided in accordance with version 7 of the WPATH Standards of Care.
7. For genital surgeries, have two referrals from mental health professionals provided in accordance with version 7 of the WPATH Standards of Care.

Electrolysis (CPT 17380) [and laser hair removal \(CPT 17110, 17111\)](#) ~~are~~ only included on this line ~~for surgical site electrolysis~~ as part of pre-surgical preparation for chest or genital surgical procedures also included on this line. ~~It is~~ [These procedures are](#) not included on this line for

Appendix A

facial or other cosmetic procedures or as pre-surgical preparation for a procedure not included on this line.

Mammoplasty (CPT 19316, 19324-19325, 19340, 19342, 19350, 19357-19380) is only included on this line when 12 continuous months of hormonal (estrogen) therapy has failed to result in breast tissue growth of Tanner Stage 5 on the puberty scale OR there is any ~~a medical~~ contraindication to, intolerance of or patient refusal of hormonal therapy.

Revisions to surgeries for the treatment of gender dysphoria are only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). Revisions are not covered solely for cosmetic issues.

Pelvic physical therapy (CPT 97001, 97001, 97110, 97140, and 97530) is included on this line only for pre- and post-operative therapy related to genital surgeries also included on this line and as limited in guideline note 6 REHABILITATIVE THERAPIES.

Appendix B Biennial List Line Changes

Merge lines 17 VERY LOW BIRTH WEIGHT (UNDER 1500 GRAMS) and 23 LOW BIRTH WEIGHT (1500-2500 GRAMS) as shown below:

- Add P10.2 (Intraventricular hemorrhage due to birth injury), P10.3 (Subarachnoid hemorrhage due to birth injury), P52.00-P52.3 (Intraventricular (nontraumatic) hemorrhage of newborn), P52.5 (Subarachnoid (nontraumatic) hemorrhage of newborn) to line 34 SEVERE BIRTH TRAUMA FOR BABY and do not add to the new merged premature baby line
- Rename line 34 SEVERE BIRTH TRAUMA FOR BABY; [INTRAVENTRICULAR HEMORRHAGE](#)

Line: 17

Condition: LOW BIRTH WEIGHT; PREMATURE NEWBORN (See Guideline Notes 64,65)

Treatment: MEDICAL THERAPY

ICD-10: P07 (Disorders of newborn related to short gestation and low birth weight), P83.0 (Sclerema neonatorum)

CPT: 94772,96154,97802-97804,98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607

HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are for line 17; line 23 scores in parentheses)

Category: 1 (1)

Healthy life years: 10 (7)

Suffering: 5 (2)

Population effects: 0 (0)

Vulnerable population: 1 (1)

Tertiary prevention:

Effectiveness: 3 (5)

Need for treatment: 1 (0.8)

Net cost: 0 (2)

Score: 4800 (4000)

Line placement: 17 (23)

Appendix B Biennial List Line Changes

Merge lines 15 CONGENITAL INFECTIOUS DISEASES and 16 CONGENITAL SYPHILIS as shown below

Line: 15

Condition: CONGENITAL INFECTIOUS DISEASES (See Guideline Notes 64,65)

Treatment: MEDICAL THERAPY

ICD-10: A50 (Congenital syphilis), P35.0-P35.9 (Congenital viral diseases), P37.0-P37.4, P37.8-P37.9 (Other congenital infections and parasitic diseases)

CPT: 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family—unique to line 15), 98966-98969, 99051, 99060, 99070, 99078, 99184, 99201-99239, 99281-99285, 99291-99404, 99408-99416, 99429-99449, 99468-99480, 99487-99498, 99605-99607

HCPCS: G0396, G0397, G0406-G0408, G0425-G0427, G0463, G0466, G0467

Line prioritization (scores are for line 15; line 16 scores in parentheses)

Category: 1 (1)

Healthy life years: 9 (8)

Suffering: 3 (3)

Population effects: 0 (1)

Vulnerable population: 0 (1)

Tertiary prevention:

Effectiveness: 4 (4)

Need for treatment: 1 (1)

Net cost: 4 (2)

Score: 4800 (4800)

Line placement: 15 (16)

Merge lines 21 SYNDROME OF "INFANT OF A DIABETIC MOTHER" AND NEONATAL HYPOGLYCEMIA, 35 NEONATAL THYROTOXICOSIS, and 45 HYPOCALCEMIA, HYPOMAGNESEMIA AND OTHER ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN as shown below

- Add P70.2 (Neonatal diabetes mellitus) to the new line and remove from line 36 HEMATOLOGICAL DISORDERS OF FETUS AND NEWBORN
- Add P72.2 (Other transitory neonatal disorders of thyroid function, not elsewhere classified) to the new line and remove from line 13 CONGENITAL HYPOTHYROIDISM

Appendix B Biennial List Line Changes

Line: ~28

Condition: ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN (See Guideline Notes 64,65)

Treatment: MEDICAL THERAPY

ICD-10: P70 (Transient neonatal disorders of carbohydrate metabolism specific to newborn), P71 (Transitory neonatal disorders of calcium and magnesium metabolism), P72.1 (Transitory neonatal hyperthyroidism), P72.2 (Other transitory neonatal disorders of thyroid function, not elsewhere classified), P72.8 (Other specified transitory neonatal endocrine disorders), P72.9 (Transitory neonatal endocrine disorder, unspecified), P74 (Other transitory neonatal electrolyte and metabolic disturbances)

CPT: 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family—unique to line 45), 98966-98969, 99051, 99060, 99070, 99078, 99184, 99201-99239, 99281-99285, 99291-99404, 99408-99416, 99429-99449, 99468-99480, 99487-99498, 99605-99607

HCPCS: G0396, G0397, G0406-G0408, G0425-G0427, G0463, G0466, G0467

Line prioritization (scores are proposed by staff; current line scores shown in parentheses)

Category: 1 (1, 6, 1)

Healthy life years: 6 (6; 8; 5)

Suffering: 1 (1; 3; 1)

Population effects: 0 (0; 0; 0)

Vulnerable population: 0 (1; 0; 0)

Tertiary prevention: NA (NA; 5; NA)

Effectiveness: 5 (5; 5; 5)

Need for treatment: 1 (1; 1; 1)

Net cost: 4 (4; 5; 3)

Score: 3500 (4000; 3300; 3200)

Line placement: approximately 28 (21; 35; 45)

Restructure line 22 OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS

- Add the following codes found only on the dysfunction lines to line 22
 - P39.3 Neonatal urinary tract infection
 - P39.4 Neonatal skin infection
 - P39.8 Other specified infections specific to the perinatal period
- Add P39.9 (Infection specific to the perinatal period, unspecified) to line 22 and remove from the dysfunction lines and line 186 SEPTICEMIA
- Remove all codes found on line 22 from the four dysfunction lines (lines 75, 297, 350 and 382)
 - P38, P39.0, P39.3, P39.4, P39.8, P39.9

Appendix B Biennial List Line Changes

- Rename line 22 ~~OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS~~
NEONATAL INFECTIONS OTHER THAN SEPSIS
- Rescore line 22 as shown below

Line: 22 (which will move to ~40)

Condition: ~~OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS~~
NEONATAL INFECTIONS OTHER THAN SEPSIS (See Guideline Notes 64,65)

Treatment: MEDICAL THERAPY

ICD-10: P38.1-P38.9 (Omphalitis), P39.0 (Neonatal infective mastitis), P39.3 (Neonatal urinary tract infection), P39.4 (Neonatal skin infection), P39.8 (Other specified infections specific to the perinatal period), P39.9 (Infection specific to the perinatal period, unspecified)

CPT: 98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607

HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are staff recommended; current scoring in parentheses)

Category: 1 (1)

Healthy life years: 5 (7)

Suffering: 1 (1)

Population effects: 0 (0)

Vulnerable population: 0 (0)

Tertiary prevention:

Effectiveness: 5 (5)

Need for treatment: 1 (1)

Net cost: 2 (3)

Score: 3000 (4000)

Line placement: 40 (22)

MINUTES

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

Members Present: Som Saha, MD, MPH, Chair; Beth Westbrook, PsyD; Wiley Chan, MD; Irene Crowell, RPh; Leda Garside, RN, MBA; Susan Williams, MD; Kim Tippens, ND, MPH; Derrick Sorweide, DO; Chris Labhart; Holly Jo Hodges, MD; Gary Allen, DMD.

Members Absent: Mark Gibson; Kevin Olson, MD.

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

Also Attending: Lorren Sandt (Caring Ambassadors); Renee Taylor (Dexcom); Kim Wentz, MD, MPH, (Oregon Health Authority); Erica Pettigrew, MD (OHSU); Valerie King, MD MPH, Adam Obley, MD, MPH, and Craig Mosbaek (OHSU Center for Evidence-based Policy); Barbara Marcant (SJM); Alejandro Perez, MD (Providence); Kriti Amerson (Willamette Valley Medical Center).

Call to Order

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

Minutes Approval

MOTION: To approve the minutes of the January 14, 2016 meeting as presented. CARRIES 11-0.

Director's Report

Membership Update

Kevin Olson, an oncologist who has been the Value-based Benefits Subcommittee (VbBS) chair since the commission began, was appointed as a Commissioner. He was unable to attend this meeting. Dr. Olson is the Providence Cancer Center executive medical director.

Kim Tippens, a naturopathic physician with a master's degree in oriental medicine and acupuncture, was appointed as a Commissioner. She is a professor at Naturopathic College of Medicine. Tippens will also participate on the Evidence-based Guidelines Subcommittee (EbGS). Former Commissioner Dr. Vern Saboe, Tippen's predecessor as the complementary and alternative medicine representative to the Commission, will now participate on VbBS, filling the place of former member Laura Ocker.

Dr. Tim Keenen has resigned from the Health Technology Assessment Subcommittee (HTAS) due to regular scheduling conflicts with meeting day. Keenen recruited Dr. Clyde Farris, a recently retired orthopedic surgeon who is still active in the specialty association, to participate on the subcommittee.

MOTION: To appoint Dr. Clyde Farris to HTAS. Carries: 11-0.

Coverage Guidance Process

Coffman said there have been several instances when topics are coming up for their 2-year review and a new study is expected out in the next 6-12 months. In some cases the commission may want to hold off the review until that study is released. He proposed having coverage guidances in that status “affirmed, but with a caveat that new studies are imminent” for the current 2-year review, then opened for review after the new studies are complete. Saha suggested there be no caveat which would lead to questioning the current coverage guidance. The topic could be reopened at any time.

Coffman asked whether a re-review should occur every two years or is there a point where, say after two re-reviews with no changes to the coverage guidance, that the commission would consider putting the topic on hiatus? After that point the commission could always bring it back for consideration if a new compelling systematic review is found or an external party suggests a review. Saha expressed concern about retiring topics in such a fashion, feeling that may lead to stagnation.

Saha advocated for a leaner process and said rescanning each topic every two years can be time consuming. He asked for a time estimate using the current rescanning process. Obley said it is actually quick; writing the 1-2 page report addressing scope questions is the part that is time consuming. After discussion, members decided reports should only be completed for topics where there have been studies significant enough to make staff believe it might change the current guidance. Topics that do not meet that milestone can be a list of topics with a blurb stating there were no significant changes in studies.

In summary, the proposed expedited rescan process allows Center for Evidence-based Practice and HERC staff permission to determine which topics:

- Should be scheduled for rescan every two years to be brought to HERC to consider new evidence
- May be included in a list of topics for which the rescan topics showed no evidence that would influence the existing coverage guidance recommendations.

Additionally, it was proposed that topics should not be retired unless that topic is no longer relevant to practice or there is another way to decide about coverage beside the HERC process.

MOTION: To approve the expedited rescan process. CARRIES: 11-0

Prioritized List

Smits began a discussion about formalizing the process to remove procedures from the Prioritized List. Here-to-for, procedures were removed only if there was evidence of ineffectiveness. The consensus reached after discussion is to also allow removal if the harms outweigh the potential benefits. Staff will prepare a written statement to present at the next meeting.

Prioritized List Publishing

The Commission publishes two Prioritized Lists a year, January and October. Smits proposed adding any changes that have a potentially significant financial impact to the January list each year, to coincide with

the ability to incorporate rate changes into CCO contracts for the next calendar year. October changes would be limited to technical issues, minor corrections and wording changes.

Staff Update

Coffman introduced the Oregon Health Authority's new Chief Medical Officer (CMO), Dr. James Rickards, who is a radiologist. Rickards has five areas of responsibility, including oversight of this Commission's work.

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

[Meeting materials](#), pages 13-94

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

Recommended Code Movement (effective 10/1/16)

- Move several newborn diagnoses to more appropriate covered lines.
- Add diagnosis codes for esophageal hernias with obstruction or gangrene to the covered hernia line with the appropriate treatment codes and delete from the covered GERD/esophagitis line.
- Delete the treatment code for intracranial vascular balloon dilation for atherosclerosis from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Delete the treatment code for intracranial vascular balloon dilation for vasospasm from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Add procedure codes for perioperative pelvic physical therapy and laser hair removal for surgical site preparation to the gender dysphoria line.
- Add various straightforward codes to appropriate lines.

Recommended Guideline Changes (effective 10/1/16)

- Modify the gender dysphoria guideline to remove the requirement for hormone therapy prior to breast or chest surgery, to add laser hair removal for surgical site preparation in the same way as restricted for electrolysis, to clarify when revision surgeries are covered, and to specify that pelvic PT procedures codes are only covered for peri-operative therapy.

Biennial Review Changes (effective 1/1/18)

- Merge the two premature baby lines and prioritize to the upper line position. Move the diagnosis codes for intraventricular hemorrhages to another line to pair with required treatments.
- Merge the congenital infections line and congenital syphilis lines and prioritize at their current position.
- Merge three lines containing endocrine conditions of the newborn and prioritize to approximately the mid position of the lines.
- Add diagnosis codes and change the line title for the line containing omphalitis and newborn mastitis codes, reprioritizing to a slightly lower position.

MOTION: To accept the VbBS recommendations on Prioritized List changes not related to coverage guidances, as stated. [See the VbBS minutes of 3/10/2016](#) for a full description. Carries: 11-0.

Review of Scoping Statements and Scoring for Proposed New Coverage Guidance Topics

[Meeting materials](#), pages 95-106

Livingston led a discussion about certain elements of the scoring criteria including “overall mortality” instead of “disease specific mortality” and whether *quality of life* should be weighed as a “critical outcome” or as an “important outcome.” Saha asserted we should avoid blanket statements because those outcomes can change topic by topic.

For this discussion, Saha said these scope statements have been through the subcommittee process and are presented today for approval. What is being decided today is whether the question is framed correctly for HERC’s decision making.

Adam Obley and Livingston gave a brief description of each topic (found in the meeting materials). The topics of Ultrasound-Enhanced Catheter Directed Thrombolysis for Deep Vein Thrombosis and Ultrasound-Enhanced Catheter Directed Thrombolysis for Pulmonary Embolism were not reviewed as their scores were below the threshold for consideration.

- Genetic Testing of Thyroid Nodules
 - Used to test non-cancerous nodules to determine if further treatment is required.
- Noninvasive Testing For Liver Fibrosis in Chronic Hepatitis C Patients
 - Used in place of liver biopsy to justify treatment.
 - Public testimony was received from Lorren Sandt, Caring Ambassadors, who warned that rural Oregon facilities might not have the equipment for this type of testing. Further, she submitted a letter from CMS stating that limiting hepatitis C treatment violates Medicaid law. The Pharmacy & Therapeutics (P&T) Committee refused to hear her testimony about it, saying treatment coverage is HERC’s responsibility.
- Prostatic Urethral Lift for Treatment of Benign Prostatic Hypertrophy
 - Rescan based on new published data because this new procedure is less invasive than alternatives.
- Sacral Nerve Stimulation for Non-Obstructive Urinary Retention
 - Implanted device that helps patient empty bladder and not need catheterization.
- Digital Breast Tomosynthesis (3d Mammography) For Breast Cancer Screening In Average Risk Women
 - This might be a more effective screening modality for younger women or women with dense breasts.
- Fecal Microbiota Transplants for *C. difficile*
 - For hard-to-treat bacterial infections causing extreme diarrhea, a stool transplant might be effective.
- Genetic Tests for Selection of Antidepressant Therapy
 - Pharmacogenetic tests designed to prospectively (or after a patient has started a medication for depression that isn’t working) determine which medication is most appropriate based on how they will metabolize it and therefore the likelihood of a response to the treatment.
- Interventions to Reduce Tobacco Use during Pregnancy
 - Rename *Tobacco Cessation during Pregnancy*
 - Multi-sector interventions to promote abstinence from smoking during pregnancy.

- Gastrointestinal Motility Tests
 - Which kind of tests are needed to determine if the stomach does not empty in a normal time frame.
- Timing of Long-Acting Reversible Contraceptive Placement
 - IUDs and other implants: When should they be implanted post-partum/post-abortion? Expulsion rates are a concern.
 - Wentz added that the issue with OHP is largely implementation related.
- Percutaneous Interventions for Low Back Pain
 - Rename to *Corticosteroid Injections for Low Back Pain*
 - Compare this treatment to all other types of treatment for low back pain.

MOTION: To approve the scope statement as presented. CARRIES: 11-0

Prioritization of Coverage Guidance Topics

[Meeting materials](#), pages 107-125

Livingston and Saha began the discussion of the proposed changes to the coverage guidance topic scoring system. Recommended changes include clarification that the disease burden is from the individual perspective (not population), tightening of the language of several sections to provide more precision and clarity, the addition of a new row on potential of intervention to improve health outcomes, and clarification to scoring descriptions ([pages 107-108 for details](#)).

For future coverage guidance scoring, members discussed using the current multiplier category of “meaningful coverage guidance” as a yes/no question to be answered before any of the other scoring is considered. If no, nothing else should be done and the topic should not be considered for a future coverage guidance. If yes, consider the scoring criteria questions. Coffman noted that this was already being done in many cases by staff in generating the list of topics being considered today.

Saha said CCOs are empowered to spend their global budget dollars to improve the health of their patients outside of a traditionally used diagnosis/procedure code model. Some topics we take up as coverage guidances will also have another document listing best practices for other interventions, called multisector interventions. These topics should not have to be scored the same way as coverage guidances.

Labhart stated his concern about the CCO in his county meeting their metric targets for smoking cessation, potentially costing his county tens of thousands of dollars. He added his concern that the CCOs across the state are not aligned with the work of this Commission. He pled with the members to bear in mind what CCOs have to accomplish.

Coffman asked that HERC use the currently approved scale for today’s set of recommendations and use the new model, if accepted, for scoring potential topics in future years.

MOTION: To change the scoring criterion “Meaningful Coverage Guidance” to be a prerequisite in the consideration of future topics. Carries: 11-0.

MOTION: To approve changes to the scoring documents as amended. Carries: 11-0.

Topics and final scoring presented (with assigned subcommittee in parentheses):

- Timing of Long-Acting Reversible Contraceptive Placement (EbGS), Score 66
- Digital Breast Tomosynthesis (3d Mammography) for Breast Cancer Screening in Average Risk Women (EbGS), Score 60
- Continuous Glucose Monitoring in Diabetes Mellitus (HTAS), Score 54
- Genetic Tests for Selection of Antidepressant Therapy (EbGS), Score 48
- Fecal Microbiota Transplants for C. difficile (EbGS), Score 45
- Tobacco Cessation during Pregnancy (EbGS), Score 45
- Percutaneous Interventions for Low Back Pain (EbGS), Score 45
- Recurrent Acute Otitis Media in Children (EbGS), Score 42
- Noninvasive Testing for Liver Fibrosis in Chronic Hepatitis C Patients (HTAS), Score 39
- Prostatic Urethral Lift for Treatment of Benign Prostatic Hypertrophy (HTAS), Score 36
- Sleep Apnea Diagnosis in Adults (HTAS), Score 36
- Sacral Nerve Stimulation for Non-Obstructive Urinary Retention (HTAS), Score 33
- Genetic Testing of Thyroid Nodules (HTAS), Score 30
- Gastrointestinal Motility Tests (EbGS), Score 27

MOTION: To accept the prioritization of topic scoring, generally starting with reviews of topics with higher scores. CARRIES: 11-0.

Topic Retirements

These topics were initially approved for potential coverage guidance development, but a coverage guidance has never been developed for the reasons listed:

- Telepsychiatry and Telecounseling
 - Significant implementation issues; unlikely to influence care
 - Westbrook asked if HERC could do a drug review
 - Coffman said the Commission is prohibited from conducting drug reviews
- Nitric oxide for the diagnosis and management of asthma
 - Lack of community interest, limited evidence base, insufficient controversy to merit an in-depth review
- Transitional care interventions to prevent readmissions for people with heart failure
 - Significant implementation issues; unlikely to influence care
- Treatments for acquired nontraumatic cognitive impairment/dementia
 - Significant implementation issues; unlikely to influence care

MOTION: To accept staff's recommendation to drop these topics from consideration for a future coverage guidance. CARRIES: 11-0.

Coverage Guidance Topic: Skin Substitutes for Chronic Skin Ulcers

[Meeting materials](#), pages 127-222

Obley presented the proposed coverage guidance from EbGS. This coverage guidance focuses on two types of ulcers:

- Diabetic foot ulcers (DFU)
 - Caused by atherosclerosis impeding blood flow to extremities and neuropathy that reduces a person's ability to detect an injury, which can lead to infection and amputation
- Venous leg ulcers (VLU)
 - Caused by venous insufficiency

Skin substitutes were initially used to treat burns. Skin ulcers occur more frequently than burns and skin substitutes are now used more commonly for treatment of chronic ulcers (not healed in 30 days of standard treatment). Skin substitutes stimulate the body to regenerate lost tissue. There are over 70 skin substitute products approved for use in humans and are derived from donor tissue, living human or animal tissues/cells or are acellular animal-derived or biosynthetic products. Obley pointed out that not all products are indicated for every wound.

The identified evidence evaluated the effectiveness of eight skin substitutes currently sold in the United States. Obley said the evidence shows moderate or low certainty of benefit in the cases where a recommendation for coverage could be made. Studies suggested during the public comment period were also reviewed. The instances where at least a low certainty of benefit were reviewed for various critical and important outcomes:

- Apligraf®
 - DFU: Complete wound healing: moderate certainty of benefit; Adverse events: low certainty of no harm
 - VLU: Complete wound healing: low certainty of benefit; Time to complete wound healing: Low certainty of benefit
- Dermagraft®
 - Complete wound healing: low certainty of benefit; Time to complete wound healing: low certainty of benefit
- EpiFix®
- Grafix®
- Graftjacket®
- OASIS®
 - Complete wound healing: low certainty of benefit; Complete wound healing: low certainty of benefit
- Tallymed®
- Theraskin®

Prerequisites for coverage are also suggested to be included in the box language (based on combination of study criteria and expert input):

- Appropriate wound care required
- Appropriate patient characteristics
- Diabetic control (<12)
- Adequate blood flow
- Failure of prior therapy
- Participation in tobacco cessation required

Livingston said there were a number of late-breaking studies as we came to the end of this coverage guidance process. When this has happened in the past, we have waited to look at these

products/procedures until the next 2-year review unless they would clearly change the recommendation.

Livingston reviewed product costs, which were included in the coverage guidance for informational purposes, but did not drive the recommendations (Appendix E: Frequency of Application and Cost of Skin Substitutes, [meeting materials](#) pages 190-191). It appears some products may be more costly than others, particularly when accounting for the potential of product waste with those that can only be ordered in larger sheets.

Livingstone touched on the GRADE-Informed Framework (page 129-140) and reviewed potential changes to the Prioritized List as a result of the draft coverage guidance.

Public comment:

Dr. Alejandro Perez, Regional Medical Director of Providence Wound Care and Hyperbaric Medicine Program and president of the Columbia Wound Care Consortium, offered testimony. He declared no conflicts of interest. Dr. Perez expressed concern that he had not heard of our process before now and was critical of the Commission's outreach to the specialty community. Coffman noted a specialty representative was appointed as an ad hoc expert during EbGS's review of the topic.

Dr. Perez noted two studies (one that was included in the coverage guidance process, Lavery, 2014) and one that was not (Zellen, 2014) that he feels might affect the coverage guidance conclusions.

Commission discussion led to a decision to open the topic up for an additional 21-day comment period followed by a review at the June EbGS meeting. It is anticipated that it will then be brought back to the August HERC meeting for final consideration.

Coverage Guidance Topic: Metabolic and Bariatric Surgery

[Meeting materials](#), pages 223-331

Saha gave a brief review about the proposed coverage guidance from HTAS. The subcommittee received a single public comment expressing support for the draft coverage guidance. This work will fold into the Obesity Task Force's work in the management of obesity as a biennial review topic.

Public Comment

There was no public comment at this time.

Adjournment

Meeting adjourned at 4:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, May 19, 2016 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon.

HIGHLIGHTS
HEALTH EVIDENCE REVIEW COMMISSION'S
Obesity Task Force
Clackamas Community College
Wilsonville Training Center, Rooms 111
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
March 3, 2016
1:00-4:00pm

Members Present: Kasey Goodpaster, Ph.D.; Bruce Gutelius, MD, MPH (arrived at 2pm); Margaret McReynolds; Tracy Muday, MD; Irma Murauskas; Taylor Simon, RD; Bruce Wolfe, MD.

Members Absent: Judy A. Sundquist, MPH, RDN; Stephen P. Fortmann, MD; Jonathan Purnell, MD

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Denise Taray, RN.

Also Attending: Troy Larsen (Takeda); Liz Kvach (OHSU).

1. CALL TO ORDER

Livingston called the meeting to order at 1:00pm. The Task Force members introduced themselves.

2. TOPIC: OVERVIEW OF OBESITY TASK FORCE

Livingston presented an overview of the Obesity Task Force, and reviewed the scope of Phase I and Phase II. The intent is to have Phase I meeting 2-3 times. Phase II will meet separately and the combined recommendations will be presented to the Value-based Benefits Subcommittee. Coffman discussed the timeline of implementation of the biennial Prioritized List. He clarified the earliest the task force recommendations could be implemented on the Prioritized List would be January 1, 2018.

3. TOPIC: PHARMACOTHERAPY FOR OBESITY

Livingston reviewed the issue summary. Wolfe discussed that there is a subgroup of patients that benefit from pharmacotherapy. Study authors and experts typically recommend that one can try a medication and if it is ineffective then it ought to be discontinued. There was a question as to why pharmacotherapy should not be covered in this way, with a restriction only if it is ineffective. Muday discussed that when deciding to include new treatments on the

Prioritized List one has to keep in mind that funding for Oregon Health Plan is a limited resource. Need to keep in mind that if additional funding is spent on certain treatments, then other things may not be covered, or fewer people would be able to be covered.

Goodpaster suggested that pharmacotherapy could help with the pre-surgical weight loss requirement, and may be able to help with weight loss maintenance. Members discussed that there is mixed evidence about the importance of a pre-surgical weight loss requirement. Others suggested that while the evidence is uncertain, pre-surgical weight loss could be an indication of commitment to lifestyle changes and follow up. After further discussion of the lack of proven health outcomes, history of harms, and mixed recommendations for their use, members were comfortable with the recommendation to make no change to noncoverage of pharmacotherapy for obesity.

4. TOPIC: DEVICES FOR OBESITY

Livingston reviewed the issue summary. Wolfe discussed one of the key issues with the intragastric balloon that it is a time-limited treatment when obesity is a chronic disease. Intragastric balloons are only FDA approved for 6 months. A temporary intervention is not going to compete with surgical interventions. Dr Wolfe mentioned he was on the board of the ReShape trial and offered to recuse himself. Coffman stated that it was not necessary to recuse himself since the Task Force does not vote, they are only making recommendations to staff on what to include in meeting materials for consideration by the Value-based Benefits Subcommittee and HERC later in the fall. That said, Wolfe's potential conflict was noted. Members agreed that not including devices for obesity on the Prioritized List was appropriate. They recommended including the statement about exclusion of devices directly into the obesity guideline.

5. TOPIC: SURGERY FOR OBESITY

Livingston reviewed the issue summary. The discussion focused on reoperations. Wolfe stated that procedures that are less invasive, but with less efficacy, are very attractive to patients. Patients undergo gastric banding under the idea that it is safer, and potentially reversible. Weight loss associated with gastric banding is less than ½ that of a gastric bypass. The question was posed, whether these folks should be denied additional intervention? On the other hand, if a patient had a gastric bypass and subsequently failed to result in ongoing weight loss, there is no surgical consensus as to whether surgery has any role.

The members deliberated on whether the language on reoperations should be fully removed from the guideline note, or if there should be specific types of reoperations that are excluded. There was a concern that sometimes the surgery performed was inadequate based on surgical technique and whether that person should then be denied an additional, more appropriate surgery. Questions were raised about whether complications were covered, and what whether

a lack of weight loss is considered a complication. Livingston clarified that complications of surgery would be covered under the draft staff recommendations, but that a failure to achieve expected weight loss would not be considered a complication. Several choices were considered: to not include reoperations, to create no limit to reoperations, and to allow reoperations when transitioning from a less invasive to more invasive procedure. Wolfe clarified that reoperations are associated with a higher complication rate. Goodpaster spoke to the fact that staged procedures are common. Also, some patients who have had an invasive surgery 20 years ago may need a revision. The question was raised as to whether the surgery has failed the patient versus the patient has failed the surgery.

Discussions then turned to the goal of surgery. The goal BMI is not known, nor is it known exactly how much weight is needed to be lost to achieve a desired effect. It was clarified that reoperation would be indicated when a patient re-met the criteria included in the guideline note.

There was a proposal to allow reoperation for conversion to Roux-en-Y from gastric banding (or other procedure reversed). That complications would be covered, and failure to achieve desired weight loss would not be considered a complication. Patients may have different definitions of failure than providers or plans. Additionally, recurrence of diabetes may not be a function of a failed operation, but rather the indicated natural progression of a chronic disease.

They proposed that repeating the same surgery would not be covered, and conversion from gastric banding or sleeve gastrectomy to Roux-En-Y gastric bypass should be covered. Staff is to return at the next meeting with draft recommendation language.

The conversation then changed to whether or not to cover surgeries performed at non-MBSAQIP (Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program) centers. The history of the development of the guideline note was discussed. Wolfe discussed MBSAQIP site visitation that reviewed protocols. There was a concern raised about requiring psychological evaluations; that this is extensive, expensive, and there is no evidence that mandatory psychological evaluation improves outcomes. It was clarified that this is not a psychological evaluation, but rather a psychosocial assessment, which is critical to determining whether or not a surgery has a chance of success. If a patient has an unstable home life or active alcohol use then their chance of success is poor. Muday related that she has had 3 patients who died in hospital post surgery because of alcohol withdrawal. Wolfe discussed that alcohol use disorder after gastric bypass rises significantly over time. There was a discussion about marijuana use and dependence. They agreed that if there is evidence of abuse or dependence of illicit substances or marijuana that the 6 month clause should apply.

The following edits were suggested for the bariatric surgery guideline:

- Modify the language allowing reoperations when converting from less intensive to more intensive operations (clause C)
- Add marijuana abuse or dependence to the 6 month abstinence requirement (D1b)
- Accepted adding a second test point for nicotine and illicit drugs (D1b)

- Remove “previous” from psychiatric illness (D1d)
- Remove the requirement of having to be continuously enrolled on OHP (D3a)
- Replace “medically supervised weight loss program” with “clinically supervised weight loss program” (D4a)
- Add language defining the program “(including intensive nutrition and physical activity counseling as defined by the USPSTF)” (D4a)

Given the lack of clarity about any programs seeking accreditation in Oregon, staff was asked to check in with CCO medical directors about their knowledge of new Centers seeking accreditation. Wolfe proposed having specific language about low acuity centers as well.

6. TOPIC: BEHAVIORAL INTERVENTIONS FOR OBESITY, SCOPE STATEMENT

Livingston reviewed the scope of the behavioral interventions for obesity to be discussed in further detail at the following task force meeting in 2 weeks. McReynolds addressed the role of physical therapy: to work on building habits, supervise therapy once a week, the need for specialized equipment (such as lifts/ramps) and water-based activities. There was a request to look at group therapy versus individualized therapy because it may be more cost-effective.

7. ADJOURNMENT

The meeting was adjourned at 4:00 pm. The next meeting is scheduled for March 17, 2016, 9:00-11:00 am Room 111 of the Wilsonville Training Center of Clackamas Community College.

HIGHLIGHTS
HEALTH EVIDENCE REVIEW COMMISSION'S
Obesity Task Force-Phase 1
Clackamas Community College
Wilsonville Training Center, Rooms 111
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
March 17, 2016
9:00-11:00 am

Members Present: Stephen P. Fortmann, MD; Kasey Goodpaster, Ph.D.; Margaret McReynolds; Tracy Muday, MD; Irma Murauskas; Taylor Simon, RD; Judy A. Sundquist, MPH, RDN; Bruce Wolfe, MD; Helen Bellanca, MD, MPH.

Members Absent: Jonathan Purnell, MD; Bruce Gutelius, MD, MPH.

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Denise Taray, RN.

Also Attending: Adam Obley, MD, Center for Evidence-based Policy (OHSU); Nash Haleem, DVM (Novo Nordisk Inc.).

1. CALL TO ORDER

Livingston called the meeting to order at 9:05 am.

2. MINUTES REVIEW

Minutes from the March 3, 2016 meeting were reviewed and modifications suggested including correcting that 2 members were actually in absentia (Fortmann and Purnell) and an edit to capture mixed evidence surrounding the requirements for pre-surgical weight loss.

3. TOPIC BARIATRIC SURGERY REVISITED

Livingston presented updated guideline note language about bariatric surgery. Members were satisfied with the language about reoperation. Muday proposed a minor grammatical change to separate out the definition of complication as its own sentence for clarity. Members agreed to the revised language.

The discussion turned to banding and whether it should only be available if contraindications to sleeve gastrectomy and Roux-en-Y were present. This proposed language was based on the fact that banding has clearly inferior outcomes to sleeve gastrectomy and Roux-en-Y and most

bariatric surgeons are not recommending this, and even then only after extensive discussions. Bellanca asked if this would allow coverage for women of reproductive age when trying to conceive. The group debated whether or not this would be considered a “contraindication.” Bellanca expressed concern that the malabsorptive procedures may potentially be more harmful to women who are planning to conceive and that some of these women may elect for banding despite its lower effectiveness because of this concern. Wolfe and Obley discussed the lack of evidence and that sleeve gastrectomy would be an option in these women. Bellanca and Sundquist raised concerns with micronutrient deficiencies and that many patients may not be compliant with nutrient supplementation post-surgery, which may exacerbate micronutrient deficiencies. Language was proposed that would enable women of reproductive age with intent to conceive a pregnancy to have gastric banding as an option. There was not consensus with some arguing that since there is no evidence of benefit in this population it should not be called out in the guideline and others arguing that because of the potential risks of a malabsorptive procedure in future child-bearing that this should be an option. The Task Force members decided to present 2 options to VbBS, one was to have this group (women of reproductive age with intent to conceive) have banding available, and the other option would be to only permit banding in the case of a contraindication to sleeve gastrectomy or Roux-en-Y.

Option 1: Banding is only included when sleeve gastrectomy or Roux-enY are contraindicated

Option 2: Banding is only included when sleeve gastrectomy or Roux-en-Y are contraindicated, or for a woman of reproductive age with intent to conceive a pregnancy who prefers a less intensive surgical treatment.

Livingston reviewed the revised language about accreditation and certification. Wolfe clarified the rationale for this. Wolfe clarified that there are currently 9 accredited bariatric centers in Oregon and none of them are low volume. The Task Force approved this revised language. See Appendix A for the proposed revisions to Guideline Note 8.

4. TOPIC PHARMACOTHERAPY REVISITED

Sundquist discussed desire to have pharmacotherapy covered as an adjunct to obesity treatment. She reviewed some guidelines that recommend pharmacologic treatment and recommended that pharmacotherapy be an adjunct to other obesity treatments available on the Prioritized List. Livingston reviewed the prior discussion leading to a recommendation for noncoverage based on a lack of long-term patient oriented health outcomes, potential harms, and costs associated with these treatments. With regard to the evidence-base supporting those recommendations, Obley clarified that orlistat + intensive behavioral interventions resulted in a 2 kg weight loss, which was similar to intensive behavioral interventions alone. Wolfe stated that they are more recent reviews, but they didn’t use same rigorous criteria for study inclusion and the American College of Cardiology guideline was written before currently available drugs were on the market.

Fortmann stated that with low risk interventions, intermediate outcomes (such as weight loss) may be acceptable; however, drugs have a lot of side effects, and these guidelines also don't consider costs. If these drugs are approved it will take money away from somewhere else. Coffman stated that Formann's raised points about costs and harms reflected discussions at the commission level 6 years ago. Bellanca agreed that that what clinicians want to try and what should be covered are different things. After some discussion, the group decided to continue to make a recommendation for noncoverage of pharmacotherapy. See Appendix A for the proposed revisions to Guideline Note 5.

5. TOPIC BEHAVIORAL INTERVENTIONS FOR OBESITY

Livingston presented the issue summary. Obley reviewed the evidence on behavioral interventions. There was a discussion about the relatively small amount of weight loss noticed in these trials and Sundquist mentioned that it is not just about weight loss but the deceleration of weight gain. Fortmann stated that exercise may not improve BMI but leads to long term improved health outcomes. Obley discussed that BMI is an imperfect measure. Fortmann said fat body mass is the best measure to follow but is difficult to do. The group discussed the problem of BMI reduction being a primary outcome, as it is not necessarily reflective of the most important health outcomes. Weight does not correlate with all cause mortality, it is about nutrition and exercise habits. In the future, some subcommittee members were hopeful that studies will focus on long-term altered energy consumption patterns, exercise patterns, and disordered eating, rather than weight loss alone. Fortmann discussed the 40 year follow-up from an Oslo dietary intervention, which indicated that simple, primary-care based dietary advice was associated with long-term reduction in cardiovascular disease outcomes.

The group discussed the availability of intensive interventions for both adults and children. Goodpasture discussed the "Live It" program at Legacy, which is once a week for 6 months. Simon discussed the diabetes prevention programs in most communities in Oregon. Muday mentioned that sometimes the programs are designed for an educational level that doesn't match the OHP population. Others discussed that there are lifestyle programs, such as the Loma Linda model, that require a financial investment by the patient, which would be a significant barrier for OHP patients. There was a concern that sometimes programs won't contract with OHP and that coverage is typically a complaint-driven process.

The discussion turned to childhood obesity and the importance of doing parent-focused interventions.

Bellanca recommended adding language about the need to clarify intensive versus multidisciplinary counseling and enabling this type of counseling to be done in a primary care or other setting. The group discussed whether intensive counseling should be completed at 6

months or at 12 months. There was disagreement with some recommending 6 months and others saying that a patient could have a major setback which would get in the way of completing the intensive phase at 6 months. The group agreed that continuing for 6-12 months was reasonable as long as there was proof of efficacy. They agreed that language about maintenance visits was important after the 6 or 12 month mark. They concurred that language limiting visits to no more than once per week may undermine multidisciplinary programs.

There was a question about whether telephonic and internet-based interventions should be included. Obley reviewed the evidence. There was a discussion that telehealth can be considered the same as an in person visit in rural areas but that telephonic and internet-based interventions are different and less efficacious, so would not be included. See Appendix A for the proposed revisions to Guideline Note 5.

5. ADJOURNMENT

The meeting was adjourned at 11:04 am. No future meeting of the Obesity Task Force Phase 1 was deemed necessary. Phase 2 will meet in April. The Task Force members were thanked for their participation.

APPENDIX A

Recommended Revisions to Obesity-Related Guideline Notes

GUIDELINE NOTE 8, BARIATRIC SURGERY

Lines ~~30,589-325~~

Bariatric/metabolic surgery (limited to Roux-en-Y gastric bypass, gastric banding¹, and sleeve gastrectomy) is included on Line 325 ~~under when~~ the following criteria are met:

- A) Age \geq 18
- B) The patient has obesity with a:
 - 1) BMI \geq 40 OR
 - 2) BMI \geq 35 with:
 - a) Type 2 diabetes, OR
 - b) at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea
 - 3) ~~a BMI \geq 35 with co-morbid type II diabetes for inclusion on Line 30 TYPE 2 DIABETES MELLITUS; OR~~
 - 4) ~~BMI \geq 35 with at least one significant co-morbidity other than type II diabetes (e.g., obstructive sleep apnea, hyperlipidemia, hypertension) or BMI \geq 40 without a significant co-morbidity for inclusion on Line 589~~
- C) Repeat bariatric surgery is included when it is a conversion from a less intensive (such as gastric band or sleeve gastrectomy) to a more intensive surgery (e.g. Roux-en-Y). Repair of surgical complications (excluding failure to lose sufficient weight) are also included on this and other lines. Reversal of surgical procedures and devices is included on this line when benefits of reversal outweigh harms. ~~No prior history of Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding, or repeat gastric banding or unless they resulted in failure due to complications of the original surgery.~~
- D) Participate in the following four evaluations and meet criteria as described.
 - 1) Psychosocial evaluation: (Conducted by a licensed mental health professional)
 - a) Evaluation to assess potential compliance with post-operative requirements.
 - b) Must remain free of abuse of or dependence on alcohol or marijuana during the six-month period immediately preceding surgery. No current use of nicotine or illicit drugs and must remain abstinent from their use during the six-month observation period. Testing will, at a minimum, be conducted within one month of the quit date and within 1 month of the surgery to confirm abstinence from nicotine and illicit drugs.
 - c) No mental or behavioral disorder that may interfere with postoperative outcomes².

- d) Patient with **previous** psychiatric illness must be stable for at least 6 months.
- 2) Medical evaluation: (Conducted by OHP primary care provider)
 - a) Pre-operative physical condition and mortality risk assessed with patient found to be an appropriate candidate.
 - b) Optimize medical control of diabetes, hypertension, or other co-morbid conditions.
 - c) Female patient not currently pregnant with no plans for pregnancy for at least 2 years post-surgery. Contraception methods reviewed with patient agreement to use effective contraception through 2nd year post-surgery.
- 3) Surgical evaluation: (Conducted by a licensed bariatric surgeon associated with program^{2,3})
 - a) Patient found to be an appropriate candidate for surgery at initial evaluation and throughout period leading to surgery **while continuously enrolled on OHP.**
 - b) Received counseling by a credentialed expert on the team regarding the risks and benefits of the procedure³ and understands the many potential complications of the surgery (including death) and the realistic expectations of post-surgical outcomes.
- 4) Dietician evaluation: (Conducted by licensed dietician)
 - a) Evaluation of adequacy of prior dietary efforts to lose weight. If no or inadequate prior dietary effort to lose weight, must undergo six-month **medically clinically supervised weight reduction program (including intensive nutrition and physical activity counseling as defined by the USPSTF).**
 - b) Counseling in dietary lifestyle changes
- E) Participate in additional evaluations:
 - 1) Post-surgical attention to lifestyle, an exercise program and dietary changes and understands the need for post-surgical follow-up with all applicable professionals (e.g. nutritionist, psychologist/psychiatrist, exercise physiologist or physical therapist, support group participation, regularly scheduled physician follow-up visits).

Option 1: ¹ Banding is only included when sleeve gastrectomy or Roux-en-Y are contraindicated OR

Option 2: ¹ Banding is only included when sleeve gastrectomy or Roux-en-Y are contraindicated, or for a woman of reproductive age with intent to conceive a pregnancy who prefers a less intensive surgical treatment.

² Many patients (>50%) have depression as a co-morbid diagnosis that, if treated, would not preclude their participation in the bariatric surgery program.

³ All surgical services must be provided by a program with current **certification accreditation (as a comprehensive center or low acuity center)** by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). ~~, or in active pursuit of such certification with all of the following: a dedicated, comprehensive, multidisciplinary, pathway-directed bariatric program in place; hospital to have performed bariatrics > 1 year and > 25 cases the previous 12 months; trained and credentialed bariatric surgeon performing at least~~

~~50 cases in past 24 months; qualified bariatric call coverage 24/7/365; appropriate bariatric-grade equipment in outpatient and inpatient facilities; appropriate medical specialty services to complement surgeons' care for patients; and quality improvement program with prospective documentation of surgical outcomes. If the program is still pursuing (MBSAQIP) certification, it must also restrict care to lower risk OHP patients including: age < 65 years; BMI < 70; no major elective revisional surgery; and, no extreme medical comorbidities (such as wheel chair bound, severe cardiopulmonary compromise, or other excessive risk). All programs must agree to yearly submission of outcomes data to Division of Medicaid Assistance Programs (DMAP).~~
~~³ Only Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding and sleeve gastrectomy are approved for inclusion.~~

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 may include: high intensity programs; multicomponent (including at a minimum diet and exercise), group-based commercial programs; Mediterranean diet; and the following subelements -- 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.

Pharmacological treatments and devices for obesity are not intended to be included as services on this line or any other line on the Prioritized List.

Back Conditions Implementation Delay

Technical summary posted 8/10/2015; updated 3/29/16

Implementation delay:

This document enumerates changes to the Prioritized List of Health Services, which had been planned for implementation January 1, 2016. However, the implementation of these changes has been delayed by OHA leadership in order to address implementation concerns.

This document also contains additional revisions made at the January 14, 2016 HERC meeting. These changes include removal of epidural steroid injections from line 407 as well as reverting criteria for Guideline Note D4, Advanced Imaging for Back Pain, to their previous state as well as correction of some ICD-10-CM diagnosis codes and removal of ICD-9 diagnosis codes.

Finally, a few codes are shown in italics (the addition of psychotherapy codes to line 366 and the removal of ICD-10-CM diagnosis code M99.1 from line 407). These proposed changes will be considered for adoption by HERC at their May 19, 2016 meeting.

Information on the delay has been [posted](#) on the [CCO Quality and Health Outcomes Committee web site](#).

For a narrative description of the changes and details about the process leading to the changes see the [Back Policy Changes Fact Sheet](#).

Note: Line numbers refer to the January 1, 2016 Prioritized List.

Changes to Line Items

Line: 351

CONDITION: CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
TREATMENT: SURGICAL THERAPY

ICD-10: G83.4 (cauda equina), M43.1 (spondylolisthesis), M47.0 (anterior spinal artery compression syndroms, vertebral artery compression syndromes), M47.1 (spondylosis with myelopathy), M48.0 (spinal stenosis), M50.0 (cervical disc disorders with myelopathy), M51.0 (intervertebral disc disorder with myelopathy), M53.2X (spinal instabilities), Q76.2 (spondylolisthesis)

CPT: 20660-20665, 20930-20938, 21720, 21725, 22206-22226, 22532-22865, 29000-29046, 29710-29720, 62287 (percutaneous disc compression), 63001-63091, 63170, 63180-63200, 63270-63273, 63295-63610, 63650, 63655, 63685, 96150-4 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99291-99292 (critical care), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (telephone/Internet consults), 99468-99480, 99605-99607

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC), S2350-S2351 (discectomy with decompression of spinal cord)

Line: 366

CONDITION: SCOLIOSIS

Back Conditions Implementation Delay

Technical summary posted 8/10/2015; updated 3/29/16

TREATMENT: MEDICAL AND SURGICAL THERAPY

ICD-10: M41 (scoliosis), M96.5 (postradiation scoliosis), Q67.5 (congenital deformity of spine), Q76.3 (congenital scoliosis due to congenital bony formation), Z47.82 (encounter for other orthopedic aftercare following scoliosis surgery)

CPT: 20660-20665, 20930-20938, 21720, 21725, 22206-22226, 22532-22855, 29000-29046, 29710-29720, 62287, 63001-63091, 63170, 63180-63200, , 63295-63610, 63650, 63655, 63685, 90785, 90832-90838,90853 (mental health visits, counseling), 96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 97760, 97762, 97810-97814 (acupuncture), 98925-98929 (osteopathic manipulation), 98940-98942 (chiropractic manipulation), 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99291-99292 (critical care), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (telephone/Internet consults), 99468-99480, 99605-99607

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC)

Line: 407

CONDITION: CONDITIONS OF THE BACK AND SPINE
TREATMENT: RISK ASSESSMENT, PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY

ICD-10: F45.42 (Pain disorder with related psychological factors), G83.4, G95.0, M24.08, M25.78, M40, M42.0, M43, M45, M46.1, M46.4-M46.9, M47, M48.00-M48.38, M48.8-M48.9, M49.8, M50, M51, M53.2-M3.9, M54, M62.830, M96.1-M96.4, M99.0, ~~M99.12-M99.13~~, M99.20-M99.79, M99.81-M99.84, Q06.0-Q06.3, Q06.8-Q06.9, Q76.0-Q76.2, Q76.4, S13.0XXA-S13.0XXD, S13.4XXA-S13.4XXD, S13.8XXA-S13.8XXD, S13.9XXA-S13.9XXD, S16.1XXA-S16.1XXD, S23.0XXA-S23.0XXD, S23.100A-S23.100D, S23.101A-S23.101D, S23.110A-S23.110D, S23.111A-S23.111D, S23.120A-S23.120D, S23.121A-S23.121D, S23.122A-S23.122D, S23.123A-S23.123D, S23.130A-S23.130D, S23.131A-S23.131D, S23.132A-S23.132D, S23.133A-S23.133D, S23.140A-S23.140D, S23.141A-S23.141D, S23.142A-S23.142D, S23.143A-S23.143D, S23.150A-S23.150D, S23.151A-S23.151D, S23.152A-S23.152D, S23.153A-S23.153D, S23.160A-S23.160D, S23.161A-S23.161D, S23.162A-S23.162D, S23.163A-S23.163D, S23.170A-S23.170D, S23.171A-S23.171D, S23.3XXA-S23.3XXD, S23.8XXA-S23.8XXD, S23.9XXA-S23.9XXD, S33.0XXA-S33.0XXD, S33.100A-S33.100D, S33.101A-S33.101D, S33.110A-S33.110D, S33.111A-S33.111D, S33.120A-S33.120D, S33.121A-S33.121D, S33.130A-S33.130D, S33.131A-S33.131D, S33.140A-S33.140D, S33.141A-S33.141D, S33.5XXA-S33.5XXD, S33.8XXA-S33.8XXD, S33.9XXA-S33.9XXD, S34.3XXA-S34.3XXD, S39.092A-S39.092D, S39.82XA-S39.82XD, S39.92XA-S39.92XD

CPT: 62311, 90785,90832-90838,90853 (mental health visits, counseling), 96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 97810-97814 (acupuncture), 98925-98929, 98940-98942 (OMT/CMT), 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99281-99285 (ER), 99304-99337 (SNF care), 99340-99359, 99366-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99449, 99487-99490, 99605-99607

Back Conditions Implementation Delay
Technical summary posted 8/10/2015; updated 3/29/16

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0425-G0427 (telehealth), G0463, G0466, G0467, G0469, G0470 (FQHC)

Line: 532

CONDITION: CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS

TREATMENT: SURGICAL THERAPY

ICD-10: G95.0, M40, M42, M43.0- M43.2, M43.8, M45, M46.4-M46.99, M47.2-M47.9, M48.0 (spinal stenosis), M48.1, M48.3, M48.8-M48.9, M49, M50.1-M50.9, M51.1-M51.9, M53.8-M53.9, M54.1, M96.1-M96.4, M99.2-M99.7, M99.81-M91.85, Q06.0-Q06.3, Q06.8-Q06.9, Q76.0-Q76.2, Q76.4, S13.0XXA-S13.0XXD, S23.0XXA-S23.0XXD, S23.100A-S23.100D, S23.110A-S23.110D, S23.120A-S23.120D, S23.122A-S23.122D, S23.130A-S23.130D, S23.132A-S23.132D, S23.140A-S23.140D, S23.142A-S23.142D, S23.150A-S23.150D, S23.152A-S23.152D, S23.160A-S23.160D, S23.162A-S23.162D, S23.170A-S23.170D, S33.0XXA-S33.0XXD, S33.100A-S33.100D, S33.110A-S33.110D, S33.120A-S33.120D, S33.130A-S33.130D, S33.140A-S33.140D, S34.3XXA-S34.3XXD

CPT: 20660-20665, 20930-20938, 21720, 21725, 22206-22226, 22532-22865, 27035, 29000-29046, 29710-29720, 62287, 63001-63091, 63170, 63180-63200, 63270-63273, 63295-63610, 63650, 63655, 63685, 96150-96154 (health and behavior assessment codes), 97001-97004, 97022, 97110-97124, 97140, 97150, 97530, 97535 (PT/OT evaluation and treatment), 98966-98968, 98969, 99051, 99060, 99070, 99078, 99201-99215 (outpatient medical visits), 99217-99239 (hospital), 99281-99285 (ER), 99291-99292 (critical care), 99304-99337 (SNF care), 99401-99404 (risk factor reduction intervention), 99408, 99409, 99411, 99412, 99441-99444, 99446-99449 (telephone/Internet consults), 99468-99480, 99605-99607

HPCPS: G0157-G0160 (PT/OT), G0396-G0397 (SBRT), G0406-G0408 (inpatient consultation), G0425-G0427 (telehealth), G0463, G0466, G0467 (FQHC), S2350-S2351 (discectomy with decompression of spinal cord)

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New Guideline Notes

GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Lines 366, 407

Patients seeking care for back pain should be assessed for potentially serious conditions (“red flag”) symptoms requiring immediate diagnostic testing, as defined in Diagnostic Guideline D4. Patients lacking red flag symptoms should be assessed using a validated assessment tool (e.g. STarT Back Assessment Tool) in order to determine their risk level for poor functional prognosis based on psychosocial indicators.

For patients who are determined to be low risk on the assessment tool, the following services are included on this line:

- Office evaluation and education,
- Up to 4 total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be considered.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers. Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.

For patients who are determined to be high risk on the validated assessment tool, the following treatments are included on this line:

- Office evaluation, consultation and education
- Cognitive behavioral therapy. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Medications, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.
- The following evidence-based therapies, when available, are encouraged: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only covered if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
 - 1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to GUIDELINE NOTE 6, REHABILITATIVE SERVICES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6
 - 2) Chiropractic or osteopathic manipulation
 - 3) Acupuncture

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These coverage recommendations are derived from the State of Oregon Evidence-based Guideline on the Evaluation and Management of Low Back Pain available here: <http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx>

Evidence Table of Effective Treatments for the Management of Low Back Pain

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	<i>Benzodiazepines</i> **	●(▲)	●(▲)
	<i>Tramadol, opioids</i> **	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●
<ul style="list-style-type: none"> ● Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit). <p>▲ <i>Carries greater risk of harms than other agents in table.</i></p>			

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: <http://www.annals.org/content/147/7/478.full.pdf>

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.

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

Lines 351, 366, 407, 532

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

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

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

For patients with chronic pain from diagnoses on these lines currently treated with long term opioid therapy, opioids must be tapered off, with a taper of about 10% per week recommended. By the end of 2016, all patients currently treated with long term opioid therapy must be tapered off of long term opioids for diagnoses on these lines. If a patient has developed dependence and/or addiction related to their opioids, treatment is available on line 4 SUBSTANCE USE DISORDER.

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

Lines 351, 532

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

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

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

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

- 1) MRI evidence of moderate to severe central or foraminal spinal stenosis AND
- 2) A history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings.

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

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

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

GUIDELINE NOTE 41 SCOLIOSIS

Line 366

Non-surgical treatments of scoliosis (ICD-10 M41) are included on line 366 when

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- 1) the scoliosis is considered clinically significant, defined as curvature greater than or equal to 25 degrees or
- 2) there is curvature with a documented rapid progression.

Surgical treatments of scoliosis are included on line 366

- 1) only for children and adolescents (age 20 and younger) with
- 2) a spinal curvature of greater than 45 degrees

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Changes to Existing Guideline Notes

DIAGNOSTIC GUIDELINE D4, ADVANCED IMAGING FOR LOW BACK PAIN

In patients with non-specific low back pain and no “red flag” conditions [see Table D4], imaging is not a covered service; otherwise work up is covered as shown in the table. Repeat imaging is only covered when there is a substantial clinical change (e.g. progressive neurological deficit) or new clinical indication for imaging (i.e. development of a new red flag condition). Repeat imaging for acute exacerbations of chronic radiculopathic pain is not covered.

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

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

Possible cause	Key features on history or physical examination	Imaging ¹	Additional studies ¹
Cancer	<ul style="list-style-type: none"> History of cancer with new onset of LBP 	MRI	ESR
	<ul style="list-style-type: none"> Unexplained weight loss Failure to improve after 1 month Age >50 years Symptoms such as painless neurologic deficit, night pain or pain increased in supine position 	Lumbosacral plain radiography	
	<ul style="list-style-type: none"> Multiple risk factors for cancer present 	Plain radiography or MRI	
Spinal column infection	<ul style="list-style-type: none"> Fever Intravenous drug use Recent infection 	MRI	ESR and/or CRP
Cauda equina syndrome	<ul style="list-style-type: none"> Urinary retention Motor deficits at multiple levels Fecal incontinence Saddle anesthesia 	MRI	None
Vertebral compression fracture	<ul style="list-style-type: none"> History of osteoporosis Use of corticosteroids Older age 	Lumbosacral plain radiography	None
Ankylosing spondylitis	<ul style="list-style-type: none"> Morning stiffness Improvement with exercise Alternating buttock pain Awakening due to back pain during the second part of the night Younger age 	Anterior-posterior pelvis plain radiography	ESR and/or CRP, HLA-B27
Nerve compression/ disorders (e.g. herniated disc with radiculopathy)	<ul style="list-style-type: none"> Back pain with leg pain in an L4, L5, or S1 nerve root distribution present < 1 month Positive straight-leg-raise test or crossed straight-leg-raise test 	None	None
	<ul style="list-style-type: none"> Radiculopathic signs² present >1 month Severe/progressive neurologic deficits (such as foot drop), progressive motor weakness 	MRI ³	Consider EMG/NCV
Spinal stenosis	<ul style="list-style-type: none"> Radiating leg pain Older age Pain usually relieved with sitting (Pseudoclaudication a weak predictor) 	None	None
	<ul style="list-style-type: none"> Spinal stenosis symptoms present >1 month 	MRI ⁴	Consider EMG/NCV

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- ¹ Level of evidence for diagnostic evaluation is variable
- ² Radiculopathic signs are defined for the purposes of this guideline defined as the presence of any of the following:
 - A. Markedly abnormal reflexes
 - B. Segmental muscle weakness
 - C. Segmental sensory loss
 - D. EMG or NCV evidence of nerve root impingement
 - E. Cauda equina syndrome,
 - F. Neurogenic bowel or bladder
 - G. Long tract abnormalities
- ³ Only if patient is a potential candidate for surgery

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

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

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

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,207,414,468,546,407

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY

Acupuncture pairs on Line 1 for the following conditions and codes.

Hyperemesis gravidarum

ICD-10-CM code: O21.0, O21.1

Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture.

Breech presentation

ICD-10-CM code: O32.1

Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 visits.

Back and pelvic pain of pregnancy

ICD-10-CM code: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions.

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Line 207 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE
Acupuncture is paired with the treatment of post-stroke depression only.

Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions, with documentation of meaningful improvement.

Line 407-CONDITIONS OF THE BACK AND SPINE

Acupuncture is included this line with visit limitations as in Guideline Note 56.

Line 414 MIGRAINE HEADACHES

Acupuncture pairs on Line 414 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), when referred, for up to 12 sessions.

Line 468 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 468 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions.

Line 546 TENSION HEADACHES

Acupuncture is included on Line 546 for treatment of tension headaches G44.2x, for up to 12 sessions.

Deleted Guideline Notes

~~GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT~~

~~Lines 374,545~~

~~Diagnoses are included on Line 374 when objective evidence of neurologic impairment or radiculopathy is present, as defined as:~~

- ~~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, disorders of spine not meeting these criteria (e.g. pain alone) fall on Line 545.~~

~~GUIDELINE NOTE 41, SPINAL DEFORMITY, CLINICALLY SIGNIFICANT~~

~~Line 412~~

~~Clinically significant scoliosis is defined as curvature greater than or equal to 25 degrees or curvature with a documented rapid progression. Clinically significant spinal stenosis is defined as having MRI evidence of moderate to severe central or foraminal spinal stenosis in addition to a history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings (see Guideline Note 37).~~

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GUIDELINE NOTE 56, ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Line 545

Disorders of spine without neurologic impairment include any conditions represented on this line for which objective evidence of one or more of the criteria stated in Guideline Note 37 is not available

GUIDELINE NOTE 60, SPINAL DEFORMITY, NOT CLINICALLY SIGNIFICANT

Line 588

Scoliosis not defined as clinically significant included curvature less than 25 degrees that does not have a documented progression of at least 10 degrees

GUIDELINE NOTE 94, EVALUATION AND MANAGEMENT OF LOW BACK PAIN

Lines 374,545

Procedures for the evaluation and management of low back pain are included on these lines when provided subject to the State of Oregon Evidence-based Clinical Guidelines dated 10/2011 located at:

<http://www.oregon.gov/oha/OHPR/pages/herc/evidence-based-guidelines.aspx>

GUIDELINE NOTE 105, EPIDURAL STEROID INJECTIONS FOR LOW BACK PAIN

Line 407

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

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