Value-based Benefits Subcommittee (VbBS) Summary

For Presentation to:
Health Evidence Review Commission on March 9, 2023

For specific coding recommendations and guideline wording, please see the text of the March 9, 2023 VbBS minutes.

Recommended Code Movement (Changes to the 10/1/2023 Prioritized List unless otherwise noted):

- Merge the three funded lines for liver transplant into a single line (effective 1/1/2024)
- Add "store and forward" codes to the ancillary file so they will be covered
- Add trigger finger and trigger thumb to a funded line for adults and children
- Add codes for several genetic tests to the diagnostic procedures file (this recommendation was not approved by HERC).
- Make various straightforward coding changes

Item Considered but No Recommendations for Changes Made:

- Vagus nerve stimulators for treat resistant depression

Recommended Guideline Changes (Changes to the 10/1/2023 Prioritized List unless otherwise noted):

- Delete the guideline relating to smoking cessation requirements before elective surgery and add a new statement of intent regarding smoking prior to elective surgery
- Edit the ancillary guideline regarding telehealth to indicate when "store and forward" codes are covered
- Edit the biliary colic guideline to only require one imaging test
- Edit the trigger thumb guideline to include treatment of adults for trigger thumb and treatment of trigger finger for adults and children
- Edit the back surgery guideline to clarify when foraminal stenosis is funded
- Remove a code related to a gene expression test from the guideline note for services not covered for any condition. Remove another code from the excluded file. Add a new guideline regarding cancer genetic testing and delete the previous guideline on biomarker tests of cancer tissue. (These changes were NOT approved by HERC.)
- Add code for vagus nerve stimulators to the line for services that will not be covered for any condition.
- Edit the guideline note related to prostatic urethral life (this change was not approved by the HERC)
- Edit the guideline for spinal fusion surgery.
- Recommend straightforward guideline note changes

Item Tabled for a future meeting:

- Breast reduction for macromastia
- Single sided-deafness coverage for adults; cochlear implants for adults and children with single-sided deafness

Minutes
Value-based Benefits Subcommittee (VbBS)

Online meeting
March 9, 2023

Members Present: Holly Jo Hodges, MD, MBA, Chair; Brian Duty, MD, Vice-Chair; Kevin Olson, MD; Cris Pinzon, MPH, RN; Adriane Irwin, PharmD; David Saenger, MD.

Members Absent: Mike Collins; Kathryn Schabel, MD.

Staff Present: Ariel Smits, MD, MPH; Amy Cantor, MD, MPH; Jason Gingerich; Liz Walker, PhD, MPH; Michelle Hatfield.

Also Attending: Val King, MD, MPH & Rita Shiau (Center for Evidence-based Policy); Chris DeMars, Mina Colon & Kristen Darmody (Oregon Health Authority); Carl Stevens; Chris DeMars (Oregon Health Authority); Chris Potters (MCCFL); Cristyn Lauer; Deb Brugman; Jacob Gigliotti; Joan Sunderland; Joanna Roquel Wilson; Joel Stegen; Justin; Laura Briggs; Michelle Bach; Noel S; rebeccagale; Renee Doan (Care Oregon); Richard Bruno; sayj; Scott Haanstad; Sheila Robertson; Shimi Sharief; Siobhan Hess; Steven; Tim Barr.

Call to Order, Minutes Approval, Staff Report

The meeting was called to order at 8:35 am and roll was called. A quorum of members was present at the meeting. Minutes from the January 19, 2023 VbBS meeting were reviewed and approved with no modifications.

Jason Gingerich gave the staff report. He updated members on OHA leadership changes, gave an update on membership, and gave a legislative update. He also updated members on retreat plans.

Straightforward/Consent Agenda

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

Recommended Actions:

1) Modify GN118 as shown in Appendix A
2) Remove CPT 22858 Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure) from lines 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS, 530 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
3) Add CPT 22858 to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
4) Modify the GN173 entry on second artificial disc as shown in Appendix A
5) Place HCPCS S9563 (Home injectable therapy, immunotherapy, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem) on all lines with E&M codes
6) Place CPT 0380U (Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and cyp2d6 deletion or duplication analysis with reported genotype and phenotype) on the DIAGNOSTIC PROCEDURES file
7) Modify Diagnostic Guideline D1 as shown in Appendix A

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

Cancer genetic workgroup report

Discussion: Smits presented the meeting materials.

Public testimony:

Deb Brugman (a genetic counselor with Foundation Medicine) testified. She noted that covering this test will reduce health disparities between Medicaid and privately insured patients. She also noted that the liquid biopsy test PLA 0239U and the tissue test 0037U are different tests and have different clinical indications. The liquid test is used when biopsy is not possible due to the location of the cancer or patient comorbidities. However, at times the liquid test does not find the mutation. The tissue test is the gold standard test. There are Medicare NCDs (National Coverage Determinations) on both of these tests. It was clarified that both of these tests will be on the fee schedule and both would be governed by the proposed new guideline.

Discussion:
Pinzon noted that CLIA approval is not necessarily evidence based. Staff replied that this is at least a low bar and that some tests are not even CLIA approved. The group discussed whether 3 tests are sufficient, as limited in the guideline. Staff noted that additional tests can be approved if medically necessary. Olson noted that 3 tests is within the usual covered amount in current practice.

Hodges requested that the cancer genetic group and the GAP meet more frequently as these tests are coming out more frequently and CCOs need more expert support and input. Staff also expressed a need for regular meetings of these groups. Gingerich also informed the subcommittee that HERC staff is monitoring genetic testing codes for frequency of billing and bringing high use ones to HERC for discussion.

Recommended Actions:

1) Make code placement changes as shown in the table below

Code	Code Description	Current Placement	Recommended Placement
81210	BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)	229 MALIGNANT MELANOMA OF SKIN	DIAGNOSTIC PROCEDURES
81235	EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	262 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS	DIAGNOSTIC PROCEDURES
81275	KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; variants in exon 2 (eg, codons 12 and 13)	157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS	DIAGNOSTIC PROCEDURES
81518-81523	Oncology (breast), mRNA gene expression profiling	191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	DIAGNOSTIC PROCEDURES
0008M	Oncology (breast), mrna analysis of 58 genes using hybrid capture, on formalin-fixed paraffin-embedded (ffpe) tissue, prognostic algorithm reported as a risk score	191	DIAGNOSTIC PROCEDURES

S3854	Gene expression profiling panel for use in the management of breast cancer treatment	191 and 662	DIAGNOSTIC PROCEDURES

2) Modify the GN173 entry for HCPCS S3854 as shown in Appendix A
3) Advise HSD to remove CPT 0037U (Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden) from the EXCLUDED FILE and add to the DIAGNOSTIC PROCEDURES file
4) Add a new guideline regarding cancer genetic testing as shown in Appendix B
5) Delete GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

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

NOTE: The above recommendations were not approved at the March 2023 HERC meeting

Smoking cessation and elective surgery

Discussion: Smits reviewed the summary document.

Public testimony:

1) Richard Bruno, MD (family doctor at Central City Concern in Portland, a clinic with many homeless patients). The current policy unfairly affects low income/homeless/communities of color/patients with serious mental illness as these groups have a higher smoking rates. Their patients are being denied needed surgeries. Many surgical groups are requiring smoking cessation for more than 4 weeks, or no nicotine, which goes beyond the current OHP requirement. Pre-surgery smoking cessation should be voluntary rather than mandatory. If policy is continued, add further types of surgery to the non-elective list. Supports option 1 or 2.
2) Shimi Sharief, MD (medical director at CareOregon, CCO). Dr. Sharief is responsible for applying this guideline to CareOregon patients. Objective testing is not readily available and is another barrier. This guideline is unique to Oregon Medicaid. Structural racism and predatory marketing make lower income people more likely to smoke. This guideline has racist impacts. Impacts communities of color disproportionately. Supports option 1. She also stressed the importance of communication of any changes to providers across the state.
3) Joel Stegan (PA at Central City Concern). Mr. Stegan gave story of patient affecting this surgery: this patient cannot get colostomy reversal due to this policy. The impacts of not having surgery is not being taking into consideration. Patients are using illicit drugs due to chronic pain. Patients not able to work, etc. He is seeing the high costs of patients not getting care. Incidence of smoking much higher in the population served by this clinic and smoking cessation is harder for patients with unmet shelter needs or in

unsafe situations. Commercially insured or Medicare patients are not affected by this policy, which is unfair.

Discussion:
Saenger asked for data on the relative impact of smoking vs other conditions like diabetes on adverse surgical outcomes. Staff could not provide this specific information. He noted that there are also synergistic effects of multiple risk factors, like people with diabetes who smoke, on surgical outcomes. Smoking affects the outcomes of cardiac procedures that he performs. This type of guideline can help push patients to quit smoking.

The group discussed the evolution of HERC staff and CCO thinking regarding this guideline.

Hodges spoke as the CCO representative to the group. She felt that the current policy expressly allowed surgical consultation without smoking cessation. The current practice by provider groups denying this is unfortunate and unexpected. She noted that this policy was implemented due to evidence. She also noted that there is an exceptions process to allow people who cannot quit smoking to have surgery approved. She said many surgeons like this policy as it takes the onus off of them to require smoking cessation. Her CCO puts patients into case management when they are having trouble stopping smoking. This policy was never intended to create inequities or access issues.

Olson expressed concern that coverage of elective surgery for smokers would increase cost and expose patients to surgical complications. Access issues may be variable across the state and among different populations.

Pinzon raised concerns that the studies did not include houseless or mentally ill or other groups that are having a greater negative impact from this policy

Recommended Actions:

1) Change Ancillary Guideline A4 into a statement of intent as shown in Appendix B

MOTION: To approve the recommendations as presented. CARRIES 4-1 (Hodges voted Nay, Duty absent)

Single sided deafness coverage

Discussion: Smits reviewed the summary document.

Public testimony:

Scott Haanstad introduced himself as a person with single sided deafness and an OHP member. He provided written testimony as well. He has been appealing lack of coverage of single sided deafness by a CCO. He is an adult who needs cochlear implant to restore hearing in right ear, after being shot in the head. His quality of life has dramatically reduced. He has been hit by electric cars on multiple occasions due to not hearing them. There is a huge quality of life impact to restore bilateral hearing. He said he is an auditory learner and that bilateral hearing aids auditory learners and aids learning for people of all ages. Many private insurers pay for cochlear implants for unilateral deafness. He would like to see coverage for cochlear implants for single sided deafness.

The discussion among the subcommittee was that the members would like expert input on this topic. Staff were directed to reach out to experts and bring this topic back to a future meeting when an expert is able to attend.

Recommended Actions:

1) Tabled to a future meeting

Merging liver transplant lines

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

Recommended Actions:

1) Merge the following lines. The new line should contain all the ICD-10-CM codes contained in these lines and all the CPT/HCPCS codes on these lines.
    a. 162 BILIARY ATRESIA
    b. 241 ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM
    c. 263 CANCER OF LIVER OTHER THAN ANGIOSARCOMA
    d. 307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE
2) Title the new line: “CONDITIONS REQUIRING LIVER TRANSPLANT” Treatment: LIVER TRANSPLANT
3) Prioritize the new line as shown below

Line scoring:
Line XXX CONDITIONS REQUIRING LIVER TRANSPLANT
Scores in parentheses are for lines 162, 241, 263, 307
Category 6 (all lines are 6)
Impact on healthy life: 7 (7, 9, 7, 5)
Pain/Suffering: 4 (all lines are 4)

Population effects: 0
Vulnerable population: 0
Tertiary Prevention: 0 (1, 0, 0, 0)
Effectiveness: 3 (4, 3, 3, 3)
Need for services: 1.0 (all lines are 1.0)
Cost: 0.5 (1, 0, 1, 0)
Score: 1320
Line: 253

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

Store and forward codes

Discussion: Smits reviewed the summary document. Pinzon advocated for using these codes to improve access to SUD treatment and for chronic illness management. Olson noted that this type of care improves access, and is a low cost buffer for the added practice expenses from this type of care. The group approved staff option 2.

Recommended Actions:

1) Remove HCPCS G2010 and G2250 from line 662 and delete the GN173 entry for these codes
    a. Advise HSD to add G2010 and G2250 to the Ancillary file
2) Modify Ancillary guideline A5 as shown in appendix A

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

Vagus nerve stimulator for treatment resistant depression

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

Recommended Actions:

1) Add HCPCS K1020 (Non-invasive vagus nerve stimulator) to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Modify GN173 as shown in Appendix A

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

Biliary colic guideline revision

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

Recommended Actions:

1) Modify GN167 as shown in Appendix A

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

Trigger finger and trigger thumb

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

Recommended Actions:

1) Add ICD-10-CM M65.30 (Trigger finger, unspecified finger) and M65.33, M65.34 and M65.35 families (Trigger finger, specified fingers) to line 376 DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT and keep on line 590 SYNOVITIS AND TENOSYNOVITIS
2) Modify GN120 as shown in appendix A

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

Prostatic urethral lift guideline edits

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

Recommended Actions:

1) Modify GN145 as shown in Appendix A

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

NOTE: The above recommendations were not approved at the March 2023 HERC meeting

Breast reduction for macromastia

Discussion: Smits reviewed the summary document. It was noted that this is a commonly-requested surgery. The subcommittee felt that experts should be consulted before a decision is made. The topic was tabled until staff can contact experts to attend a future meeting for input and to answer questions.

Recommended Actions:

1) Tabled until a future meeting

Foraminal stenosis and spinal fusion

Discussion: Smits reviewed the summary document. Members generally supported staff option #2. Hodges raised concerns about some of the requirements in staff option #2. The guideline changes were modified to remove disc height loss and expectation that decompression alone would not be sufficient, as these criteria are not normally found in clinical notes.

Recommended Actions:

1) Modify GN37 as shown in Appendix A

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

Public Comment

No additional public comment was received.

Issues for next meeting

- Single sided deafness coverage for adults; cochlear implants for adults and children with single sided deafness
- Breast reduction for macromastia
- Note: due to lack of approval at the March 2023 HERC meeting, the following topics will be brought back to the next VBBS meeting:
    - Genetic testing for malignancies
    - Prostatic urethral lift guideline modifications

Next meeting

May 18, 2023, online.

Adjournment

The meeting adjourned at 12:45 PM.

Appendix A
Revised Guideline Notes

~~**ANCILLARY GUIDELINE A4, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES**~~

~~Surgical consultation is covered for patients who actively smoke and who are referred for surgical consultations; if elective surgery is recommended based on a consultation, the requirements of this guideline note apply.~~

~~Smoking cessation is required prior to elective surgical procedures for active tobacco users. Cessation is required for at least 4 weeks prior to the procedure and requires objective evidence of abstinence from smoking prior to the procedure.~~

~~Elective surgical procedures in this guideline are defined as surgical procedures which are flexible in their scheduling because they do not pose an imminent threat nor require immediate attention within 1 month. Procedures for contraceptive/sterilization purposes, procedures targeted to active cancers (i.e. when a delay in the procedure could lead to cancer progression), diagnostic procedures, and bloodless surgery (e.g., cataract surgery) are not subject to the limitations in this guideline note. This guideline applies regardless of procedure location and anesthesia type.~~

~~The well-studied tests for confirmation of smoking cessation include cotinine levels and exhaled carbon monoxide testing. However, cotinine levels may be positive in nicotine replacement therapy (NRT) users, smokeless tobacco and e-cigarette users (which are not contraindications to elective surgery coverage). In patients using nicotine products aside from combustible cigarettes the following alternatives to urine cotinine to demonstrate smoking cessation may be considered:~~

- ~~Exhaled carbon monoxide testing~~
- ~~Anabasine or anatabine testing (NRT or vaping)~~

~~Certain procedures, such as lung volume reduction surgery, bariatric surgery, erectile dysfunction surgery, and spinal fusion have 6 month tobacco abstinence requirements. See Guideline Notes 8, 100, 112 and 159.~~

ANCILLARY GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ONLINE/TELEPHONIC SERVICES

Telehealth services include a variety of health services provided by synchronous or asynchronous electronic communications, including secure electronic health portal, audio, or audio and video and clinician-to-clinician virtual consultations.

Criteria for coverage

The clinical value of the telehealth service delivered must reasonably approximate the clinical value of the equivalent services delivered in-person.

Coverage of telehealth services requires the same level of documentation, medical necessity, and coverage determinations as in-person visits.

Examples of covered telephone or online services include but are not limited to:

A) Extended counseling when person-to-person contact would involve an unwise delay or exposure to infectious disease.
B) Treatment of relapses that require significant investment of provider time and judgment.

C) Counseling and education for patients with complex chronic conditions.

Examples of non-covered telehealth services include but are not limited to:

A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Services which are part of care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).
F) Services which relate to or take place within the postoperative period of a procedure provided by the physician are not separately covered. (Such a service is considered part of the procedure and is not be billed separately.)

Codes eligible for telehealth delivery include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, 96156-96171, 96160, 96161, 97802-97804, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0438-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088. Additional codes are covered when otherwise appropriate according to this guideline note and other applicable coverage criteria.

The originating site code Q3014 is covered only when the patient is present in an appropriate health care setting and receiving services from a provider in another location.

Clinician to Patient Services billed using specified codes indicating telephone or online service delivery

Covered telephonic and online services include services related to evaluation, assessment and management as well as other technology-based services (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2012, G2061-G2063, G2251-G2252).

Covered telephone and online services billed using these codes do not include either of the following:

A) Services related to a service performed and billed by the physician or qualified health professional within the previous seven days, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
B) Services which result in the patient being seen within 24 hours or the next available appointment.

Clinician-to-Clinician Consultations (telephonic, online or using electronic health record)

Covered interprofessional consultations include consultations delivered online, through electronic health records or by telephone (CPT 99446-99449, 99451-99452).

Store and Forward

Store and forward codes (HCPCS G2010, G2250) are only covered when billed concurrently with a code that includes medical decision making and communication with the patient (for example, HCPCS G2012).

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.

D) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
   1) CPT 81228, 81229 and 81349, 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.

E) Related to preconception testing/carrier screening:

1) The following tests are covered for a pregnant patient or patient contemplating pregnancy as well as the male reproductive partner:
   a) Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:

i) Screening for cystic fibrosis carrier status (CPT 81220-81224)
ii) Screening for fragile X status (CPT 81243, 81244, 81171, 81172)
iii) Screening for spinal muscular atrophy (CPT 81329)
iv) Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier
status (CPT 81255). Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
v) Screening for hemoglobinopathies (CPT 83020, 83021)

b) Expanded carrier screening (CPT 81443): A genetic counseling/geneticist consultation must be offered prior to
ordering test and after test results are reported. Expanded carrier testing is ONLY covered when all of the
following are met:
i) the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater per ACMG Guideline (2021), AND
ii) the included genes have well-defined phenotype, AND
iii) the included genes result in conditions have a detrimental effect on quality of life OR cause cognitive or
physical impairment OR require surgical or medical intervention, AND
iv) the included genes result in conditions have an onset early in life, AND
v) the included genes result in conditions that must be diagnosable prenatally to inform antenatal
interventions and/or changes in delivery management and/or education of parents about special needs
after birth.

F) 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 ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS.
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) 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.

d) CPT 81225-81227, 81230-81231, 81418, 0380U (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 in the FDA labeling (e.g. psychiatric, anticoagulant, opioids).

e) CPT 81240, F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

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

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

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

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

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

k) CPT 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.

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

m) 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.

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

o) CPT 81425-81427, whole genome sequencing: testing is only covered when
   i) The testing is for a critically ill infant up to one year of age admitted to an inpatient intensive care unit (NICU/PICU) with a complex illness of unknown etiology; AND
   ii) Whole genome sequencing is recommended by a medical geneticist or other physician sub-specialist, including but not limited to a neonatologist or pediatric intensivist with expertise in the conditions and/or genetic disorder for which testing is being considered.

* 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.

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

Lines 346,530

Spine surgery is included on Line 346 only in the following circumstances:

A) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
   1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND either
      a) Has neurogenic claudication OR
      b) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
         i) Markedly abnormal reflexes
         ii) Segmental muscle weakness
         iii) Segmental sensory loss
         iv) EMG or NCV evidence of nerve root impingement
         v) Cauda equina syndrome
         vi) Neurogenic bowel or bladder
         vii) Long tract abnormalities

   Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 530.

B) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central or foraminal spinal stenosis only when one of the following conditions are met:
   1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR
   2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
   3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)
   4) Note: for foraminal stenosis, there must be MRI evidence of moderate or severe foraminal stenosis of the nerve root that correlates with the objective findings above

For all other indications, spine surgery is included on Line 530.

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

- local injections (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression
- radiofrequency denervation
- corticosteroid injections for cervical pain
- intradiscal injections, including platelet rich plasma, stem cells, methylene blue, or ozone

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 530. Diagnostic anesthetic injections for selective nerve root blocks are included on Line 530 for lumbar or sacral symptoms.

The development of this guideline note was informed by HERC coverage guidances on Percutaneous Interventions for Low Back Pain, Percutaneous Interventions for Cervical Spine Pain, Low Back Pain: Corticosteroid Injections and Low Back Pain: Minimally Invasive and Non-Cordicosteroid Percutaneous Interventions. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

GUIDELINE NOTE 118, SEPTOPLASTY

Lines 42,119,202,246,287,466,506,525,577

Septoplasty is included on these lines when

A) The septoplasty is done to address symptomatic septal deviation or deformity which
   1) Fails to respond to a minimum 6 week trial of conservative management (e.g. nasal corticosteroids, decongestants, antibiotics); AND
   2) Results in one or more of the following:

a. Persistent or recurrent epistaxis, OR
b. Documented recurrent sinusitis felt to be due to a deviated septum and the patient meets criteria for sinus surgery in Guideline Note 35, SINUS SURGERY; OR
c. Nasal obstruction with documented absence of other causes of obstruction likely to be responsible for the symptoms (for example, nasal polyps, tumor, etc.) [note: this indication is included only on Line 577; OR

B) Septoplasty is performed in association with cleft lip or cleft palate repair or repair of other congenital craniofacial anomalies; OR

C) Septoplasty is performed as part of a surgery for a neoplasm or facial trauma involving the nose.

Septoplasty is not covered for treatment of obstructive sleep apnea.

GUIDELINE NOTE 120, ~~PEDIATRIC~~ TRIGGER THUMB AND TRIGGER FINGER

Line 376,590

Trigger finger and trigger thumb (ICD-10-CM M65.3 family) are included on line 376 only when there is documented interference with function of the hand. Up to 3 steroid injections are covered per digit.

Surgery is limited to

1) open surgical procedures under local anesthesia; AND
2) only after at least one steroid injection or a minimum of 3 weeks of splinting has been tried and the triggering persists or recurs; OR
3) the patient is diabetic; OR
4) the finger is permanently locked in the palm; OR
5) the patient is a child up to age 21 who has a trigger thumb that does not spontaneously resolve within 48 months of diagnosis. Immediate surgery may be considered for bilateral trigger thumb or trigger thumb with locking symptoms in children.

Otherwise trigger finger and trigger thumb are included on line 590.

NOTE: The guideline note changes below were not approved at the March 2023 HERC meeting

GUIDELINE NOTE 145, TREATMENTS FOR BENIGN PROSTATE ENLARGEMENT WITH LOWER URINARY TRACT SYMPTOMS

Line 327

For men with lower urinary tract symptoms (LUTS) due to benign prostate hyperplasia (BPH), surgical procedures are included on this line for patients with one of the following:

A) Refractory urinary retention; OR
B) Recurrent urinary tract infections due to BPH; OR
C) Recurrent bladder stones or gross hematuria due to BPH; OR
D) Severe symptoms (International Prostate Symptom Score (IPSS) of 20-35) in patients who are not candidates for drug treatment due to intolerable side effects or have failed ~~combination~~

~~therapy with an alpha-blocker and 5-alpha reductase inhibitor~~ a minimum of a 3-month trial of at least one standard BPH medication therapy ~~for at least 3 months~~.

Prostatic urethral lift procedures (CPT 52441, 52442, HCPCS C9739, C9740) are included on Line 327 when the following criteria are met:

- Age 45 ~~50~~ or older
- Estimated prostate volume < 100 ~~80~~ cc
- IPSS ≥ 13
- ~~No obstructive median lobe of the prostate identified on cystoscopy at the time of the procedure~~
- Not a candidate for drug treatment due to intolerable side effects or have failed a minimum of a 3-month trial of at least one standard BPH medication therapy.

The following interventions for benign prostate enlargement are not included on Line 327 due to lack of evidence of effectiveness:

- Botulinum toxin
- HIFU (High Intensity Focused Ultrasound)
- TEAP (Transurethral Ethanol Ablation of the Prostate)
- Laser coagulation (for example, VLAP/ILC)
- Prostatic artery embolization

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

NOTE: The guideline note changes below were not approved at the March 2023 HERC meeting

~~GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE~~

~~*Lines 157,184,191,229,262,271,329*~~

~~The use of tissue of origin testing (e.g. CPT 81504) is included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.~~

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

- ~~Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.~~
- ~~EndoPredict (CPT 81522) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.~~
- ~~MammaPrint (using CPT 81521, 81523 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.~~

Appendix A
Revised Guideline Notes

~~For early stage breast cancer that is estrogen receptor positive, HER2 negative, and either lymph node negative or lymph node positive with 1-3 involved nodes, Breast Cancer Index (CPT 81518) is included on Line 191 when the patient is willing to use the test results in a shared decision-making process regarding prolonged adjuvant endocrine therapy.~~

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

~~Oncotype DX Breast DCIS Score (CPT 81479) is included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.~~

~~For melanoma, BRAF gene mutation testing (CPT 81210) is included on Line 229. DecisionDx-Melanoma (CPT 81529) is included on Line 662.~~

~~For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on Line 262 only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on this line.~~

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

~~For bladder cancer, Urovysion testing is included on Line 662.~~

~~For prostate cancer, Oncotype DX Genomic Prostate Score and Prolaris Score Assay (CPT 81541) are included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.~~

~~For thyroid cancer, Afirma gene expression classifier (CPT 81546) is included on Line 662.~~

~~The development of this guideline note was informed by a HERC coverage guidance on Biomarkers Tests of Cancer Tissue for Prognosis and Potential Response to Treatment; the prostate-related portion of that coverage guidance was superseded by a Coverage Guidance on Gene Expression Profiling for Prostate Cancer. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx~~

GUIDELINE NOTE 167, CHOLECYSTECTOMY FOR CHOLECYSTITIS AND BILIARY COLIC

Lines 55,641

Cholecystectomy for cholecystitis and biliary colic are including on Line 55 when meeting the following criteria:

A) For cholecystitis, with either:
   1) The presence of right upper quadrant abdominal pain, mass, tenderness or a positive Murphy's sign, AND

2) Evidence of inflammation (e.g. fever, elevated white blood cell count, elevated C reactive protein) OR
3) Ultrasound findings characteristic of acute cholecystitis or non-visualization of the gall bladder on oral cholecystegram or HIDA scan, or gallbladder ejection fraction of < 35%.

B) For biliary colic ~~(i.e. documented clinical encounter for right upper quadrant or epigastric pain with gallstones seen on imaging during each episode)~~ without evidence of cholecystitis or other complications ~~is included on Line 55~~ only when
1) Recurrent (i.e. 2 or more ~~episodes~~ documented clinical encounters with an exam consistent with gallstone induced pain in a one year period with at least one imaging study demonstrating gallstones) OR
2) A single episode in a patient at high risk for complications with emergent cholecystitis (e.g. immunocompromised patients, morbidly obese patients, diabetic patients) OR
3) When any of the following are present: elevated pancreatic enzymes, elevated liver enzymes or dilated common bile duct on ultrasound.

Otherwise, biliary colic is included on Line 641.

ICD-10-CM K82.8 (Other specified diseases of gallbladder) is included on Line 55 when the patient has porcelain gallbladder or gallbladder dyskinesia with a gallbladder ejection fraction <35%. Otherwise, K82.8 is included on Line 641

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
~~G2010, G2250~~	~~Remote assessment of recorded video and/or images~~	~~Clinical value not established~~	~~January 2021~~
K1020	Non-invasive vagus nerve stimulator	Insufficient evidence of effectiveness	March 2023
22858, 22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, cervical/lumbar	Insufficient evidence of effectiveness	November 2022

Appendix A
Revised Guideline Notes

Procedure Code	Intervention Description	Rationale	Last Review
Breast Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999~~,~~ ~~S3854~~)	Mammostrat Oncotype DX Breast DCIS Score IHC4 **NOTE:** This guideline note entry change was not approved at the March 2023 HERC meeting	Insufficient evidence of effectiveness	May, 2018 Coverage guidance

Appendix B
NEW GUIDELINE NOTES

NOTE: The guideline note below was not approved at the March 2023 HERC meeting

DIAGNOSTIC GUIDELINE DX, GENETIC TESTING OF MALIGNANCIES

A) Genetic tests on tumor tissue are covered as diagnostic, unless they are listed in guideline note 173 INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS. To be covered, cancer genetic tests must be a CLIA-approved test or panel of tests that will affect clinical decision making after a biopsy proven diagnosis of malignancy. Examples of covered genetic panels include Foundation Medicine FoundationOneCDX (PLA 0037U), Knight Diagnostic Laboratories GeneTrails (CPT 81455) and Caris Life Sciences Molecular Intelligence (CPT 81479). A single CPT or HCPCS code is covered for each multigene panel performed on tumor tissue. Additional codes for individual genes and for molecular pathology procedures CPT 81400-81408 are excluded from coverage when the multigene panel is covered under the appropriate CPT or HCPCS code.

B) Such tests should have one of the following impacts on medical decision making:
   1) find a mutation for which there is an available therapy that is effective in slowing the growth of the cancer, OR
   2) exclude the use of ineffective therapies, OR
   3) select alternative treatment modalities, OR
   4) determine suitability for directing patients toward promising investigational therapies, OR
   5) establish a definitive diagnosis when other diagnostic approaches yield ambiguous results, OR
   6) find a mutation that indicates prognosis AND influences treatment unrelated to targeted therapies, such as decisions around bone marrow transplantation, high-intensity or low-intensity chemotherapy or radiation therapy, surgery, or palliation

C) Repeat testing may be required in the setting of patients who have clinically progressed per standardized professional guidelines after therapy. Coverage in this situation is limited to 3 times per primary malignancy unless there is indication for additional testing after individualized review of medical necessity.

STATEMENT OF INTENT X: SMOKING CESSATION AND ELECTIVE SURGERGICAL PROCEDURES

Tobacco smoking has been shown to increase the risk of surgical complications. It is the intent of the Commission that current tobacco smokers should be given access to appropriate smoking cessation therapy prior to elective surgical procedures. Pharmacotherapy (including varenicline, buproprion and all five FDA-approved forms of nicotine-replacement therapy) and behavioral counseling are included on line 5 TOBACCO DEPENDENCE.