Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on January 16, 2020

For specific coding recommendations and guideline wording, please see the text of the 1/16/2020 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 10/1/2020 Prioritized List unless otherwise noted)

- Add several diagnosis codes for chronic lower extremity venous disease to a covered line with a new guideline
- Delete the procedure code for intracardiac echocardiograms from an uncovered line and recommend addition to the Diagnostic Procedures File
- Move vitamin D testing codes from the Diagnostic Procedures File to specific lines
- Add the procedure code for fetal myelomeningocele repair to a covered line
- Add an additional procedure code for aqueous shunts to the covered glaucoma line
- Delete the procedure codes for spinal cord stimulators from one covered line with no appropriate diagnoses
- Make various straightforward coding and guideline changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Acupuncture and yoga were not added as treatment for post-traumatic stress disorder or anxiety

RECOMMENDED GUIDELINE CHANGES (changes to the 10/1/2020 Prioritized List unless otherwise noted)

- Add a clause allowing an exception for pre-operative testing prior to epilepsy surgery to the neuropsychological testing guideline
- Add a new guideline specifying when treatment of chronic lower extremity venous disease is covered
- Delete the pharmacist prescribing guideline
- Expand the guideline note entry for TENS to apply to all similar therapies that include the same CPT code
- Edit the guideline on Yttrium 90 therapy for hepatocellular carcinoma to clarify that pre-treatment mapping is covered but not pre-treatment embolization
- Edit the fetal surgery guideline to include fetal myelomeningocele repair
- Edit the guideline regarding aqueous shunts to remove the brand name reference
- Add a new guideline specifying when spinal cord stimulators are covered

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
January 16, 2020
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-chair (via phone); Vern Saboe, DC (via phone); Gary Allen, DMD (via phone); Kathryn Schabel, MD; Brian Duty, MD (arrived 8:10), Adriane Irwin, PharmD.

Members Absent: None.

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

Also Attending: Michael Collins (Warm Springs Tribe); Shauna Williams (Glaukos); Billy Ray Pitt (Sirtex); Trisha Wong, MD, Eneida Nemecek MD, Rochelle Williams-Belizaire, and Stefan Sang (OHSU), Joevantae Thompson; Jennifer Batchela, Robyn Tyran, and Mary Hlady (Providence); Dawn Mautner (OHA), Andrei Sdrulla (OHSU); Laura Ocker (OCOM); Rosa Schnyer (University of Texas; via phone).

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

  The meeting was called to order at 8:00 am and roll was called. A quorum of members was present at the meeting. Minutes from the November 14, 2019 VbBS meeting were reviewed and approved.

  Smits noted the errata document was available for review; there were no questions regarding any of the errata. She also noted that the back lines review might be delayed from March as the AHRQ reviews have been delayed.

  Gingerich introduced Mike Collins as a new HERC member who will likely be added to VbBS at today's HERC meeting. He also noted that the planned discussion of conflict of interest forms has been delayed from today's HERC meeting to March, 2020.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) Add CPT 99490 (Chronic care management services) and HCPCS G2058 (Chronic care management services) to lines 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS, 361 SCOLIOSIS, 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS, 661 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
  2) Remove ICD-10-CM M40.0 codes (Postural kyphosis), M40.4 (Postural lordosis) and M40.5 (Lordosis, unspecified) from lines 402 CONDITIONS OF THE BACK AND SPINE and 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
     a. Add ICD-10-CM M40.0, M40.4 and M40.5 to line 659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
  3) Remove CPT 81225 (CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)) from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and recommend that HSD add the code to the Diagnostic Procedure File
  4) Modify the entry regarding P450 testing in section D of DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE as shown in Appendix A.
  5) Remove CPT 93792-93793 (INR) monitoring) from all current lines on the Prioritized List and advise HSD to add to the Diagnostic Procedures File
  6) Remove ICD-10-CM Z79.01 (Long term (current) use of anticoagulants) from all current lines on the Prioritized List and advise HSD to add to the Diagnostic Workup File

  MOTION: To approve the recommendations stated in the consent agenda. CARRIES 5-0. *(Absent: Duty)*

- **Topic: Bone marrow transplant for sickle cell disease**

  Discussion: Smits introduced the summary document and answered clarifying questions from members.

  Testimony was heard from:
  Eneida Nemecek MD, bone marrow transplant director at OHSU, who also works with the national bone marrow registry. She described the clinical course of sickle cell disease. She noted that as fetal hemoglobin decreases as kids age, they get more and more symptoms such as excruciating pain. They have repeat hospitalizations, and the spleen fails so they get increased infection. The many complications result in a shortened life expectancy. A new coverage recommendation for bone marrow transplant (BMT) was approved by CMS recently. If a patient has a matched sibling donor, then the recommendation is to have a BMT as early as possible. If there is no matched sibling, then organ damage criteria are used to determine when to consider transplant.

  Tricia Wong MD, director of Sickle Cell program at OSHU. This is a quality of life issue. The Arnold study used pediatric data only and did not capture cost savings of adults who can be more

productive and have lower health costs for a long period. She agrees with the proposed requirements that the patient have severe disease and a matched sibling donor for now. She believes that data will be forthcoming about non-sibling transplants and less-symptomatic patients and will be coming back to ask for expanded coverage.

Schabel asked the experts what they felt about the HERC staff-proposed guideline criteria. Nemecek felt that the data is there for matching sibling donors at any age. She testified that she does not know of evidence for transplants after age 40, so she agrees with 40-year age limit in cases with no matched sibling. She also agreed patients should be required to meet study inclusion criteria related to organ damage (she offered to provide this criteria). No one recommends BMT for patients over the age of 40. She would not recommend limiting coverage to sibling matched donors as the research is rapidly changing. She noted that CMS has approved sibling HLA-matched transplant at any age. Wong recommended including coverage for patients with non-sibling matched donors if done as part of a registered trial. Essentially, the experts recommended requiring no complications if there is a sibling match and the patient is under age 40; they recommend requiring patients to meet the complications criteria from an ongoing study if they have a non-sibling match and the patient is under age 40. They did not recommend coverage of BMT for patients over age 40.

Irwin asked for a clarification of the CMS criteria. Nemecek stated that CMS approves all kids (under age 15) with a matched sibling so their guidance is just for ages 15 and above and sibling or non-sibling matched donor. There is also a half-matched protocol (allowing coverage for patients with strokes and adults with many symptoms).

Olson asked about gene therapy. Nemecek replied that gene therapy is experimental and must be done in a clinical trial. Wong noted that gene therapy was recently approved for thalassemia—she will bring this to HERC in the future.

Rochelle Williams-Belizaire from the OHSU Knight Cancer Institute testified. There is evidence to support BMT for sickle cell disease. She has an 18-month-old son with the condition, who has already been in the hospital twice. Her son has a matched sibling, and the family plans BMT for her toddler.

Joevantae Thompson, a sickle cell disease patient testified. He had frequent pain and hospitalizations before his transplant in August 2019. Now he has no pain. He is 17.

Nemecek summarized that she feels coverage should include patients of any age who have a matched sibling donor. If a patient does not have a matched sibling donor, then a patient should be eligible for BMT under the criteria of registered trial (she recommended not being detailed about end organ damage as criteria for trials are changing). Schabel asked whether the donor should be related or a sibling. Nemecek replied that they need to simply be related.

The VbBS generally agreed with adding coverage for BMT for sickle cell disease, and asked staff to work with experts to fine tune the guideline and bring back to the March 2020 VbBS meeting.

Recommended Actions:

1) HERC staff to work with experts on the proposed new guideline wording and bring this topic back to a future VbBS meeting

- **Topic: Neuropsychological testing guideline**

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

  Recommended Actions:
  1) Modify Diagnostic Guideline D26 as shown in Appendix A

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

- **Topic: Chronic lower extremity venous disease (CLEVD)/compression stockings**

  Discussion: Smits introduced the summary document. Schabel noted that in the case of a non-healing ulcer, compression stockings can be harmful and are not indicated. She also noted that patients with various lower extremity conditions also frequently have neuropathy, and compression stockings can be dangerous in that situation.

  Testimony:
  Robyn Tyran, a physical therapist with Providence, testified that high compression stockings can be harmful, but there are medical compression devices which have Velcro wraps and better skin protection. These devices also have higher compliance.

  The members requested that the proposed guideline note replace "compression stockings" with "medical compression garments" to allow the use of these more effective devices.

  Tyran then gave a presentation, requesting that compression garments be covered for all levels of venous insufficiency to prevent downstream complications. She noted that untreated venous insufficiency leads to a downward spiral in health and function. She presented a flowchart of treatment recommendations from Eberhardt et al. She requested that compression garments be covered at the first symptom, before any imaging is done to look for venous reflux. She noted there is level 1 evidence for compression stockings for treatment of post-thrombotic syndrome, prevention of progression of occupational leg syndromes, and in management of lymphedema.

  Jennifer Batchela, also a physical therapist from Providence, testified that the biggest barrier to compliance with compression garments is the cost of the garments. Providing coverage for these garments would help to overcome this barrier. She noted that fit and skin issues can affect compliance with use.

  Tyran noted that there will be no studies of compression garments against non-treated controls, as not offering compression would be unethical. The studies that are published essentially compare compliant patients with non-compliant patients, which is not a random comparison.

  Hodges noted that gradient compression stockings are coded with an HCPCS "A" code (the series used for durable medical equipment (DME)) and covered based on criteria in Oregon Administrative Rules (OAR). Staff noted that they will need to check with the Health Systems Division regarding the OARs for DME such as compression stockings.

It was noted that superficial thrombophlebitis, which was proposed for coverage in the new guideline, is actually on line 516 and those ICD-10-CM codes were not proposed to be moved to the covered line. The members suggested substituting "recurrent cellulitis resulting from chronic venous disease" in that portion of the new guideline. There was also a suggestion to make medical treatment of CLEVD a separate section in the guideline from the surgical treatment.

Olson noted that the discussion regarding compression garments went beyond the topic at hand, which was coverage for chronic lower extremity venous disease. The group agreed that the modified guideline and coding change recommendations were adequate for their intent to widen coverage slightly for chronic lower extremity venous disease. There was also discussion that if varicose veins resulted in significant bleeding, then surgical treatment should be covered. The members suggested changing that entry in the guideline to say "clinically significant bleeding" to reflect that it cannot be a small amount of bleeding, but something that might affect health. Massive bleeding would be covered as an exception without any other requirements.

The group requested that HERC staff work with the physical therapy group and HSD staff regarding coverage of compression garments for non-CLEVD indications, such as edema from heart disease, liver disease, obesity, or other causes. Staff was also directed to explore coverage of compression garments for less severe CLEVD.

Recommended Actions:

1) Add varicose veins with other complications to line 379 CHRONIC ULCER OF SKIN and keep on line 519 POSTTHROMBOTIC SYNDROME/639 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION
    a. ICD10 I83.89 (Varicose veins of lower extremities with other complications)
    b. ICD10 I87.09 (Postthrombotic syndrome with other complications of lower extremity)
2) Adopt a new guideline note to line 379 as shown in Appendix B
3) Modify the line title of line 379 to CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS

MOTION: To recommend the code and guideline note changes as modified. CARRIES 6-0.

- **Topic: Delete pharmacist prescribing guideline**

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

Recommended Actions:

1) Delete GN64 as shown in Appendix A

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

- **Topic: Intracardiac echocardiogram**

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

Recommended Actions:

1) Remove CPT 93662 (Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure) from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Modify Guideline Note 173 as shown in Appendix A
3) Advise HSD to add CPT 93662 to the Diagnostic Procedure File

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

- **Topic: Frequency specific microcurrent therapy and similar TENS-like therapies**

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

Recommended Actions:

1) Modify the GN173 entry for CPT 97014 (Application of a modality to 1 or more areas; electrical stimulation (unattended)) as shown in Appendix A

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

- **Topic: Yttrium 90 embolization mapping**

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

Recommended Actions:

1. Do not add **CPT 37242** *Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)* **to Line 315**
2. Modify Guideline Note 185 as shown in Appendix A.

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

- **Topic: Vitamin D screening**

Discussion: Livingston reviewed the summary document. There was a brief discussion about the change in vitamin D recommendations for fall prevention.

Recommended Actions:

1) Advise HSD to remove 82306 *Vitamin D; 25 hydroxy* and 82652 *Vitamin D; 1, 25 dihydroxy*, from the Diagnostic File
2) Add 82306 to the following lines:

- 24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
- 55 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS
- 102 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
- 117 NUTRITIONAL DEFICIENCIES
- 151 DISORDERS OF MINERAL METABOLISM, OTHER THAN CALCIUM
- 195 ACUTE PANCREATITIS
- 224 DISORDERS OF PARATHYROID GLAND; BENIGN NEOPLASM OF PARATHYROID GLAND; DISORDERS OF CALCIUM METABOLISM
- 227 INTESTINAL MALABSORPTION
- 239 SHORT BOWEL SYNDROME - AGE 5 OR UNDER
- 248 METABOLIC BONE DISEASE
- 250 CHRONIC PANCREATITIS
- 259 CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME
- 288 OSTEOPETROSIS
- 293 ANOMALIES OF GALLBLADDER, BILE DUCTS, AND LIVER
- 307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE
- 334 ALCOHOLIC FATTY LIVER OR ALCOHOLIC HEPATITIS, CIRRHOSIS OF LIVER
- 339 CHRONIC KIDNEY DISEASE
- 352 URINARY SYSTEM CALCULUS

3) Add 82652 *Vitamin D; 1, 25 dihydroxy* to the following lines

- 224 DISORDERS OF PARATHYROID GLAND; BENIGN NEOPLASM OF PARATHYROID GLAND; DISORDERS OF CALCIUM METABOLISM
- 151 DISORDERS OF MINERAL METABOLISM, OTHER THAN CALCIUM
- 248 METABOLIC BONE DISEASE
- 352 URINARY SYSTEM CALCULUS

3) Add R82.994 Hypercalciuria (currently in the Diagnostic Workup File) to Lines 224 and 352

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

- **Topic: Fetal myelomeningocele repair**

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

Recommended Actions:

1) Add HCPCS S2404 (Repair, myelomeningocele in the fetus, procedure performed in utero) to line 1 PREGNANCY
2) Modify GN2 as shown in Appendix A

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

- **Topic: iStent Inject**

Discussion: Smits reviewed the summary document. There was minimal discussion. Hodges requested that the CPT codes for the procedure be added to the guideline.

Recommended Actions:

1) Add CPT 0376T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; each additional device insertion) to line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
2) Add HCPCS C1783 (Ocular implant, aqueous drainage assist device) and L8612 (Aqueous shunt) to line 139
3) Modify Guideline Note 184 as shown in Appendix A

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

- **Topic: Spinal cord stimulators**

Discussion: Smits introduced the summary documents regarding both spinal cord stimulators for conditions of the back and spine and for complex regional pain syndrome.

Testimony was heard from Dr. Andrei Sdrulla, from the anesthesia department at OHSU. CRPS is uncommon and therefore few clinical trials. 50-100 Oregonians have this condition. Patients have severe neuropathic pain, and have no other treatment options. Patients with CRPS have significant disability and poor quality of life. Anything we can do to help would be worthwhile. Adding coverage for spinal cord stimulators would not a high budget item as small handful of patients a year would get SCS. SCS technology has developed greatly over time. Four different manufacturers make devices with different technology. There is a need to correctly maintain the device as well. Study heterogeneity is high due to different devices and different levels of maintenance. Older trials have high complications rates; newer devices and techniques have much lower complication rates. The Deere study had much lower complication compared to the Kemler study (an earlier study). In Deere—both arms did very well. Complication rate were reasonable. Do not put as much weight on the older studies. His experience in that these devices work well in certain patients and can be life changing. CRPS can often be mislabeled. He also noted that you cannot do sham control for SCS, so inherently get low quality studies.

Members asked what other treatments exist for CRPS. The answer was some medications, physical therapy.

Duty asked what percent of patients getting a test SCS qualify for permanent placement with CRPS. Sdrulla responded that 65-80% of CRPS patients qualify for permanent placement, which is higher than with failed back surgery syndrome.

Sdrulla noted that dorsal root ganglion (DRG) stimulation is very technically difficult, few surgeons in Oregon are doing this.

Olson noted that CRPS patients could access SCS through the exception process. Duty noted this process could be quite onerous. Hodges stated that she did not see problems with CRPS patients getting approved for SCS through the exceptions process at her CCO.

Gingerich noted that 251 pts on OHP had paid claims for CRPS in 2018.
Saboe asked what is the cost of the procedure? Livingston reported that she found costs of $32,882 for Medicare (hospitalization, procedure, device, $5,000-$21,000 yearly maintenance cost) in a brief internet search.

Schabel requested that the clause stating that coverage for SCS placement would not be covered if a patient had a contraindication be struck from the proposed guideline, as no surgeon would operate on a patient with a contraindication.

Irwin asked about the diagnostic criteria for CRPS. Sdrulla answered: pain out of proportion to the stimulus or after normal healing. There are criteria that include symptoms and exam findings.

There were two votes. The vote to accept the staff coding changes and guideline note modifications excluding the sentence regarding CRPS was approved unanimously. The vote to include wording excluding CRPS from coverage was 4 ayes to 2 nays.

Recommended Actions:

1) Remove all spinal cord stimulator CPT and HCPCS codes from line 361 SCOLIOSIS
    a. CPT 63650, 63655, 63685
    b. HCPCS C1767, C1778, C1816, C1820, C1822, C1823, C1897
2) Add the new guideline shown in Appendix B to lines
    a. 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
    b. 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
    c. 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
3) Delete the coding specification regarding spinal cord stimulators from line 292 as this exclusion for CRPS will be addressed in the new guideline note.
    a. "~~Spinal cord stimulation (63650-63688) is not included on this line when paired with ICD-10-CM-CM category G90.5 Complex regional pain syndrome/reflex sympathetic dystrophy.~~"

MOTION: To recommend the code, coding specification, and guideline note changes as presented. CARRIES 4-2 (Opposed: Schabel, Irwin)

- **Topic: Yoga and acupuncture for PTSD and anxiety**

Discussion: Smits introduced the summary document.

Testimony was heard from Laura Ocker, LAc and Rosa Schnyer, LAc (via phone).

Schabel asked the experts about ongoing research efforts in this area. Schnyer replied that the Department of Defense (DOD) is actively collecting data on acupuncture for PTSD among veterans. Duty asked what the DOD protocol was. Schnyer replied that she did not know the details of that research.

Ocker noted that acupuncture can have variable time of benefit and may improve the effectiveness of other treatments such as medications.

Schabel suggested that the CCOs could develop and use local resources rather than having the coverage required. There was consensus that this was the best approach at this time. There was no recommendation to make a change to the current lack of pairing of acupuncture and yoga with PTSD and anxiety at this time.

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**
  - Bone marrow transplant for sickle cell disease

- **Next meeting:**

  March 12, 2020 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

- **Adjournment:**

  The meeting adjourned at 12:54 PM.

Appendix A
Revised Guideline Notes

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

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

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

C) A more expensive genetic test (generally one with a wider scope or more detailed testing) is not covered if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
   1) CPT 81228 and 81229, Cytogenomic constitutional microarray analysis: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
   2) CPT 81243, 81244, 81171,81172 Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
   3) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.

D) Related to other tests with specific CPT codes:
   1) Certain genetic tests have not been found to have proven clinical benefit. These tests are listed in Guideline Note 173, INTERVENTIONS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN INTERVENTIONS

Appendix A
Revised Guideline Notes

2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
   a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
   b) Diagnostic testing for cystic fibrosis (CF)
      i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81221, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
   c) Carrier testing for cystic fibrosis
      i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220-81224) is covered once in a lifetime.
   d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.
   e) CPT 8122556-81227, 81230-81231 (cytochrome P450). Covered only for determining eligibility for medication therapy if required or recommended in the FDA labelling for that medication. These tests have unproven clinical utility for decisions regarding medications when not required or recommended in the FDA labeling for that medication (e.g. psychiatric, anticoagulant, opioid medications, etc.).
   f) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
   g) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
   h) CPT 81247. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-) should only be covered
      i) After G6PD enzyme activity testing is done and found to be normal; AND either
         (a) There is an urgent clinical reason to know if a deficiency is present, e.g. in a case of acute hemolysis; OR

(b) In situations where the enzyme activity could be unreliable, e.g. female carrier with extreme Lyonization.

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

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

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

l) CPT 81332, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the anpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.

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

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

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

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

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

* American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories. 2008 Edition, Revised 7/2018 and found at http://www.acmg.net/PDFLibrary/Cystic-Fibrosis-Population-Based-Carrier-Screening-Standards.pdf.

DIAGNOSTIC GUIDELINE D26, NEUROBEHAVIORAL STATUS EXAMS AND NEUROPSYCHOLOGICAL TESTING

Neurobehavioral status exams (CPT 96116 and 96121) and neuropsychological testing services (CPT 96132 and 96133) are only covered when all of the following are met:

1) Symptoms are not explained by an existing diagnosis; AND

Appendix A
Revised Guideline Notes

2) When the results of such testing will be used to develop a care plan.

OR when neuropsychological testing is done as part of the pre-operative evaluation prior to epilepsy surgery.

GUIDELINE NOTE 2, ~~FETOSCOPIC~~ FETAL SURGERY

Line 1

Fetal surgery is only covered for the following conditions: repair of urinary tract obstructions via placement of a urethral shunt, repair of congenital cystic adenomatoid malformation, repair of extralobal pulmonary sequestration, repair of sacrococcygeal teratoma, ~~and~~ therapy for twin-twin transfusion syndrome, and repair of myelomeningocele.

Fetoscopic repair of urinary tract obstruction (S2401) is only covered for placement of a urethral shunt. Fetal surgery for cystic adenomatoid malformation of the lung, extralobal pulmonary sequestration and sacrococcygeal teratoma must show evidence of developing hydrops fetalis.

Certification of laboratory required (76813-76814).

~~**GUIDELINE NOTE 64, PHARMACIST MEDICATION MANAGEMENT**~~

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

~~Pharmacy medication management services must be provided by a pharmacist who has:~~

~~1) A current and unrestricted license to practice as a pharmacist in Oregon.~~

~~2) Documentation must be provided for each consultation and must reflect communication with the patient's primary care provider. Documentation should model SOAP charting; must include patient history, provider assessment and treatment plan; follow up instructions; be adequate so that the information provided supports the assessment and plan; and must be retained in the patient's medical record and be retrievable.~~

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
~~93662~~	~~Intracardiac echocardiography during therapeutic/diagnostic intervention~~		

Appendix A
Revised Guideline Notes

Procedure Code	Intervention Description	Rationale	Last Review
97014, 97032, 0278T, E0720, E0730, G0283	Transcutaneous electrical nerve stimulation (TENS), frequency specific microcurrent therapy, microcurrent electrical stimulation, and all similar therapies; Scrambler therapy; Cranial electrical stimulation; all similar transcutaneous electrical neurostimulation therapies	No clinically important benefit (CES) or insufficient evidence of effectiveness (all other) for chronic pain; insufficient evidence of effectiveness for all other indications	January 2020

GUIDELINE NOTE 185, YTTRIUM 90 THERAPY

Line 315

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

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

Pretreatment mapping is included on this line, however, pre-treatment embolization is not included on this line due to insufficient evidence of effectiveness.

GUIDELINE NOTE 184, ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE INSERTION

Line 139

Anterior segment aqueous drainage device ~~(e.g. iStent©)~~ insertion (e.g. CPT 0191T, O376T or HCPCS C1783, L8612) is only included on this line when done at the same time as cataract removal and when the two procedures are billed together as a bundled service.

Appendix B
New Guideline Notes

GUIDELINE NOTE XXX, TREATMENT OF CHRONIC LOWER EXTREMITY VENOUS DISEASE

Lines 379,519,639

Medical treatment of chronic lower extremity venous disease with major complications (skin ulceration, recurrent cellulitis or clinically significant bleeding) is included on line 379, including medical compression garments.

Surgical treatment of chronic lower extremity venous disease is only included on line 379 when

1) The patient has had an adequate 3-month trial of conservative therapy and failed; AND
2) Ultrasound findings of severe axial venous reflux (>1 second in the greater or small saphenous vein or accessory saphenous vein; AND
3) The patient has one of the following:
    a. Non-healing skin ulceration in the area of the varicose vein(s), OR
    b. Recurrent episodes of cellulitis associated with chronic venous disease OR
    c. Clinically significant bleeding from varicose vein(s).

Otherwise, these diagnoses are included on lines 519 or 639.

GUIDELINE NOTE XXX SPINAL CORD STIMULATOR THERAPY

Lines 292, 346, 529

A spinal cord stimulator trial is included on lines 292 and 346 only when a patient meets all of the following criteria:

1) The patient has moderate to severe (>5 on the VAS pain scale) neuropathic pain and objective neurologic impairment with documented pathology related to pain complaint (i.e. abnormal MRI). Neurologic impairment is defined as objective evidence of one or more of the following:
    a. Markedly abnormal reflexes
    b. Segmental muscle weakness
    c. Segmental sensory loss
    d. EMG or NCV evidence of nerve root impingement
    e. Cauda equina syndrome
    f. Neurogenic bowel or bladder
    g. Long tract abnormalities; AND
2) The patient has failed 12 or more months of other treatment modalities (e.g. pharmacological, surgical, physical therapy, cognitive therapy, and activity lifestyle modification); AND
3) The patient has had an evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) which revealed no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) and the patient receives written clearance from the mental health provider for device placement.

Implantation of a spinal cord stimulator is included on lines 292 and 346 when the trial criteria above are met and the patient experienced significant pain reduction (50% or more) with a 3 to 7 day trial of percutaneous spinal stimulation.

Appendix B
New Guideline Notes

Spinal cord stimulation (CPT 63650-63688) is not included on line 292 when paired with ICD-10-CMcategory G90.5 Complex regional pain syndrome/reflex sympathetic dystrophy.

Otherwise, spinal cord stimulation therapy is included on line 529.