Health Evidence Review Commission

November 8, 2018

2:00 PM - 3:30 PM

Clackamas Community College
Wilsonville Training Center, Room 111-112
29373 SW Town Center Loop E, Wilsonville, Oregon, 97070

Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION

Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
November 8, 2018
2:00-3:30 pm
(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	2:00 PM	Call to order	Kevin Olson	
2	2:05 PM	Approval of minutes (10/4/18)	Kevin Olson	X
3	2:10 PM	Director's report	Darren Coffman	
4	2:15 PM	Value-based Benefits Subcommittee report	Ariel Smits Cat Livingston	X
5	2:45 PM	Potential New Multisector Intervention Topics • Community health workers • Multisector interventions to reduce the frequency of asthma exacerbations	Cat Livingston	X
6	3:00 PM	Planned Out-of-Hospital Birth • Scoping statement • Rescan of literature for potential re-review	Cat Livingston Valerie King	X
7	3:20 PM	Priorities for evidence-based reports	Cat Livingston Jason Gingerich	X
8	3:25 PM	Next steps • Schedule next meeting – January 17, 2019 Location TBD	Kevin Olson	X
9	3:30 PM	Adjournment	Kevin Olson	

Note: Public comment will be taken on each topic per HERC policy at the time at which that topic is discussed.

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
October 4, 2018

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, Vice-Chair; Mark Gibson; Leda Garside, RN, MBA (by phone, listen only); Angela Senders, ND; Gary Allen, DMD; Devan Kansagara, MD; Lynnea Lindsey, PhD (by phone); Leslie Sutton; Adriane Irwin, PharmD.; Michael Adler, MD; Susan Williams, MD (by phone); Kevin Cuccaro, DO.

Members Absent:

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

Also Attending: Adam Obley, MD, MPH (OHSU Center for Evidence-based Policy); Laurel Soot, MD (Providence Health Plan); Georgia Smithee (Legal Aid Services of OR).

Call to Order

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

Minutes Approval

MOTION: To approve the minutes of the 8/9/2018 meeting as presented. CARRIES 12-0. (Absent: Garside)

Director's Report

Membership:
Coffman welcomed newly appointed Dr. Kevin Cuccaro, a doctor of osteopathy (DO), to the Commission. Cuccaro is vice-chair of the Pain Management Commission and serves on the Chronic Pain Task Force. Cuccaro gave a brief overview of his professional background, which focuses on pain. Each commissioner gave a brief statement of their background and current positions.

Coffman discussed a subcommittee assignment for Cuccaro, stating the previous DOs served on the Heath Technology Assessment Subcommittee.

MOTION: To appoint Cuccaro to the Health Technology Assessment Subcommittee. Carries: 12-0 (Absent: Garside)

HB 3391:
Livingston reminded the Commission they had made four recommendations to the Legislature to update the Reproductive Health Equity Act. One thing was left outstanding: to edit some language making sure the required covered services were evidence-based, so staff created some modified language for the final report that is due November 1, 2018.

Coffman added he still has not gotten clarity from the Department of Consumer and Business Services (DCBS) regarding a planned bulletin emphasizing post-partem LARCs being covered under this statute. Staff have draft language in the report that may be modified at the last minute if the DCBS bulletin adequately covers the topic.

Sutton asked if any legislative follow up was anticipated, as in a hearing, or is it just a submission. Coffman said all they have been asked to do is submit the report but would be ready if asked for more.

HB 4020:
Gingerich said the HTAS met on 9/27/18 and had an orientation to the topic of extended stay centers. Staff are working through the contracting process with a vendor and hope to have a contract complete soon so work can begin. They hope to have a draft report, that will have been out for public comment by the Commission's March meeting, with a final report planned for review in May. The Legislature will receive a progress report after the March meeting. HTAS has several surgeons on the subcommittee and will reach out to other specialists as needed.

Chronic Pain Task Force update:
Smits said the Task Force met recently, in September. It was mostly an information gathering meeting, hearing from experts and a lot of public testimony. The Task Force will come up with a new proposal to be discussed at their December meeting. They will likely bring a recommendation back to VbBS in January and to HERC in March.

Next Generation Sequencing Tests for Tumors of Diverse Histology:
Coffman said this coverage guidance topic was tabled at the 9/27/2018 HTAS meeting until new evidence emerges that is expected next year.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials 52-176

Ariel Smits reported the VbBS met earlier in the day, 10/4/2018. She and Livingston summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (effective 1/1/2019)

- Delete the procedure codes for cardiac magnetic resonance imaging from the Prioritized List and recommended that HSD place on the Diagnostic Procedures File
- Delete the procedure codes for serum and skin allergy testing from the uncovered mild eczema line
- Add codes for postpartum depression screening to the preventive services line
- Add the code for processing of human donor breast milk to several covered lines
- Add the procedure code for ultrasound guided focused ultrasound (MRgFUS) for essential tremor to an uncovered line

- Add a procedure code for treatment of humeral damage from recurrent shoulder dislocation to a covered line
- Add the codes for CardioMEMS™ for heart failure monitoring to an uncovered line
- Various straightforward coding changes were made

RECOMMENDED GUIDELINE CHANGES (effective 1/1/2019)

- Add a new guideline regarding brow ptosis
- Edit the guideline regarding blepharoplasty to help clarify its meaning
- Add a new guideline for medically indicated circumcision
- Add a new guideline on postpartum depression screening
- Add a new diagnostic guideline for cardiac magnetic resonance imaging
- Add a new guideline on human donor breast milk in high-risk infants, although further modifications are expected
    - Adler asked about donor breast milk costs. Livingston explained the NW Mother's Milk Bank, a non-profit organization, processes the donated milk, pasteurizes, tests and packages it. The cost is ~$4/ounce. He asked if private payers cover for it. Smits explained that NICUs cover it as part of the DRG up to a certain point, then after that the coverage is variable. Livingston said 7-8 state Medicaid agencies pay for it, but she did not do an exhaustive look at commercial payers.
    - Sutton said her son was born with a blood incompatibility type between them and ended up with extreme jaundice very quickly and was getting NICU services. They gave him donor breast milk at 12 hours old. She continued to use donor breast milk at home even though her private insurance didn't cover it. She ended up being a milk bank donor.
- Add a new guideline regarding testosterone therapy
- Various straightforward guideline changes were made

2020 BIENNIAL REVIEW (effective 1/1/2020)

- Reprioritize the redundant prepuce line (elective neonatal circumcision); however, the new priority line remains below the current funding line

MOTION: To accept the VbBS recommendations on *Prioritized List changes* not related to coverage guidances, as stated. See the VbBS minutes of 10/4/2018 for a full description. Carries: 12-0. *(Absent: Garside)*

Coverage Guidance Topic: Single Fraction Radiotherapy for Palliation of Bone Metastases

Meeting materials, pages 127-171

Obley presented an overview of the evidence. He then read through the remainder of the GRADE Table (page 149) as well as the proposed coverage guidance from HTAS.

Cancer that has metastasized to the bones can rarely be cured, but can be treated to slow the cancer's growth and reduce pain. Effects of bone metastases on patients' quality of life. Single fraction radiotherapy provides a higher dosage at a single visit as opposed to lower doses at multiple visits with similar outcomes, so is less costly and more convenient for the patient.

There was minimal discussion.

Lindsey noticed E&M codes were used on the guideline inappropriately. She offered her help to find the correct codes.

MOTION: To approve the proposed coverage guidance for* Single Fraction Radiotherapy for Palliation of Bone Metastases *as presented. Carries 12-0. *(Absent: Garside)*

MOTION: To approve the amended guidelines for the Prioritized List as proposed. Carries 12-0. *(Absent: Garside)*

Approved Coverage Guidance:

HERC Coverage Guidance

Single fraction radiotherapy for palliation of bone metastases is recommended for coverage *(strong recommendation)*. Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).

Changes for the Prioritized List of Health Services:

1) Revise Guideline Note 12 to read as follows:

GUIDELINE NOTE 12, PATIENT-CENTERED CARE OF ADVANCED CANCER
Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall heath, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see STATEMENT OF INTENT 1, PALLIATIVE CARE).

Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with

A) Severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy; OR

B) A continued decline in spite of best available therapy with a non-reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.

Treatments with intent to relieve symptoms or improve quality of life are covered as defined in STATEMENT OF INTENT 1, PALLIATIVE CARE.
Examples include:

A) Single-dose radiation therapy for painful bone metastases with the intent to relieve pain and improve quality of life. Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).
B) Surgical decompression for malignant bowel obstruction.
C) Medication therapy such as chemotherapy with low toxicity/low side effect agents with the goal to decrease pain from bulky disease or other identified complications. Cost of chemotherapy and alternative medication(s) should also be considered.

To qualify for treatment coverage, the cancer patient must have a documented discussion about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. This discussion may take place with the patient's oncologist, primary care provider, or other health care provider, but preferably in a collaborative interdisciplinary care coordination discussion. Treatment must be provided via evidence-driven pathways (such as NCCN, ASCO, ASH, ASBMT, or NIH Guidelines) when available.

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

2) Revise Statement of Intent 1 to read as follows:

STATEMENT OF INTENT 1: PALLIATIVE CARE
It is the intent of the Commission that palliative care services are covered for patients with a life-threatening or serious progressive illness to alleviate symptoms and improve quality of life.

Palliative care services should include culturally appropriate discussions and medical decision making aligned with patient's personal goals of therapy, assessment of symptom burden, assistance with advance care planning, care coordination, emotional, psychosocial and spiritual support for patients and their families. Palliative care services may be provided concurrently with life prolonging/curative treatments.

Some examples of services associated with an encounter for palliative care (ICD-10 Z51.5) that should be available to patients without regard to Prioritized List line placement:

A) Inpatient palliative care consultations
    1) Hospital Care E&M (CPT 99218-99233)
B) Outpatient palliative care consultations provided in either the office or home setting
    1) E&M Services (CPT 99201-99215)
    2) Transitional Care Management Services (CPT 99495-6)
    3) Advance Care Planning (CPT 99497-8)
    4) Chronic Care Management (CPT 99487-99490)
C) Psychological support and grief counseling (CPT 99201-99215)
D) Medical equipment and supplies for the management of symptomatic complications or support activities of daily living

E) Medications or acupuncture to reduce pain and symptom burden
F) Surgical procedures or therapeutic interventions (for example, palliative radiation therapy) to relieve pain or symptom burden

Other services associated with palliative care includes:

A) Social Work
B) Clinical Chaplain/ Spiritual Care
C) Care Coordination

It is NOT the intent of the Commission that coverage for palliative care encompasses those treatments that seek to prolong life despite substantial burdens of treatment and limited chance of benefit. See Guideline Note 12 PATIENT-CENTERED CARE OF ADVANCED CANCER.

3) No change in Prioritized List placement of radiation therapy services is recommended based on this coverage guidance.

Coverage Guidance Topic: CardioMEMS for Monitoring of Heart Failure

Meeting materials, pages 172-227

Obley presented an overview of the evidence. Livingston then read through the remainder of the GRADE Table (page 198) as well as the proposed coverage guidance from EbGS.

Heart failure occurs when the heart muscle is damaged and cannot meet the body's needs for blood and oxygen. Nearly 6 million adults in the U.S. have heart failure. CardioMEMS are designed to monitor heart failure remotely and early indications are promising that it can have a benefit; however, only one study has been conducted with high potential for bias, and since the device is invasive and more costly than the alternative of medical management, further evidence is needed before recommending these devices for coverage.

Olson asked if there are other studies coming out in the near future. Obley said there is a study of 3,600 participants expected to be completed in 2023.

There was minimal discussion.

MOTION: To approve the proposed coverage guidance for* CardioMEMS for Monitoring of Heart Failure *as presented. Carries 12-0. *(Absent: Garside)*

MOTION: To approve the proposed changes for the Prioritized List as proposed. Carries 12-0. *(Absent: Garside)*

Approved Coverage Guidance:

HERC Coverage Guidance

CardioMEMS™ is not recommended for coverage for heart failure monitoring *(weak recommendation).*

Changes for the Prioritized List of Health Services:

1) Place HCPCS code C2624 (Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components) on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Place HCPCS code C9741 (Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report) on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS, remove from the Diagnostic Procedures File

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
C2624, C9741	CardioMEMS™ – Implantable wireless pulmonary artery pressure monitor for heart failure monitoring	Insufficient evidence of effectiveness	October, 2018 Coverage guidance

Public Comment

There was no public comment at this time.

Adjournment

Meeting adjourned at 3:05 pm. Next meeting on Thursday, November 8, 2018 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon. The start and end times for this meeting is to be determined as it is expected to be of shorter duration than normal.

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on October 4, 2018

For specific coding recommendations and guideline wording, please see the text of the 10/4/2018 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 1/1/2019)

- Delete the procedure codes for cardiac magnetic resonance imaging from the Prioritized List and recommended that HSD place on the Diagnostic Procedures File
- Delete the procedure codes for serum and skin allergy testing from the uncovered mild eczema line
- Add codes for postpartum depression screening to the preventive services line
- Add the code for processing of human donor breast milk to several covered lines
- Add the procedure code for ultrasound guided focused ultrasound (MRgFUS) for essential tremor to an uncovered line
- Add a procedure code for treatment of humeral damage from recurrent shoulder dislocation to a covered line
- Add the codes for CardioMEMS™ for Heart Failure Monitoring to an uncovered line
- Various straightforward coding changes were made

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- A new guideline regarding F39 (unspecified mood disorder) was considered but not adopted
- Allergy testing (serum or skin) was not added to the covered line containing severe eczema

RECOMMENDED GUIDELINE CHANGES (effective 1/1/2019)

- Add a new guideline regarding brow ptosis
- Edit the guideline regarding blepharoplasty to help clarify its meaning
- Add a new guideline for medically indicated circumcision
- Add a new guideline on postpartum depression screening
- Add a new diagnostic guideline for cardiac magnetic resonance imaging
- Add a new guideline on human donor breast milk in high-risk infants, although further modifications are expected
- Add a new guideline regarding testosterone therapy
- Various straightforward guideline changes were made

2020 BIENNIAL REVIEW (effective 1/1/2020)

- Reprioritize the redundant prepuce line (elective neonatal circumcision); however, the new priority line remains below the current funding line

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
October 4, 2018
8:30 AM – 1:00 PM

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

Members Absent: None.

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

Also Attending: Renae Wentz, MD, MPH (Oregon Health Authority, via phone); Andy Kranenburg MD (via phone); Nan Dahlquist (Westside Breastfeeding); Lesley Mondeaux, Joanne Ransom, and Emily Hopper (Northwest Mothers Milk Bank); Julie Kasler (ThermoFischer Scientific); Ann Loeffler, MD (Randall Children's Hospital); Anna Daud (NICU Families NW); Georgia Snuther (Legal Aid Services of Oregon).

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

  The meeting was called to order at 8:30 am and roll was called. Minutes from the August 9, 2018 VbBS meeting were reviewed and approved.

  Smits updated the group on the Chronic Pain Task Force work. Coffman updated the group on HERC membership changes, noting that Williams' term is expiring at the end of the year.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) Add ICD-10 H93.8X (Other specified disorders of ear) to line 444 HEARING LOSS - OVER AGE OF FIVE
  2) Add Z87.891 (Personal history of nicotine dependence) to Line 3 PREVENTIVE SERVICES
  3) Add 58541-58544 (Laparoscopy, surgical, supracervical hysterectomy) to line 395 ENDOMETRIOSIS AND ADENOMYOSIS
  4) Add 33724 (Repair of isolated partial anomalous pulmonary venous return (eg, Scimitar Syndrome)) to line 105 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES
  5) Add ICD-10 L55.2 (Sunburn of third degree) to the new line 57 SEVERE BURNS effective Jan 1, 2020; remove from line 181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE) at that time
  6) Remove ICD-10 L73.0 (Acne keloid) from line 373 ACNE CONGLOBATA (SEVERE CYSTIC ACNE)
  7) Modify GN~~1~~65 as shown in Appendix A
  8) Add GN166 BREAST REDUCTION SURGERY FOR MACROMASTIA to line 401 CONDITIONS OF THE BACK AND SPINE

9) Remove S86.11, S86.21, S86.31, S86.81, S86.91 (Strain of muscle(s) and tendon(s) of various muscle groups at lower leg level) from line 430 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT and add to line 376 DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
10) Add CPT 53405 (Urethroplasty; second stage (formation of urethra), including urinary diversion) and 53410 (Urethroplasty, 1-stage reconstruction of male anterior urethra) to line 312 GENDER DYSPHORIA/TRANSEXUALISM

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 7-0.

- **Topic: F39 unspecified mood disorder**

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

Recommended Actions:
1) No recommended changes to the Prioritized List

- **Topic: Brow ptosis repair**

Discussion: Smits introduced the summary document with two possible staff recommended options. Option 2 was felt to be too vague. Option 1 was thought to give the CCOs the ability to require ophthalmologists to give numbers. Option 2 might allow subjective complaints to get approval without objective documentation. CMS guidelines are basically the same as Option 1. Option 1 was decided to be the preferred option and was approved.

Recommended Actions:
1) Place H57.81 (Brow ptosis) on line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN for congenital brow ptosis and on lines 469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT/Treatment: PTOSIS REPAIR and line 652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY for acquired brow ptosis
2) Remove ICD-10 Q10.0 (Congenital ptosis) from line 469 and leave only on line 393
3) Adopt a new guideline as shown in Appendix B

MOTION: To recommend the code and guideline note changes as presented in Option 1. CARRIES 7-0.

- **Topic: Blepharoplasty**

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

Recommended Actions:
1) Modify GN 130 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 7-0.

- **Topic: 2020 Biennial Review: Neonatal circumcision**

Discussion: Smits reviewed the summary document. There was discussion about how well neonatal circumcision reduced UTI rates. Smits noted that vesicoureteral reflux was reported to be approximately 1% of all children, and this would be covered in the medical indications for circumcision proposed changes for later discussion. This group of children probably experienced a large portion of the overall rate of childhood UTI.

There was discussion about the need for service. If social/religious reasons were taken into account, the need for service would probably be in the 0.3-0.4 range. The staff proposed 0.1 number was felt to reflect the percent of parents who would elect circumcision solely for prevention of UTI and other preventive reasons.

Recommended Actions:

1) Rescore the redundant prepuce line as shown below (current scores/line in parentheses):

Line 623 REDUNDANT PREPUCE
Category: 7 (9)
HL: 0 (0)
Suffering: 0 (0)
Population effects: 1 (0)
Vulnerable population: 0 (0)
Tertiary prevention: 2 (0)
Effectiveness: 5 (5)
Need for service: 0.1 (0)
Net cost: 4 (2)
Score: 30 (0)
Approximate line placement: 569 (623)

MOTION: To approve the recommended line rescoring as presented. CARRIES 6-0. *(Absent: Saboe)*

- **Topic: Medical indications for circumcision**

Discussion: Smits reviewed the summary document. There were two friendly staff amendments to the proposed guideline: 1) adding line 21 which includes vesicoureteral reflux and 2) adding CPT 54160 to the guideline. There was a discussion about how to make clear that balanoposthitis was covered, but not balanitis. Smits noted that Dr. Skoog, the pediatric urology expert consulted on this topic, recommended coverage for balanitis. It was also noted that there was a sentence at the end of the guideline excluded balanitis. The group feel that the wording "not balanitits" should be added to item #2 to be completely clear on intent. There was also discussion about not covering vesicoureteral reflux of grade 1, as this usually spontaneously regresses. Wording to this effect was added to the guideline.

Recommended Actions:

1) A new guideline regarding medical indications for circumcision was added as shown in Appendix B

MOTION: To approve the new guideline as amended. CARRIES 7-0.

- **Topic: Postpartum depression screening**

Discussion: Livingston presented the issue summary. Holly Jo raised the issue of the G codes and whether they should be included. Coffman and others discussed that these appear to be related to quality metrics and may be informational, so are not separately reimbursed. Livingston discussed that there may be interest in having clarity in the specific recommended codes for this as part of the implementation and education effort to providers. Members discussed that there are significant efforts to increase postpartum depression screening across provider groups (pediatricians, family physicians, and obstetricians/gynecologists).

Irwin raised questions about some logistical issues that may be involved. For example, if the mother is screened during a child's health visit and is in a different health system than the child, how would the translation of that medical information happen? How does this take into account autonomy, consent, and privacy? Concerns were raised about whether those connections to care were established for women identified with postpartum depression. Members agreed that processes need to be in place. An example was given about SBIRT, and how that work might similarly help with implementation of this benefit. Despite the logistical challenges, Hodges discussed that risks raised during this discussion are important, but they are a risk payers are willing to take, because the benefit to the child is so significant if maternal depression is identified and effectively treated.

The group discussed other recommendations including the payment amount. Members thought it was reasonable to recommend HSD review the payment amount.

Recommended Actions:

1. Add Z13.32 Encounter for screening for maternal depression to Line 3 (per BHAP recommendations), although pairing with this would not be necessary as any well child or postpartum visit would be appropriate pairing
2. Add 96160, 96161, and 96127 to Line 3 (and continue to have them included in the Diagnostic Procedures File as well)
3. Add a guideline as shown in Appendix B
4. HSD may need to clarify that this code can be billed in addition to other screens such as developmental screening
5. Recommend to HSD to review the reimbursement rate for these codes. Other states are reimbursing between $8.67 and $15.60. The current reimbursement rates for FFS are $3.23.
6. Other parts of OHA will need to work with partners on promoting the uptake of postpartum depression screening and additional resources to ensure adequacy of follow-up and access to appropriate treatment. There are excellent examples from other states.

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

- **Topic: Cardiac MRI**

  Discussion: Smits reviewed the summary document. The VbBS recommended adopting the proposed guideline on cardiac MRI as well as the staff recommendation to change cardiac MRI to a diagnostic test.

  Recommended Actions:
  1) Remove CPT 75557-75565 (Cardiac magnetic resonance imaging) from all current lines on the Prioritized List
  2) Advise HSD to add CPT 75557-75565 to the Diagnostic Procedures File
  3) Adopt a new diagnostic guideline as shown in Appendix A

  MOTION: To approve the coding and guideline note as presented. CARRIES 7-0.

- **Topic: SI joint dysfunction prioritization**

  Discussion: Smits reviewed the summary document. Kranenburg gave a presentation in which he outlined his suggested scoring numbers for SI joint dysfunction, with supporting literature. Kranenburg argued that SI joint dysfunction is inappropriately classified as a back condition when it should be categorized as a hip or pelvic condition. The guideline restricting coverage of surgery for back conditions to those with abnormal neurological findings is not appropriate for SI joint conditions. He suggested moving SI joint dysfunction to a line with pelvic conditions. His suggested scoring including making tertiary prevention 1 (not 0 as in slides); increase the scores for healthy life years and suffering as well as effectiveness. Healthy life years should increase to 6 due to the high disability scores. Oswestry Disability Index scores averaged 60 (0-100 scale) in studies prior to surgery, with 30 or greater considered disabled. After surgery, ODI on average was <30. Suffering should increase to 5 as SI joint pain results in high pain. Effectiveness is around 90% and this score should increase (he suggested 5 but would accept 4) as there is better evidence for SI joint fusion than most orthopedic procedures. Multiple RCTs published with patient satisfaction >90%. Patient satisfaction with non-surgical treatment is <20%.

  The discussion amongst VbBS members centered on the need to re-look at the published RCTs to look at the reported effectiveness. Smits briefly reviewed the evidence review on SI joint fusion done in 2016, in which most of the RCTs were noted to be heavily conflicted. Kranenberg noted that a non-industry funded RCT is not likely to be feasible due to lack of funding.

  Saboe noted that SI joint fusion requires a high level of evidence of effectiveness as there is high level of adverse events with this procedure. He disagrees that SI joint is not part of spine and back and felt that it was appropriate to keep on the back lines. SI joint dysfunction can cause referred pain mimicking a radiculopathy. He also noted that the contralateral SI joint can become symptomatic after fusion.

  Saboe asked about the rate of later required fusion of the contralateral SI joint. Kranenburg reported that the rate was approximately 20%. Saboe also expressed concerned with correlation with degenerative changes in lumbrosacral joint. Kranenburg said that based on biomechanics studies such degenerative changes were not expected.

Saboe asked if any new literature regarding SI joint fusion had been submitted. Smits replied that no literature meeting HERC criteria had been submitted since the 2016 review. Gibson requested that a new review of the literature be done to supplement the 2016 review and brought back to VbBS for evaluation.

Olson requested that scoring information for conditions with similar values for health life years, etc. as proposed by Dr. Kranenburg (e.g. sickle cell, or rheumatoid arthritis) be added to the scoring comparison to help put the scores in context.

There was a request for information on the overall incidence of SI joint dysfunction, as well as the incidence of severe enough dysfunction to warrant surgical intervention.

There was a discussion about whether SI joint fusion should be referred to HTAS for consideration for a coverage guidance; however, the group felt the question was more about the prioritization of SI joint dysfunction, which is a VbBS topic.

Recommended Actions:

1) HERC staff to conduct an updated literature review on SI joint fusion, summarize the 2016 review on SI joint fusion, obtain information on the prevalence of severe SI joint dysfunction, and update the comparative line scoring proposals with similarly scored conditions. This updated review will be brought back to a future VbBS meeting.

- **Topic: Human donor breast milk**

Discussion: Livingston reviewed the information presented in the meeting materials.

Olson clarified the difference between the two options presented. Option 2 would only allow breast milk for infants with low birth weight; Option 1 would allow breast milk for other conditions. Smits asked to clarify Option 1; does the patient need to have low birth weight and other conditions, or do the other conditions apply independently? Livingston suggested adding an "or" to clarify that they are independent of birth weight.

Hodges asked for clarification of the levels of evidence supporting each option. Livingston said the best evidence supports human milk for infants under 1500 grams during hospitalization to prevent necrotizing enterocolitis. Both these options would provide human milk outside the hospital. Option 1 would add other conditions without low birth weight. Hodges said a low birth weight infant might spend 3 to 6 months in the NICU.

Renae Wentz expressed concern about the mention of intolerance to multiple formulas and risk for bronchopulmonary dysplasia, as these could be difficult to assess objectively.

Olson invited public testimony.

Nan Dahlquist, Medical Director of the Westside Breastfeeding Center, fellow with the Academy of Breastfeeding Medicine, member of the American Academy of Pediatricians, a lactation consultant

and member of the advisory board for to Northwest Mother's Milk Bank. Dalhquist spoke about complications related to cow's milk use in micropreemies.

She said the use of pooled human donor milk is unquestionably standard of care in the hospital. The costs of this product need to be considered alongside the data about keeping the babies in the hospital if they develop necrotizing enterocolitis.

There was an average 18-day reduction in care for medically managed enterocolitis, and a 50-day difference for surgically managed necrotizing enterocolitis. She works with families after their babies are outside the NICU. Many of these families are overwhelmed by their time in the unit and are grappling with how sick their babies were. Helping the babies grow and thrive with as little sequalae as possible improves the long-term health of the infant as well as the sustainability of the families. These babies will be raised alongside term peers and face a risk of higher demand for medical services. She believes this milk deserves the classification of a medication rather than a medical product.

Dr. Ann Loeffler, a pediatric infectious disease doctor at Randall Children's Hospital and an unpaid Medical advisor to the Northwest Mother's Milk bank, also spoke. She shared information about the safety of pasteurized milk. There has never been a case of infection in North America through the milk banks. She said women believe human milk is better and are sharing it and selling it on the internet. They lace it with cow's milk or take illicit drugs when selling their milk. Correctly pasteurized milk is of higher quality compared to milk that is informally sold or shared. The subcommittee's recommendation for coverage will legitimize pasteurized donor breast milk. We have data about babies getting pasteurized milk in the NICU and the moms going on to successfully breastfeed those babies. As we look to promote health in a proactive way, what could be better than supporting breastfeeding by promoting donor breast milk.

Olson asked about inability to provide the milk. Loeffler said for premature babies, the mother's body may not produce milk. Dahlquist said some mothers have HIV or drug use and their milk is not appropriate for the babies.

Livingston asked those giving testimony to comment on the proposed length of time for coverage.

Anna David spoke next, representing her family and NICU Families Northwest. Her daughter received donor milk when born at 26 weeks of gestation, and she has donated milk. NICU families are sometimes faced with bills of over a million dollars. In addition, the stress anxiety and depression resulting from a NICU stay can drastically compromise moms' ability to produce milk. Human milk is medicine that can prevent deadly disease. Donor milk is the best solution when mother's milk is compromised or unavailable. She has seen devastation for families whose insurance cuts off coverage of donor breast milk. These families can sometimes fight insurance companies for weeks or even months to gain coverage. Adding coverage will ensure that families are given access to lifesaving medicine and food that is safe and nutritionally superior to the alternatives. Donor milk can strengthen the babies' immune system and reduce the length of expensive hospital stays and reduce the need for continued treatment after discharge. She said that the lack of sleep, hydration and good nutrition, as well as difficulties with emotional stability, can affect milk production for mothers with infants in the NICU.

Lesley Mondeaux spoke next. She is Executive Director of Northwest Mother's Milk Bank. She said the milk bank does charge a processing fee. Medicaid would support the work of the milk bank and improve its reach. They prioritize fragile infants in providing a safe source for human milk. They have distributed over 1 million ounces of pasteurized human milk to hospitalized and outpatient infants. In 2017, 900 families received prescribed human milk. They receive incredible support from mothers who donate their milk. Her organization is accredited with the Human Milk Bank Association of North America. They follow strict guidelines to ensure safety and quality and appropriate prioritization.

Livingston asked whether all NICUs are providing human donor breast milk and to what group of infants. Mondeaux said her organization serves all level 3 NICUs in the state and serves 68 hospitals throughout the Pacific Northwest (Oregon, Washington, Alaska, a little bit of Idaho and backup service for Montana). Each hospital has its own criteria and guidelines and these vary widely.

Gibson asked about Prolacta and other fortifications for human milk. Mondeaux replied Prolacta is the only entity making human milk-based fortifier. Olson asked whether there is a supply problem. Mondeaux said they have had the milk they have needed to meet hospital orders, which are the number one priority. About 20 percent of the milk they have at the milk bank reaches outpatient families. They prioritize the milk very carefully. Many families requesting milk for nonmedical reasons do not receive it. They have a charitable program to eliminate the processing fees if needed. The prioritization involves reviewing chart notes and often communication with the provider. They also look at the lactation support provided to the mother. Babies with low birth weight will have higher priority.

Allen asked what is driving the demand for black market human milk. Mondeaux said mothers want to do what they have been told—provide breast milk, as it is best. If banked milk is not available, they may seek milk from other places. David said cost is also a barrier. Formula is very expensive. If they are not able to be prioritized above the critically ill infants they don't have a lot of other choices. She said her organization has 400 member-families and they hear these questions a lot. NICU families especially desire it because they know from their experience in the NICU that their babies are better off with human milk. Barriers include finding a provider identifying the need to prescribe, lack of access, lack of lactation support and lack of insurance coverage.

A member asked about the prioritization and how gestational age factors in. Mondeaux said it's case-by-case but younger babies tend to be higher on the priority list. They have served 4 OHP babies [in an outpatient setting]. All but 1 were CCOs and were older babies that were not tolerating formula or experiencing failure to thrive. They talk to the provider, get chart notes, do a trial period and ensure there is good follow-up. Older babies eat a lot more volume so they have to look at the big picture and get as much information as possible.

Olson asked about the length of coverage. Livingston said the evidence isn't really clear. The most restrictive would be to not cover it at all outside the hospital; the least restrictive would be to cover it for six months after the term birth date (which could represent more than six months in the case of a premature baby). There is not great evidence of benefit in the outpatient setting but we know there are many benefits of human milk so it's likely there is a benefit for patients with gastrointestinal disease and possibly pulmonary disease. Option 2 is based on summarizing what others have done.

Hodges said in the NICU it gets included in the hospital fee so is covered now. A member of the audience said hospitals may cap payment for donor milk when babies reach a certain weight, even while the child is still admitted. Those parents aren't allowed to bring milk into the hospital, even if they purchase it themselves. Mondeaux said they do get calls from families in this situation. Olson said that this coverage decision may not affect that, but when the babies are discharged they would receive donor milk under the proposal.

Livingston suggested that the three-month limit may be more in alignment due to the limited supply. Coffman suggested you could allow the longer limit, knowing that the other prioritization process from the milk bank might ensure appropriate prioritization better than a stricter limit. It would be similar to organ transplants, where UNOS prioritizes who should receive organs.

Olson asked whether the milk bank is the only supplier in Oregon. Mondeaux said many hospitals have a backup milk bank, but to date her organization has never failed to meet a hospital order. He suggested that the group approve coverage that would seem ideal and that if the coverage turns out to cause issues in the supply chain, providers could request a change. He said risk of coverage under Option 1 is pretty limited since the patients will likely be in the hospital much of the time anyway. Smits clarified that adjusted age means that a baby born 5 months premature who is six months old would have an adjusted age of 1 month.

Gibson asked about the evidence around duration. Livingston said there is extensive evidence that human milk is the best food for any infant up to six months of age. However the evidence in high-risk babies is during hospitalization. After discussion and consideration of the option of coverage for six months after discharge, the subcommittee decided to go with six months of adjusted age.

Gibson asked about the conditions in Option 1. The subcommittee decided to remove the references to bronchopulmonary dysplasia as well as intolerance to multiple formulas. Wentz asked about Prolacta. It was clarified it is not covered by this decision. Gibson asked about line 34 OTHER CONGENITAL ANOMALIES OF MUSCULOSKELETAL SYSTEM. Livingston said the thought was to include these conditions for infants who had surgery on their bowels at birth who might be at higher risk. It would also include some other diagnoses. Gibson asked that these be clarified.

The subcommittee also decided to remove the guideline note from lines 11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN and 48 CHRONIC RESPIRATORY DISEASE ARISING IN THE NEONATAL PERIOD in association with the removal of brochodysplasia. Staff will re-evaluate the diagnoses which appear on the included lines to see if more updates are required. In addition, they added the word "appropriate" to cover the situations where the mother may use illicit substances or have a condition which makes her milk inappropriate for the baby.

Recommended Actions:

1) Add HCPCS code T210~~2~~1 Human breast milk processing, storage and distribution only to the following lines:
    a. Line 2 BIRTH OF INFANT
    b. Line 16 LOW BIRTH WEIGHT; PREMATURE NEWBORN
    c. Line 18 FEEDING PROBLEMS IN NEWBORNS
    d. Line 34 OTHER CONGENITAL ANOMALIES OF MUSCULOSKELETAL SYSTEM
        i. **Modify Line 34 Title** to ~~OTHER~~ CONGENITAL ANOMALIES OF ~~MUSCULOSKELETAL SYSTEM~~ ABDOMINAL STRUCTURES

e. Line 88 NECROTIZING ENTEROCOLITIS IN FETUS OR NEWBORN
f. Line 101 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION

2) Recommend that HSD remove T210~~2~~1 from the Ancillary File.
3) Add a new guideline note as shown in Appendix B.
4) Staff is to bring back the topic to further evaluate the evidence and ensure appropriate line placement given which gastrointestinal diseases are intended to pair with human donor breast milk.

MOTION: To approve the recommendations above as modified during the meeting, with staff returning to ensure that the appropriate lines and diagnoses are included at the next meeting. CARRIES 7-0.

- **Topic: Allergy testing for eczema**

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

Recommended Actions:

1) Remove allergy testing from line 530 MILD ECZEMA
   a. CPT 86003 and 86008 (Allergen specific IgE)
   b. CPT 86486, 95004, 95018, 95024-95028, 95044, 95052, 95056, 95060, 95065, 95070-95071, 95076, 95079 (Allergy testing, skin, mucous membrane, inhalation)
   c. CPT 95115-95134 (Professional services for allergen immunotherapy)
   d. CPT 95144-95170 (Professional services for the supervision of preparation and provision of antigen)
   e. CPT 95180 (Rapid desensitization procedure)
2) Do not add IgE and skin patch testing for allergens to line 424 SEVERE INFLAMMATORY SKIN DISEASE

MOTION: To approve the code changes as presented. CARRIES 7-0.

- **Topic: MRI guided focused ultrasound (MRgFUS)**

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

Recommended Actions:

1) Add CPT 0398T (MRgFUS) to line 660 CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS
2) Add an entry to GN173 as shown in Appendix A

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

- **Topic: Testosterone hypofunction**

Discussion: Smits reviewed the summary document. Irwin raised the concern about patients who are newly on OHP who are already on testosterone therapy. It would be difficult to get the two required low testosterone levels. Livingston noted that the guideline would exclude men who have low testosterone due to opioid use, which she felt was a benefit. Overall, the group felt the guideline was a reasonable addition.

Recommended Actions:

1) A new guideline was added to line 467 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT regarding testosterone therapy as shown in Appendix B

MOTION: To recommend the guideline note addition as presented. CARRIES 7-0.

- **Topic: iStent for open angle glaucoma**

Discussion: Smits reviewed the summary document. The VbBS agreed that the evidence supported cocverage of the iStent procedure. However, the group wanted further clarification about whether Medicaid was required to follow CMS rules for bundling services. Specifically, can a CCO require that the iStent procedure be bundled with cataract removal as CMS requires for Medicare. HERC staff will consult with HSD staff regarding whether there is a rule regarding this or whether such a rule could be written about iStent. Once there is clarify on how this procedure is covered, this topic should be brought back to a future meeting. If bundling is required, then this topic will be a straightforward topic. If bundling is not required, then the VbBS may need to discuss this topic again.

Recommended Actions:

1) HERC staff to discuss bundling iStent with cataract removal with HSD staff and bring this topic back to a future meeting.

- **Topic: Humeral osteotomy for recurrent shoulder dislocation**

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

Recommended Actions:

1) Add CPT 24400 (Osteotomy, humerus, with or without internal fixation) and 22420 (Osteoplasty, humerus (eg, shortening or lengthening) to line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS

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

- **Topic: Coverage Guidance— CardioMEMS™ for Heart Failure Monitoring**

Discussion: Obley and Livingston presented the draft Coverage Guidance. Hodges raised a concern that this device does not encourage patients to further engage with their health care, which is key to survival in heart failure. Livingston presented an issue summary applying the draft Coverage Guidance recommendations to the Prioritized List. There was minimal discussion.

Recommended Actions:

1) Place C2624 on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Place C9741 on Line 660, recommend that HSD remove from the Diagnostic Procedures File
3) Add entries to Guideline Note 173 in association with C2624 and C9741.

MOTION: To approve the recommended code changes to the Prioritized List based on the draft coverage guidance *CardioMEMS™ for Heart Failure Monitoring* scheduled for review by HERC at their afternoon meeting. CARRIES 7-0.

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**
  - iStent and cataract removal bundling
  - Human donor breast milk indications
  - SI joint dysfunction prioritization

- **Next meeting:**

  November 8, 2018 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

- **Adjournment:**

  The meeting adjourned at 1:05 PM.

Appendix A
Revised Guideline Notes

GUIDELINE NOTE 65, TELEPHONE AND EMAIL CONSULTATIONS

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

Telephone and email consultations (CPT 98966-98969, 99441-99443) must meet the following criteria:

1) Patient must have a pre-existing relationship with the provider as demonstrated by at least one prior office visit within the past 12 months.
2) E-visits must be provided by a physician or licensed provider within their scope of practice.
3) 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; must be retained in the patient's medical record and be retrievable.
4) Telephone and email consultations must involve permanent storage (electronic or hard copy) of the encounter.
5) Telephone and email consultations must meet HIPAA standards for privacy.
6) There needs to be a patient-clinician agreement of informed consent for E-visits by email. This should be discussed with and signed by the patient and documented in the medical record.

GUIDELINE NOTE 130, BLEPHAROPLASTY

Line 469

Blepharoplasty is covered when 1) ~~visual fields demonstrate an absolute superior defect to within 15 degrees of fixation~~ a minimum of 30 degrees of visual field loss exists with upper lid skin/margin in repose, 2) upper eyelid position contributes to difficulty tolerating a prosthesis in an anophthalmic socket, OR 3) essential blepharospasm or hemifacial spasm is present., ~~OR 4) when there is significant ptosis in the downgaze reading position.~~

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

The following treatments are prioritized on Line 660, CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS, for the conditions listed here:

CPT/HCPCS Code	TREATMENT	Rational	Date of Last Review/Link to Meeting Minutes
O398T	MRI guided focused ultrasound for the treatment of essential tremor	Insufficient evidence of effectiveness	October, 2018

Appendix B
New Guideline Notes

DIAGNOSTIC GUIDELINE DX, CARDIAC MAGNETIC RESONANCE IMAGING

Cardiac magnetic resonance imaging (CMR) is covered only after it has been determined that echocardiogram and Doppler studies are inconclusive or expected to be nondiagnostic.

GUIDELINE NOTE XXX, BROW PTOSIS

Lines 393,469,652

Brow ptosis repair is included on line 393 for congenital brow ptosis in children only when ALL the following criteria are met:

1) The condition developed within the first year of life, and
2) Ptosis interferes with field of vision, and
3) The child has abnormal head posture (e.g., head tilt or turn, chin up or chin down), amblyopia or strabismus or is at high risk for development of amblyopia.

Brow ptosis repair is included on line 469 for acquired brow ptosis only when ALL the following criteria are present:

1) Brow ptosis is causing a functional impairment of upper/outer visual fields with documented complaints of interference with vision or visual field related activities such as difficulty reading or driving due to upper brow drooping, looking through eyelashes, or seeing the upper eyelid skin, and
2) Photographs show the eyebrow below the supraorbital rim, and
3) Overhanging skin due to brow ptosis is sufficiently low to produce a visually significant field restriction of approximately 30 degrees or less from fixation or a central "pseudo- margin to reflex distance" of 2.0 mm or less, and
4) The visual field impairment cannot be corrected by an upper lid blepharoplasty alone.

Otherwise, brow ptosis repair is included on line 652.

GUIDELINE NOTE XXX, MEDICALLY INDICATED CIRCUMCISION

Lines 21,327, 412

Circumcision (CPT 54150, 54160, 54161) is included on these lines only for patients with

1) Balanitis xerotica obliterans, or
2) Recurrent balanoposthitis (2 or more bouts, not balanitis), or
3) Severe foreskin scarring causing physiologic complications, or
4) Vesicoureteric reflux (grade 2 or higher) or other urologic abnormalities, or
5) Recurrent urinary tract infections (2 or more with documented positive urine cultures).

Balanitis (ICD-10 N48.1) does not pair with circumcision.

Appendix B
New Guideline Notes

GUIDELINE NOTE XXX, POSTPARTUM DEPRESSION SCREENING

Line 3

Postpartum depression screening using a validated instrument (e.g. Edinburgh Postpartum Severity Score, PHQ-9) is included on this line during the child's visit (CPT 96161) or during the mother's visit (CPT 96160, 96127) when there is a plan in place to address positive depression screens.

GUIDELINE NOTE XXX, TESTOSTERONE REPLACEMENT FOR TESTICULAR HYPOFUNCTION

Line 467

Testosterone replacement therapy is included on this line for testicular hypofunction or dysfunction only when all of the following inclusion criteria are met and none of the exclusion criteria apply:

Inclusion criteria:

1) The patient is a male 18 years of age or older; AND
2) The patient has had TWO morning (between 8 a.m. to 10 a.m.) tests (at least 1 week apart) at baseline demonstrating low testosterone levels as defined by the following criteria:
    a. Total serum testosterone level less than 300ng/dL (10.4nmol/L); OR
    b. Total serum testosterone level less than 350ng/dL (12.1nmol/L) AND free serum testosterone level less than 50pg/mL (or 0.174nmol/L); AND
3) Patient has received ONE of the following diagnoses:
    a. Primary Hypogonadism (congenital or acquired): as defined as testicular failure due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, trauma, or toxic damage from alcohol or heavy metals; OR
    b. Hypogonadotropic Hypogonadism (congenital or acquired): as defined by idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation

Exclusion criteria:

1) Patient has ANY of the following contraindications:
    a. Breast cancer or known or suspected prostate cancer
    b. Elevated hematocrit (>50%)
    c. Untreated severe obstructive sleep apnea
    d. Severe lower urinary tract symptoms
    e. Uncontrolled or poorly-controlled heart failure
2) Patient has experienced a major cardiovascular event (such as a myocardial infraction, stroke, acute coronary syndrome) in the past six months
3) Patient has uncontrolled or poorly-controlled benign prostate hyperplasia or is at a higher risk of prostate cancer, such as elevation of PSA after initiating testosterone replacement therapy

This guideline does not apply to testosterone replacement therapy for HIV-associated weight loss, delayed puberty, treatment of metastatic breast cancer, or transgender health.

Appendix B
New Guideline Notes

GUIDELINE NOTE XXX DONOR BREAST MILK FOR HIGH RISK INFANTS

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

Donor breast milk is included on these lines for infants up to 6 months of age (adjusted for gestational age) who are low birth weight (<1500g) or have underlying gastrointestinal disease (e.g. gastroschisis) AND where maternal breast milk is not available, appropriate or sufficient to meet the infant's needs, despite lactation support for the mother.

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

MINUTES

Health Technology Assessment Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 210
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
September 27, 2018
1:00-4:00pm

Members Present: Vinay Prasad , MD, MPH, (Chair); Leda Garside, RN, MBA; Mark Bradshaw, MD; Kathryn Schabel, MD, Mike Adler, MD.

Members Absent: Brian Duty, MD

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

Also Attending: Adam Obley, MD, & Craig Mosbaek (OHSU Center for Evidence-based Policy), Criag Gonzales, Endogastric Systems; James Gajewski (Oregon Society of Medical Oncology), Cindy Langhorne (Caring Ambassadors), Anne Murray (Bristol Myers-Squibb), Rocky Dallum (Oregon Bio/Quest), Seema Singh Bhan (Foundation Medicine), Julia Elvin (Foundation Medicine), Charles T. Koyias (Roche Diagnostics), Dann Wonster, Jacqueline Fusari, Matt Krebs (Pfizer), Fouad Otaki, MD, OHSU

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1. Call to Order

Vinay Prasad called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:06 pm.

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2. Minutes Review

Minutes from the June 28, 2018 meeting were reviewed and approved 5-0.

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3. Coverage Guidance: Newer Interventional Procedures for Gastroesophageal Reflux Disease

Wally Shaffer introduced Dr. Fouad Otaki, assistand professor of gastroenterology at OHSU, who will serve as ad hoc expert for this topic. Adam Obley and Shaffer reviewed the draft coverage guidance. Prasad asked whether the sham-controlled studies were pooled separately from those which used medications as a control. Obley said they were not. Of the studies, two were sham controlled and three controlled with proton pump inhibitor (PPI) therapies. Obley said the Long review showed that all four trials were positive for the transoral incisionless fundoplication (TIF).

Otaki said that GERD is a dynamic process. Lifestyle choices aren't effective for the majority of patients, but it's an important step in that it tunes the patient in to their symptoms. He also said that there isn't much evidence that conventional Nissen fundoplication reduces stricture or Barrett's esophagus.

In discussion of magnetic sphincter augmentation (MSA), Schabel asked about the high rates of dysphagia related to TIF. Obley said that is from the randomized trial, but the indirect method of getting

at the answer was the rate of endoscopic dilation from the observational studies, which was not different between MSA and Nissen fundoplication. Otaki added that these patients may have a hypersensitivity or a strong gut-brain axis. Sometimes, long-term reflux can lead to dysmotility in the esophagus. These studies don't differentiate existing mild esophageal motility disorders, so it's not clear whether these disorders were caused by the MSA procedure.

Otaki also said that in order to do a fundoplication, you have to have a fundus. In some cases the MSA procedure has been tried in conjunction with a sleeve gastrectomy. A segment of the stomach is removed for bariatric purposes and the excluded stomach would be used for a fundoplication in an otherwise healthy patients. This procedure is one of the approved and frequently-used bariatric surgeries. Prasad asked whether there was evidence in that population. Shaffer confirmed there is not; presumably they weren't included in the studies reviewed for this coverage guidance. Schabel asked whether TIF is an option in gastric resection patients. Otaki said patients who have had gastric bypass or a sleeve gastrectomy cannot have a TIF. But patients who have had a gastric bypass are less prone to reflux. There is data to support that a sleeve increases the chances of symptomatic reflux while a gastric bypass is an accepted form of antireflux surgery. Schabel said trends are towards sleeves and away from bypass. Otaki said this has to do with the side effect profile. Patients who have had a sleeve gastrectomy and who have reflux may be converted to a gastric bypass.

Craig Gonzales, drector of healthcare economics for Endogastric Solutions, offered public testimony. Endogastric Solutions makes the Esophyx device used in the TIF procedure. He thanked the committee for the review of these procedures. He said there are more and more patients looking for alternatives to surgery and PPIs. He referred to a comment he submitted by email requesting consideration of newer studies in support of the recommendation. He said he expected a recommendation for noncoverage based on the included studies. He said the Huang article included in the coverage guidance doesn't distinguish between iterations in the device and procedures. He said some of the early studies cited in Huang were ELF (endoluminal fundoplication) studies. There is a huge difference in where the fasteners are placed, and there are three versions, ELF, TIF 1.0 and TIF 2.0. Since 2009, there have been 20,000 of the TIF 2.0 procedures. He expressed concern that this confuses studies of procedures from the past which no longer apply to the procedure being performed today. The randomized trials are all TIF 2.0 RCTs. He said there is a metaanlysis by McCarty he would prefer to have included or used instead of Huang. He said the other issues he raised in the letter are less important.

He answered several questions that came up in discussion. There was a question about the number of procedures in the Richter article. He said that could be calculated from a table in the Gerson article. He said there were two sham controlled studies included. Some studies used a European GERDHRQL score so the results can't be considered side-by-side. He said that if the BMI is >=35, some kind of bariatric surgery is the best choice.

In response Obley thanked Gonzales and addressed his questions. The McCarty review was identified in the search used to inform the coverage guidance. It was not included because it lacked critical appraisal of the included studies and combined results of observational and randomized studies. He said the estimates of effectiveness in Huang were based solely on TIF 2.0 data. Some of the observational trials, which were used for the harms and PPI cessation outcomes, used earlier versions of the surgery. Prasad said that of the 32 studies in McCarty, there are at most 4 randomized trials. Obley agreed. With regards to the Manufacturer and User Facility Device Experience (MAUDE) database, the appropriate denominator would be all TIF procedures ever performed, since harms can be reported regardless of whether the surgery was in a study.

The subcommittee discussed the criteria and decided to clarify the timeframes around GERD symptoms and recent PPI therapy as conditions for coverage of the TIF procedure.

Shaffer said the subcommittee will have a written comment period, during which Gonzales could submit his comments.

A motion was made to post the draft coverage guidance, as amended, for a 30-day comment period. **Motion approved 5-0.**

DRAFT HERC COVERAGE GUIDANCE

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

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

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

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

5. Review Public Comment: FDA-approved Next Generation Sequencing Tests for Tumors of Diverse Histology

Shaffer reviewed a summary of the public comments based on the discussion table from the public comment disposition in the meeting materials. Prasad invited attendees to provide public testimony.

James Gajewski, President of the Oregon Society of Medical Oncology, spoke first. He declared no conflicts of interest and referenced his participation in a 2013 HERC workgroup related to a guideline note on cancer treatment at the end of life. He said that the Affordable Care Act requires that cancer treatment access be without regard to the impact of the therapy on the length of survival, quality of life and disability. He also said that the current HERC guidelines require access to care defined by national guidelines, which we interpret as ASCO, NCCN, ASH and ASBMT, as well as access for patients with rare tumors to best available therapy when the provider needs to consult other outside physicians. He said that as a clinical hematologist stem cell transplanter, next generation sequencing (NGS) is very important in bone marrow failure states to separate aplastic anemia from mild dysplasia or to decide when to give immunosuppressive therapy or take patients to transplant. Secondly, for some patients who are "watch and wait" with mild dysplasia, repeated NGS can detect mutations which might help him decide to transplant earlier. For his long-term transplant survivors, NGS helps make decisions about preemptive treatment with a donor lymphoctye transplant prior to an all-out relapse. There are a lot of issues with the statistics. He said it's difficult to do large trials. Often the decisions are based on understanding of cancer biology and the mutations. The addition of new mutations predicts a worsening cancer prognosis.

Cindy Langhorne with Caring Ambassadors spoke next. Her organization receives pharmaceutical support but none from FoundationOne. She began her career and advocacy as the founding member of the Lung Cancer Alliance. She is also co-leader of the Lung Cancer Action Network, a coalition of 24 organizations advocating for detecting, treating and curing the disease. She said cancer is not seen as a single disease and that most new treatments now target specific biomarkers. These targeted therapies are improving outcomes in patients with that biomarker. Still, next generation sequencing is often seen as an 'extra service' by patients and their providers. Twenty years ago survival was 12 months. Now stage four patients are living longer and longer. She told the story of a colleague who was diagnosed in 2011 and is thriving. On behalf of half a million people living with lung cancer in the U.S., she encouraged HERC to reconsider the recommendation. All patients deserve the same access to care.

Prasad clarified that many of the biomarkers for non-small cell lung cancer are already covered under the Oregon Health Plan, but with tests focused on specific targetable mutations.

Anne Murray with Bristol Myers Squibb testified in reference to a letter submitted by email. She wanted to ensure it had been received by members and provided copies.

Rocky Dallum of Tonkin Thorpe said he represents Quest, Oregon Bio and National Bio. He said that the issues are covered in the letters which have been submitted previously and provided copies.

Julia Elvin testified next. She is anatomic and molecular pathologist at Foundation Medicine. She said that this complicated and rapidly-evolving area of laboratory medicine is critical for patients making difficult choices and to hopefully live better and longer with their disease. Foundation Medicine disagrees with the recommendation, which uses outdated studies and disregards the conclusions of the FDA and CMS based on their review of 280 relevant articles as well as extensive validation from our analytic information from tumor samples. As a pathologist she said the understanding of cancer subtypes has been fueled by understanding of the molecular drivers. This is giving physicians a more complete picture of each patient's disease and may reveal targeted treatments and eligibility for mutation-matched clinical trials. Possibly more importantly, comprehensive molecular characterization will demonstrate the lack of mutations in relevant pathways, and thus the lack of probable therapeutic

benefit for certain treatments that were approved only in a particular tumor subtype. She recommended that the subcommittee recommend coverage for the test. Patients most impacted by coverage denial are the most vulnerable and will further reinforce disparities in cancer outcomes and clinical trial enrollment of lower socieoeconomic groups. With regard to clinical utility she said her organization disagreed with the characterization that the FDA and CMS conflated clinical utility with proven effectiveness of targeted therapies. She said CMS and FDA specifically focused on clinical utility and whether the molecular profiling can help guide physicians in decisionmaking. NGS testing is part of standard care for many advanced cancers rather than an empiric or scattershot approach. NCCN guidelines have been evolving due to NGS technology and have changed their guidelines for many cancers. She asked the subcommittee whether they truly believed that the patient was going to get a less effective or less safe therapy if it is informed by an NGS-based profile. She said the answer is no. She said profiling can predict how a patient's disease will behave and what interventions may or may not be successful. This is similar to the move from gram-stain analysis in infectious disease to routine antibiotic resistance testing.

Charles Koyias, a physician with Roche Diagnostics in the noncommercial division of medical and scientific affairs, testified. He believes personalized care will continue transforming lives and improving patient outcomes. He expressed concern by the approach taken. Specifically, he asked why the HTAS asserts that adequate coverage exists for targeted therapies when individual mutations are analyzed yet no evidence exists for the use of NGS. Analytic and clinical validity have been well-established. NGS-based tests cited in the HTAS review have undergone rigorous review with the FDA and have been approved as elements that are essential to the use of a targeted therapy in a particular indication. CMS' coverage and analysis group reviewed over 280 peer-reviewed studies on the evidence supporting clinical utility for these tests. The use of NGS tests is supported in NCCN guidelines for patients with lung, melanoma, ovarian and prostate cancers. He said CAP ISALC and AMD updated their guidelines for the selection of patients with targeted tyrosine-kyrine inhibitor therapies. He referenced evidence showing that survival of patients receiving a targeted therapy is significantly longer than patients with no mutation. The HTAS must take all this into account before finalizing a negative recommendation. He said ignoring evidence not reviewed under the HTAS methodology threatens patient access to these tests but will serve to undermine and stifle progress in this area of personalized medicine. The subcommittee should either postpone its decision until it can perform a comprehensive review of the literature or reverse the recommendation.

Dann Wonster spoke next, reading a letter from Jacqueline Fusari, who was not present. The letter said she had been living with stage 4 non small-cell lung cancer for six years, since 2012. At the time she was running, hiking and doing yoga, and had never smoked, but somehow this cancer had spread through her lungs at the age of 26. The prognosis was not good and she didn't have options. After receiving next generation tests it was discovered that she had the ALP gene mutation, giving her the opportunity to use a targeted medication for the ALP mutation. The drug worked miraculously. Without this she knows she wouldn't be here today. These tests are necessary parts of treatment for all patients. She is currently in her second year of grad school studying Chinese medicine and cycling, while she receives another targeted therapy.

Wonster then proceeded to tell his own story. His lung cancer was discovered after a broken rib. He is a nonsmoking vegetarian who works out at the gym every day and had no risk factors. After chemotherapy and surgery he had additional chemotherapy. His life expectancy was measured in months. He continued working out, eating healthy and got lots of sleep. He said lung cancer can happen to anyone. The chemotherapy he took had a low success rate but worked for him for a time. Five years

later he was rediagnosed with stage 4 lung cancer. The chemotherapy did not work, and the chemotherapy maintenance drug caused kidney damage but stopped the cancer for 18 months. After next generation sequencing he found he could be treated with a targeted therapy. After 16 months he qualified for another trial of a new targeted therapy, which was only available to those who have next generation sequencing. The new drug has been working for 47 months without progression. There are 11 targeted therapies available and none can be given without next generation sequencing. He asked the subcommittee not to send Oregonians to an early grave by restricting them to the same crude options available decades ago.

Prasad acknowledged the poignant testimony and clarified that the Oregon Health Plan does cover targeted testing for genetic mutations associated with the FDA-approved targeted therapies for non small-cell lung cancer. The scope of the current coverage guidance is a broad screen of over 300 genes that detects mutations and goes beyond the current coverage guidance, which covers all the druggable mutations for FDA-approved drugs.

Schabel asked how people know they have the mutation without the test. Prasad said that they do a different test, just not the 300-gene test. There are four druggable mutations for lung cancer. Some other cancers have one or no targeted therapies available. Many of the 300 genes being tested for do not have data to support targeted therapies. The tests for the druggable genes are covered under the Oregon Health Plan, though the biomarkers coverage guidance may be due for an update. Obley added that this coverage guidance is not intended to look at targeted therapies when a targetable mutation is present. The scope was narrow, essentially asking the question of whether patients managed on the basis of next generation sequencing fare better than patients managed on the current standard of care which may include targeted therapies selected based on narrower genetic testing. Unfortunately there is very little evidence in this area. Our conclusion is measured. It doesn't say this is an ineffective therapeutic approach. It simply says the evidence is insufficient at this point. Shaffer gave examples of what is currently covered including EGFR gene mutation testing for lung cancer, KRAS for colorectal cancer, BRAF for melanoma. This coverage may need to be updated, but that is not the scope of today's discussion. Today's question is whether broad companion testing improves outcomes.

Schabel asked whether there is a role for using broad testing for tumors that have known treatable mutations. Prasad said that the question today is whether every single solid tumor needs this kind of broad genetic panel. These panels are often in excess of 300 gene mutations.

Prasad said that one of the challenges is that if we find a mutation for which there is an FDA-approved drug, Medicaid may not pay for that drug for the off-label use for a different cancer. If the medication may not be covered, the information from the NGS test may be of limited use. Shaffer said the Oregon Health Plan does not pay for investigational drugs or clinical trials. Medicaid has no obligation to cover targeted therapy for non-FDA approved indications. This doesn't mean that there isn't some flexibility for certain circumstances where preliminary evidence is presented.

Gajewski said that clinical trials are covered under the Oregon cancer guideline. Coffman clarified that the trial drugs are not covered but supportive care necessary to access the clinical trial (such as hospitalization) is covered.

Shaffer reviewed questions on the discussion table in the public comment disposition. He said the subcommittee does need to decide whether to review observational evidence not included in the original review. This would not typically be part of the process but can be done on request. Prasad said

the preference is for prospective, randomized data. Schabel asked how this topic came to the subcommittee. Staff said it came up after the FDA approval of the FoundationOne test. Schabel asked whether CMS approves this for all solid tumors. Obley confirmed this. Shaffer said that Oregon Medicaid decisions can be, and often are, separate from those that CMS makes for Medicare. Schabel asked what the basis was for the CMS decision. Obley said that CMS relied on a chain of logic, determining that there are targetable mutations in solid tumors associated with FDA-approved therapies and that this test is effective for detecting those mutations and therefore it warrants coverage. Prasad clarified that these treatments would be approved for a specific mutation in one cancer type, but these tests might suggest using the medication to target the same mutation in a type of cancer the drug is not approved for. He said CMS may pay for some of the drugs off label, but may not pay for others. Prasad said some trials require genetic testing for patients who enroll, but generally the sponsor pays for those tests.

Garside asked about private insurance coverage for these tests, given that that Medicare is covering them. Craig Mosbaek said he updated the private payer coverage search this morning. They looked at Aetna, Cigna and Regence. None of these payers cover broad next generation tests. Moda does not have a policy on these tests.

Bradshaw asked whether there would ever be sufficient numbers of participants for a randomized trial of these tests. Prasad said there are ongoing trials. Prasad said it is possible to generate higher-quality evidenced. He said the Shiva trial included in the review has many flaws but it does demonstrate that a trial could have been possible in a different world. He asked Obley whether there was the possibility of randomized trials. Obley said there are two randomized trials currently underway which are cited in the public comment disposition. Prasad looked them up and they appear to be multicenter randomized prospective cohort studies scheduled for completion in March 2020 and May 2019. Obley said trials often take longer than predicted to complete.

Schabel asked what the next trigger would be to re-evaluate this coverage. Prasad said these studies could trigger such a review, but even if a recommendation were made today, that would go to another committee and there would be an implementation delay.

Bradshaw asked whether these tests are being used right now as a standard for decisionmaking. Prasad said there is a movement towards using these tests. Still, a paper recently published in the Journal of the American Medical Association (JAMA) was a propensity-scored observational study for lung cancer. Unfortunately, it showed that beyond the FDA-approved biomarker testing, the addition of next generation sequencing did not appear to confer any additional survival benefit in a propensity-matched population. Obley said this study wasn't picked up in our rapid review methodology because it is not a randomized trial and has not been included in a systematic review. Prasad said it is quite clear that this technology is coming and the committee can always re-evaluate when evidence becomes available. Prasad said any of the ongoing studies would be national news if they show a benefit.

Obley offered to look more deeply into the observational evidence if the subcommittee so desires, but it will take time. Prasad said reviewing observational data would be deeply inconclusive because of the variables in the people in whom the tests are employed versis those not tested. Shaffer said the subcommittee has added observational studies in the past when issues have arisen. Schabel said with the breast cancer tumor testing, observational studies and values and preferences did push the subcommittee to recommend broader coverage than would have been approved based on the randomized data alone. She said the values and preferences and the rapidly-evolving nature of cancer treatment were important in that decision. She moved to table the topic pending completion of

anticipated randomized studies. After discussion, the motion was modified to state that when the topic was picked up again it should be reframed in the greater context of the existing biomarker coverage guidance.

Motion approved 5-0.

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6. Extended Stay Centers

Shaffer and Gingerich reviewed the summary included in the meeting materials. The subcommittee discussed the proposed workplan. Schabel added that even at OHSU where an ambulatory surgery center is located on a hospital complex, patients not ready for discharge to home must be transported by ambulance. She said urinary retention can be another reason for failure to discharge. Adler asked how patients get from an ambulatory surgery center to an extended stay center. Gingerich said that by law the centers must be separately licensed but must be continguous. Shaffer said that the Health Licensing Office would have to define these requirements; that is not in scope for the HERC, though understanding the rules may influence the subcommittee's decisions. Schabel asked what the driver for this bill was. Shaffer said that Gingerich and he discussed this with representatives of organizations supporting the bill. The idea is to provide an alternative to the inconvenience and expense of hospitalization for certain lower-acuity patients. Some hospitals are supportive as they are frequently at capacity. He also said rural hospitals expressed concerns about the bill, but the bill only allows these in urban areas.

Bradshaw asked to clarify Medicare coverage. Shaffer said Medicare would not pay for services in these facilities and it is unclear whether they would be reimbursed by Medicaid either. Commercial insurers may prefer to support these centers due to cost concerns; each insurer has its own policies. Schabel said that Medicare recently added knee replacement to its list of procedures for ambulatory surgery, but not hip replacement. She said this is true even though hip replacement patients are easier to discharge sooner. Shaffer said that payers might use the HERC guideline as they see fit. The scope of this report is limited to the patient characteristics and procedures that may be appropriate in this setting.

Shaffer said that evidence is likely to be limited and indirect. Extended stay centers do not exist in other states, though some states have facilities that provide recovery services in different forms. Schabel said there are limits to prospective observational studies at ASCs, as researchers may have no way to know whether a patient was later admitted to a hospital due to a complication. She said transition to outpatient surgery is in vogue in orthopedics now and financial considerations are driving it, so this needs to be taken into account. Finally, there is no method of collecting ASC quality data as there is with hospitals. ASCs report lower complication rates as they should given the lower acuity. Shaffer said there may also be benefits including convenience and lower infection rates. Prasad asked about cost-effectiveness. Coffman said cost-effectiveness is not part of the subcommittee's charge for this guideline. Schabel said there is data about what proportion of the population meets safe criteria for ambulatory orthopedic surgery and what percent of these made it through surgery without hospital transport. It is a significant minority of the population. It would be interesting to see whether patients who did get transferred look like patients who would fit the profile for using an extended stay center.

Shaffer presented the sample guideline statements in the meeting materials.

The subcommittee discussed which five procedures to look at for the November meeting. Schabel said the list was good. She said that bariatric surgery may be interesting as high body mass index is

sometimes a contraindication to ambulatory surgery. Neck dissection would require an otorhinolaryngologist, as bleeding in the neck can cause airway difficulties. She suggested some names of potential experts. After brief discussion the subcommittee discussed these five surgeries for review at the November meeting:

- Total knee replacement
- Mastectomy
- Trasurethral resection of the prostate (TURP)
- Hysterectomy
- Bariatric Surgery

There was additional discussion of cholecystectomy, but members thought the majority of those were urgent/emergent and would be done in a hospital setting. Schabel asked about what specific staffing or service requirements exist for extended stay centers. Gingerich said that rulemaking was expected to be completed soon. Shaffer said that rules about nursing backup and other services are under development, and these may affect the guideline recommendations. Gingerich said that staff would include the most recent draft of licensing rules in the materials for the next meeting.

Shaffer asked whether the list of experts looked correct. Coffman suggested a general surgeon. Schabel suggested an otorhinolaryngologist. She offered to make some introductions. Garside suggested infection control and discharge planning or case management. Shaffer said he was concerned about having more experts than subcommittee members, but we could have a larger number for this topic since it is not a coverage guidance. After discussion the group decided to recruit up to eight experts, expecting that we might not find representatives for all the specialties of interest.

Schabel said that it's important to remember that ambulatory surgery centers can be hugely profitable investments, so it's important to have that in context as the work goes forward. She highlighted a comment suggesting they should be not-for-profit. Surgeons might face conflict of interest if they make more money when operating in a certain setting.

Shaffer said that the issue of patient mix for facilities actually came up in public comment. Currently most ASC patients are commercially-insured or have Medicare. Medicaid patients tend to have more comorbidities and so might face risks in an ASC setting. On the other hand, they might be able to safely benefit from an ASC if an ESC is present for recovery. Schabel agreed this is the case.

A motion was made to approve the selection of the above procedures for initial review. **Motion approved 4-0. (Garside and Adler not present)**

7. Adjournment

The meeting was adjourned at 4:00 pm. The next meeting is scheduled for November 15, 2018 from 1:00-4:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070

MINUTES

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

Clackamas Community College
Wilsonville Training Center, Room 155
October 11, 2018
9:00-11:00 a.m.

Members Present: Gary Allen, DMD, Chair; Bruce Austin, DMD; Alison Noble (via phone); Laura McKeane; DDS; Deborah Loy.

Members Absent: Eli Schwarz, DDS, MPH, PhD; Len Barozzini; Karen Nolon.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH.

Also Attending: Kellie Skenandore (OHA), Dayna Steringer (Willamette Dental).

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 9:00 am and roll was called. Minutes from September 18, 2017 were reviewed and no changes were suggested.

- **Topic:**

2019 CDT Codes

1) D0412: The dental board is reviewing whether glucose testing is in the scope of practice of dentistry. Blood stick glucose meters would make a dental office a lab for legal purposes. This is an integration issue. No issue with code being diagnostic. Scope of practice is beyond the purview of the OHAP or HERC.
2) D1516-D1527, D5282-D5283: just split existing codes into more specific new codes.
3) D5876: Used to strengthen dentures. Already being done in certain cases in dental practice. Adds cost up front but may save cost in repairs downstream. OHA could make rules about when this procedure is covered. Decision was to place on line 451 DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE) and have OHP All Plans Dental Group look at rules around this procedure.
4) D9130: Austin reports that specific massage can be effective, but no way to determine if this code is being used for actual effective massage. TMJ is historically non-covered. Adding a service for TMJ would require HERC to re-evaluate the prioritization of TMJ as a condition. Decision was line 547 TMJ DISORDER.

5) D9613: cannot be used for short acting local anesthetic. May be used for dental blocks. Question about whether this could be used in the ED for dental pain. Question about whether to cover separately from the procedure. Concern that this might be abused. These are not expensive drugs. Discussion about covering long-acting anesthetic rather than corticosteroids. Many private plans roll this into the procedure as a bundle. Concern with unbundling and increasing cost. OHAP wanted to get further input from commercial plans to see how they are handling this code. OHAP needs information on whether this is bundled with the procedure. Also, need input on whether this could be billed as a second visit if a patient returns later for the injection. Return visit might also be bundled with the procedure, so concern for extra cost as a separate code. Concern that this should be done when appropriate, and already being done without extra payment now. Medicaid already pays high fees for oral surgery; concern for adding cost. Currently, D9610 is being used for this type of injection, which is on line 54 DENTAL CONDITIONS (E.G., INFECTION, PAIN, TRAUMA). Input from Karen Nolan indicated that commercial plans are not covering this as a separate procedure unless a group requires it in its contract. If it is in a contract, it will only be paid on the date of service and when paired with dental extraction codes (D7220-D7241). Decision was Excluded File.
6) D9944-D9946: no discussion
7) D9961: this is standard of care, but rules exclude payment. Will make Excluded and will change to covered in the future if OHA rules change.
8) D9990: this should be covered, but unclear how OHA will cover it. It is bundled for CCOs. T1013 is the medical equivalent code, which was on the Exempt File (which no longer exists). Decision was to make Ancillary and have OHA work on rules.

<u>Update on orthodontia and craniofacial anomalies</u>

Skenandore reported that further discussion is needed between the HERC and OHA leadership on incidence of these abnormalities. Dr. Garfinkle should be consulted about how often these craniofacial abnormalities are needing treatment under OHP. Need this data prior to being able to calculate cost. HERC staff will do a data search to see number of unique claims for patients with these types of diagnoses, as these patients should already be getting services for medical issues, surgeries, etc. HERC staff will reach out to Dr. Garfinkle to better determine incidence as well. Once incidence is determined, then this data needs to be taken to actuarial services to determine if any changes in rates is required. Skenandore reported that cleft lip and cleft palate are now both being covered with a temporary rule. A permanent rule is in the works.

<u>Other business</u>:

Tori removal coverage will be effective November 1, 2018. The codes are already loaded into the OHA billing system per Skenandore.

- **Public Comment:**
  No public comment was received.

- **Issues for next meeting:**
  HERC staff will accept issues from members and other stakeholders as they arise over the year and bring them to the next OHAP meeting, along with 2020 CDT code changes.

- **Next meeting:**
  - TBD

Highlights

Genetic Advisory Panel
Conference Call hosted at:
Lincolin Building
421 SW Oak Street, Suite 750
OEI Conference Room
Portland, OR 97204
October 10, 2018
9:00-12:00 a.m.

Members Present: Karen Kovak; Catherine Murray; Nicoletta Voian

Staff Present: Ariel Smits, MD, MPH; Jason Gingerich

Also Attending: Jim Gajewski (OASCO), Jim Clark and Ashley Allen from Roche Diagnostics; Devki Saraya and Karen Heller from Myriad; Ashley Svensen from Counsyl; Andrew Yu from NW Oncology

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The meeting was called to order at 9AM. Roll was called. The highlights from the 2017 GAP meeting were reviewed and no changes were suggested.

Review of New Genetics CPT Codes for 2019

The 2019 Genetic CPT codes were reviewed. There were no suggested changed from the staff recommendations. Specific code discussions:

1) CPT **81329** (SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed) is a prental genetic test for carrier status. It should be included on the prenatal genetic testing guideline. It is replaceing CPT 81401 as the code for this test, which is a non-specific code. Smits will make this change to the prenatal testing guideline.
2) CPT **81443** (Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes).
    a. Gap discussion: This test is a big panel offered for carrier testing for prenatal or preconception counseling/testing. Panel tests used now have 170+ genes. Could be used for any panel 15 genes or larger. The reason this CPT code was added was that the

same code is to be used for any panel with one rate of reimbursement. All GAP members felt that this was reasonable to cover. Often cost is the same to test for a single gene as a panel. All pregnant patients should be offered expanded carrier screening per ACOG guidleines. It was noted that carrier panel testing is specifically excluded currently in the prenatal testing guideline, but the rationale for that exclusion was not recalled. Gingerich felt that it was likely a result of the coverage guidance done on this topic some years ago.

a. Public testimony: Ashley Spensen with Counsyl: this code is for over 15 genes. ACOG committee opinion is that over 15 genes in one panel is an acceptable strategy. Over ½ of all screening in US is now done with expanded panel tests. ACOG has criteria, requires that a panel must have childhood onset, have a 1 in 100 carrier frequency, etc. This can be found in ACOG committee opinions 690 and 691. The purpose of this new code is to prevent code stacking. Consider coverage for a limited group of patients (adopted, unexplained family history, h/o repeated miscarriages).
b. Decision: HERC staff will identify the ACOG guidelines referenced (#690 and #691). Staff will also research why carrier panel testing was specifically excluded from the prenatal genetic testing guideline. The GAP recommendation is to place this code on the Diagnostic Procedures File, and staff will have this further research done prior to the VBBS discussion of this recommendation. Staff will work on edits to the prenatal genetic testing guideline regarding this test and circulate among GAP members for final approval.

Review of the Non-prenatal Genetic Testing Guideline

Smits first reviewed the annual updates required for the NCCN guidelines and changes required for the 2019 CPT codes. There was no discussion of this section. Smits then reviewed the requests for changes to the guideline from Myriad. The GAP members agreed that the hereditary cancer testing section should be revmoed from the larger guideline and become its own guideline. Hereditary cancer testing is different than other genetic testing in symptomatic individuals, and has extensive guidelines from NCCN governing utilization. This will help clarify that hereditary cancer testing does not fall under the 10% probability of finding a genetic mutation required in the larger non-prenatal genetic testing guideline.

Withing hereditary cancer genetic testing, the GAP agreed that the section on breast and ovarian cancer syndrome genetic testing for patients with a history of cnacer should have “women” changed to “patient” to include men with a history of breast or associated cancers. The section for patients without a personal history of cancer should be changed to include other associated cancers which are included in NCCN guidelines.

There was discussion about the suggested wording changes to the hereditary cancer panel testing section. The GAP members felt that this section should not be restricted to just colon and breast/ovarian cancer, as there are many other hereditary cancer syndromes. They approved removing the section requiring the panel to have at least 5 genes mentioned in the NCCN breast/ovarian or colon cancer guidelines and remove

the limit of "a reasonable number of genes." GAP member noted that they routinely use panel testing rather than single or a few gene tests, and that these panels are more cost effective. Many of these panels have 150+ genes.

There was extensive discussion regarding who should be allowed to provide genetic counseling in the guideline. Currently, only providers with board certification or eligibility in certain genetic related areas are acceptable as genetic counselors. Myriad requested broadening this out to include a wide variety of providers, including PCPs. GAP members noted that this was consistent with NCCN guidelines, but expressed concern that some providers might be well trained and experienced, while others may not be. There was concern that without a demonstrable board certification, there would be no way to verify training and experience. If the counseling requirement is changed, the GAP members felt that the term "genetic counseling" needed to be changed to "informed consent" as most of these provider types did not actually do genetic counseling. Generally, GAP members were uncomfortable with broadening the range of providers for genetic counseling. Access was noted to be limited in certain areas of the state to genetic counselors, although there has been more work on virtual visits. The GAP members did note that hereditary cancer testing should be opened to any provider mentioned in the NCCN guidelines. For the new hereditary cancer guideline, they suggested taking out the wording specifying the type of provider. However, this wording should be left in the general non-prenatal genetic testing guideline. If this suggestion is not acceptable to the HERC, the GAP suggests convening a work group on genetic counseling, with hereditary cancer testing separated from cancer testing and other types of genetic testing. This workgroup should balance access with appropriateness of services.

Review of microarray testing

Smits reviewed the summary document and the Washington HTA review of the technology. Kovak was in favor of continuing coverage for microarray testing. In her experience, most of the kids seen for consideration of such testing have more than one symptom. It is rare to see kid for genetic testing with just autism. Kovak felt the testing was appropriate to continue to cover as listed. This testing may also affect reproductive decision making. Most of these conditions are rare individually, so it is hard to find literature on change in outcome for any one condition which might be found on microarray testing. Other GAP members agreed on no change in coverage. GAP members felt that such testing helps to get kids needed services.

Review of the Prenatal Genetic Testing Guideline

Smits reviewed the summary document of suggested changes. There was no discussion of the changes based on 2019 CPT codes in the guideline. Next the group discussed which of the additional CPT codes identified by staff were appropriate to add. This section was reviewed in response to a GAP request that staff identify missing CPT codes for amniocentesis, serum genetic screening, etc. The GAP members agreed to all the staff suggested additions except for 84163, 84702 and 86336, which were not added.

There was discussion about adding male partners of pregnant women to this guideline for women who are found to be the carrier of a recessive condition. The GAP members were unsure if such testing should be added to the prenatal or the non-prenatal genetic testing guideline. Currently, in the non-prenatal guideline, there is wording about testing for carrier status for cystic fibrosis and for Ashkenazi Jewish carrier testing panel. However, spinal muscular atrophy carrier screening is a new 2019 CPT code and not included in the non-prenatal genetic testing guideline. Staff added SMA carrier screening to the non-prenatal genetic testing guideline with the restriction that it be covered once in a lifetime.

The GAP then looked at the remainder of the prenatal genetic screening guideline. Based on the GAP desire to cover 2019 CPT 81443 regarding expanded carrier screening, the GAP recommended deleting section "P. Expanded carrier screening only for those genetic conditions identified above" of the prenatal guideline and section "C. Expanded carrier screening which includes results for conditions not explicitly recommended for coverage" of the section specifying non-covered tests. Staff could not recall why such expanded carrier screening was expressly called out for non coverage. Gingerich thought that it might be due to an old coverage guidance. Staff will research why expanded carrier testing was explicitly excluded in the past and bring this as a separate topic for discussion at the November VBBS/HERC meetings.

GAP members requested that the second genetic screening test explicitly listed for non-coverage, "B. Screening for thrombophilia in the general population or for recurrent pregnancy loss" be reviewed for deletion at the 2019 GAP meeting.

Cell free fetal DNA screening for low risk women

Smits reviewed the summary document and reviewed the literature about the sensitivity, specificity, and economic analyses around non-invasive prenatal screening (NIPS). The GAP discussed that ACOG is expected to be coming out soon with a new guideline recommending universal NIPS screening (high and low risk women). There is concern about use of NIPS to determine the gender of the baby. The GAP members did feel that it was a better screening test for trisomies that traditional screening tests. There is a newer form of NIPS that can also give a pre-eclampsia risk which could allow for treatment with aspirin in pregnancy to lower the risk of pre-eclampsia. GAP members noted that NIPS is a rapidly changing field.

Ashley Allen from Roche Diagnostics noted that NIPS is a more sensitive and specific test that traditional screening, and will reduce the number of women requiring invasive procedures such as amniocensis, which lowers cost and adverse outcomes. She states that most private payers in Oregon (Premara, Regence, Anthem) cover all risk women for NIPS. Not covering for OHP causes disparities.

It was noted by an audience member that the ACOG guideline says that any type of screening is appropriate, but does not say that NIPS should be restricted to high risk women. Therefore, the current ACOG opinion could be interpreted to indicate that ACOG feels that NIPS is appropriate for all risk women. Far more women have false positive tests with traditional screening methods, causing increase invasive testing and expense.

The GAP decision was to make no change in the current restriction of NIPS to high risk women. HERC staff will monitor for the new ACOG statement expected to come out in favor of universal NIPS screening. If ACOG publishes such an opinion, GAP would be in favor of changing the prenatal genetic testing guideline to allow use for low and high risk women. Such a change can be made prior to the next GAP meeting or can be taken up at the 2019 GAP meeting.

Public testimony:
Jim Gejewsky testified that GAP should consider recommending coverage of whole exome sequencing. This test is appropriate for a child with clinical descriptive genetic abnormality and no specific diagnosis. Children and families need a specific diagnosis in many cases to receive services from schools, appropriate medical supportive services, etc.

The GAP members felt that this was worth consideration, but that there were no materials to review for this meeting. Whole exome sequencing will be placed on the agenda for the 2019 GAP meeting. HERC staff were directed to relook at the literature on this topic, including any available MED reports and national guidelines prior to that meeting.

Adjournment
The meeting adjourned at 11:30 AM

Section 2.0

VBBS Report

Diabetes Prevention Program Coding Update

Question: Should additional codes for the Diabetes Prevention Program (DPP) be added to Line 3, the Preventive Services line?

Issue: HERC adopted a new guideline and coverage of the national Diabetes Prevention Program to go into effect January 1, 2019. Medicare has a series of specific G codes for offering the Medicare Diabetes Prevention Program. FFS is not using these codes because it would not result in sustainable funding, however, CCOs could pay differently than FFS and may choose to use these codes.

The other issue identified is that the CDC calculator for BMI goes through age 19 and the guideline starts at age 18. So it is possible that an 18 or 19 year old would come through the system with the BMI percentile codes inserted rather than BMI codes. The CDC defines overweight as a BMI at or above the 85th percentile and below the 95th percentile for children and teens of the same age and sex. Obesity is defined as a BMI at or above the 95th percentile for children and teens of the same age and sex.

DPP CDC Standards and Operating Procedures 2018:
https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf

Codes in question:

Z68.53	Body mass index (BMI) pediatric, 85th percentile to less than 95th percentile for age
Z68.54	Body mass index (BMI) pediatric, greater than or equal to 95th percentile for age

G9873	First Medicare Diabetes Prevention Program (MDPP) core session was attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions
G9874	Four total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.
G9875	Nine total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions
G9876	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7-9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7-9.

G9877	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10-12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10-12.
G9878	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7-9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions.The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7-9.
G9879	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10-12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions.The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10-12
G9880	The MDPP beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight in months 1-12 of the MDPP services period under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 5% weight loss from baseline as measured by an in-person weight measurement at a core session or core maintenance session.
G9881	The MDPP beneficiary achieved at least 9% weight loss (WL) from his/her baseline weight in months 1-24 under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 9% weight loss from baseline as measured by an in-person weight measurement at a core session, core maintenance session, or ongoing maintenance session.
G9882	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 13-15 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 13-15.

G9883	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 16-18 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 16-18.
G9884	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 19-21 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 19-21.
G9885	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 22-24 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 22-24.
G9890	Bridge Payment: A one-time payment for the first Medicare Diabetes Prevention Program (MDPP) core session, core maintenance session, or ongoing maintenance session furnished by an MDPP supplier to an MDPP beneficiary during months 1-24 of the MDPP Expanded Model (EM) who has previously received MDPP services from a different MDPP supplier under the MDPP Expanded Model. A supplier may only receive one bridge payment per MDPP beneficiary.
G9891	MDPP session reported as a line-item on a claim for a payable MDPP Expanded Model (EM) HCPCS code for a session furnished by the billing supplier under the MDPP Expanded Model and counting toward achievement of the attendance performance goal for the payable MDPP Expanded Model HCPCS code.(This code is for reporting purposes only).

<u>Prioritized List Status</u> (as of January 1, 2019)

GUIDELINE NOTE XXX DIABETES PREVENTION PROGRAM

Line 3

Prediabetes (R73.03) and personal history of gestational diabetes (Z86.32) are included on this line only for the Diabetes Prevention Program (DPP). The only programs included are CDC-recognized lifestyle change programs for DPP.

To be eligible for referral to a CDC-recognized lifestyle change program, patients must meet the following requirements:

- Be at least 18 years old and
- Be overweight (body mass index ≥25; ≥23 if Asian) and
- Have no previous diagnosis of type 1 or type 2 diabetes and
- Not have end-stage renal disease and
- Have a blood test result in the prediabetes range within the past year:
    - Hemoglobin A1C: 5.7%–6.4% or
    - Fasting plasma glucose: 100–125 mg/dL or
    - Two-hour plasma glucose (after a 75 gm glucose load): 140–199 mg/dL or
    - Be previously diagnosed with gestational diabetes

HERC Staff Recommendations

1. Add G9873 – G9885, and G9890-G9891 to Line 3
2. Add Z68.53-Z68.54 to Line 3 for pediatric overweight/obesity (i.e. for 18-19 year olds)

Latent TB

Question: where should the ICD-10 codes for latent TB be placed on the Prioritized List?

Question source: P&T staff, CCO

Issue: Latent TB is an asymptomatic infection with tuberculosis bacteria. It is diagnosed with a positive skin test or a positive blood test. Usually following the positive screening test, additional testing such as a chest Xray will be done. Latent TB is treated following CDC guidelines, to prevent the development of active TB disease and reduce the transmission of TB to others.

From the CDC:

> People with latent TB infection do not have symptoms, and they cannot spread TB bacteria to others. However, if latent TB bacteria become active in the body and multiply, the person will go from having latent TB infection to being sick with TB disease. For this reason, people with latent TB infection should be treated to prevent them from developing TB disease. Treatment of latent TB infection is essential to controlling TB in the United States because it substantially reduces the risk that latent TB infection will progress to TB disease. In the United States, up to 13 million people may have latent TB infection. Without treatment, on average 1 in 10 people with latent TB infection will get sick with TB disease in the future

Currently, the ICD-10 codes for latent TB (ICD10 R76.11 Nonspecific reaction to tuberculin skin test without active tuberculosis and R76.12 Nonspecific reaction to cell mediated immunity measurement of gamma interferon antigen response without active tuberculosis) are on the Diagnostic Workup File (DWF). Recently a question arose about the HERC's intent for treatment of latent TB, as diagnoses on the DWF are not eligible for treatments such as medications. Latent TB is treated with various anti-tubercular medications such as isoniazid.

ICD10 Z20.1 (Contact with and (suspected) exposure to tuberculosis) is on line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

HERC staff recommendations:

1) Add ICD10 R76.11 (Nonspecific reaction to tuberculin skin test without active tuberculosis) and R76.12 (Nonspecific reaction to cell mediated immunity measurement of gamma interferon antigen response without active tuberculosis) to line 50 PULMONARY TUBERCULOSIS
    a. Alternative placement options:
        i. Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
        ii. line 152 NON-PULMONARY TUBERCULOSIS

Yttrium-90 for Hepatocellular Carcinoma
November 2018

Question: Should yttrium-90 (Y90) be added back to the liver cancer line with a guideline limiting use to a select group of patients?

Question source: Providence oncology group, OHSU oncology and radiology groups

Issue: Y90 for treatment of hepatocellular carcinoma (HCC) and colorectal cancer (CRC) liver metastases to the liver was reviewed in 2015 and 2018. During the 2015 review, it was noted that the data was limited on outcomes, but that two large trials were currently underway. These trials were completed and reviewed during the January 2018 VBBS/HERC meetings.

The SARAH trial (Vilgrain 2017) examined the efficacy of Y90 for treatment of locally advanced or intermediate stage hepatocellular carcinoma (HCC) who had previously had unsuccessful transarterial chemoembolization. The SARAH study found that Y90 did not have a significant difference in survival compared to sorafenib (standard chemotherapy). It was noted that 22% of patients in the Y90 arm did not receive that treatment.

Wasan (2017) reported on the FOXFIRE, SIRFLOX and FOXFIRE-Global studies of yttrium-90 with chemotherapy compared to chemotherapy alone for colorectal liver metastases to the liver. Addition of SIRT to first-line FOLFOX chemotherapy for patients with liver-only and liver-dominant metastatic colorectal cancer did not improve overall survival compared with that for FOLFOX alone.

During the January 2018 review, it was noted that NCCN recommended locoregional therapy (Y90 being one option) for "patients who are not candidates for surgical curative treatments, or as part of a strategy to bridge patients to other curative therapies" for HCC.

Based on the SARAH and FOXFIRE/SIRFLOX/FOXFIRE-Global studies, the HERC determined that Y90 was no more effective that standard chemotherapy for treatment of HCC or metastatic CRC to the liver, but had increased costs. Based on this determination, Y90 (CPT 79445, HCPCS C2616, S2095) was added to GN172/line 500 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS for treatment of primary hepatocellular carcinoma, or colorectal cancer metastatic to the liver.

A later review in March 2018, added Y90 therapy to line 660, CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS for all cancers other than primary hepatocellular carcinoma or colorectal cancer metastatic to the liver.

The Providence and OHSU oncology groups have reached out to HERC staff requesting consideration of use of Y90 in particular clinical situations. These groups have shared their treatment algorithm for HCC, which is based on NCCN guidelines and two large retrospective studies. Based on their algorithm, Y90 is used for patients who are not candidates for surgical resection with a single lesion to allow downsizing which may allow resection; or as a palliative treatment option for patients with late stage HCC.

Current Prioritized List status

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

Line 500

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

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

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

Line 660

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

79445 C2616 S2095	Radiopharmaceutical therapy, by intra-arterial particulate administration for use in treating cancers other than primary hepatocellular carcinoma or colorectal cancer metastatic to the liver Brachytherapy source, non-stranded, yttrium-90, per source in treating cancers other than primary hepatocellular carcinoma or colorectal cancer metastatic to the liver. Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres, in treating cancers other than primary hepatocellular carcinoma or colorectal cancer metastatic to the liver	No evidence of effectiveness	March, 2018

Yttrium-90 for Hepatocellular Carcinoma
November 2018

From Philippa Newell, MD, Medical Director, Liver Cancer Program, Providence Cancer Center; Hepatobiliary Surgeon

> …we try to get as many patients we can to a cure. Curative treatments include resection, transplantation, and ablation. These are limited to patients with a healthy liver reserve and/or small tumors. Y-90 embolization is more successful at downsizing tumors than chemoembolization (TACE) (ref: Downstaging HCC, Hepatol 2016, Vouche). Also, it can result in hypertrophy of the other side of the liver and therefore can allow us to get patients to resection.
>
> If patients are incurable, we use Y90 in patients who cannot get TACE because of portal vein tumor thrombosis. Portal vein tumor thrombosis occurs when the HCC progresses into the portal vein. This is considered advanced stage HCC and the survival of these patients is usually around 6 months, 8 months on sorafenib systemic therapy (ref: SHARP Trial, NEJM 2008, Llovet). In patients with good liver reserve and unilateral portal vein tumor thrombosis, Y90 can palliate pain and can sometimes lead to complete devascularization. A small percentage of these patients (10-15%) can live over 5 years if they have a complete response (ref: Multimodal Tx HCC, HPB 2015, Newell).
>
> The SARAH Trial (ref: Efficacy of SIRT or sorafenib, Ann Oncol 2017, Mohamed) that was used for the decision not to fund Y90 was performed in France, where in many centers Y90 was used for the first time as part of this study. 26% of patients randomized to Y90 did not get treated with Y90. 70% of the patients in the SARAH study had advanced stage HCC. Again, we often use Y90 in patients with early and intermediate stage HCC, and only sparingly in patients with advanced stage HCC (please see attached algorithm).

After review of the initial HERC staff proposed guideline for limited use of Y90, experts agreed with all entries, except requested that staff include patients with lesions >5cm who do not have portal vein thrombosis. Per Dr. Newell, "These patients can have complete responses with only 1 or 2 Y-90 treatments, rather than 6-10 TACE treatments. There is a lot of data showing the Y90 procedure is better tolerated than chemoembolization, meaning, less overnight hospital stays and readmissions for post embolization syndrome and hepatic decompensation."

Evidence

1) **Kulik 2018**, https://www.aasld.org/sites/default/files/Kulik_Therapies%20for%20HCC%20Patients%20Awaiting%20LT%20et_al-2018-Hepatology-bookmarked.pdf Systematic review and meta-analysis of therapies for HCC awaiting liver transplantation
    a. No RCTs identified
    b. For adults with T1 HCC waiting for liver transplant (LT): two nonrandomized comparative studies, both with a high risk of bias
        i. In one series, the rate of dropout from all causes at 6 months in T1 HCC patients who underwent locoregional therapy (LRT) was 5.3%, while in the other series of T1 HCC patients who did not receive LRT, the dropout rate at median follow-up of 2.4 years and the progression rate to T2 HCC were 30% and 88%, respectively
    c. For adults with T2 HCC awaiting LT, transplant with any bridging therapy: 3 comparative studies with high risk of bias
        i. A nonsignificant reduction in the risk of waitlist dropout due to progression (relative risk [RR], 0.32; 95% confidence interval [CI], 0.06-1.85; I2 5 0%) and of waitlist dropout from all causes (RR, 0.38; 95% CI, 0.060-2.370; I2 5 85.7%) compared to no therapy
    d. There were five comparative studies which reported on posttransplant survival rates and 10 comparative studies which reported on posttransplant recurrence, and there was no significant difference seen in either of these endpoints.
    e. For adults initially with stage T3 HCC who received LRT, there were three studies reporting on transplant with any downstaging therapy versus no downstaging with serious risk of bias and imprecision
        i. A significant increase in 1-year (two studies, RR, 1.11; 95% CI, 1.01-1.23) and 5-year (1 study, RR, 1.17; 95% CI, 1.03-1.32) post-LT survival rates for patients who received LRT.
    f. Conclusion: In patients with HCC listed for LT, the use of LRT is associated with a nonsignificant trend toward improved waitlist and posttransplant outcomes, though there is a high risk of selection bias in the available evidence.
2) **Rognoni 2017**, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5342166/pdf/oncotarget-07-72343.pdf systematic review and meta-analysis of trans-arterial radioebolization in intermediate and advanced HCC
    a. N=22 studies, all cohort except 1 RCT with 13 patients
    b. The pooled post-TARE observed survival (OS) was 63% (95% CI: 56-70%) and 27% (95% CI: 21-33%) at 1- and 3-years respectively in intermediate stage HCC, whereas OS was 37% (95% CI: 26-50%) and 13% (95% CI: 9-18%) at the same time intervals in patients with sufficient liver function (Child-Pugh A-B7) but with an advanced HCC because of the presence of portal vein thrombosis. When an intermediate and advanced case-mix was considered, OS was 58% (95% CI: 48-67%) and 17% (95% CI: 12-23%) at 1- and 3-years respectively.
    c. As for TTP, only four studies reported data: the observed progression probability was 56% (95% CI: 41-70%) and 73% (95% CI: 56-87%) at 1 and 2 years respectively.
    d. The safety analysis, focused on the risk of liver decompensation after TARE, revealed a great variability, from 0-1% to more than 36% events, influenced by the number of procedures, patient Child-Pugh stage and treatment duration.

e. Conclusion: Evidence supporting the use of radioembolization in HCC is mainly based on retrospective and prospective cohort studies. Based on this evidence, until the results of the ongoing randomized trials become available, radioembolization appears to be a viable treatment option for intermediate-advanced stage HCC.

Expert guidelines

1) **NCCN 2018,** guideline for hepatobiliary carcinoma
   a. Arterially directed therapies including radioembolization with Y90 microspheres are appropriate for patients with unresectable or inoperable tumors that are not amenable to ablation therapy.
   b. Bridge therapy to liver transplant: the small size and retrospective methodology of studies as well as the heterogeneous nature of the study populations, and the absence of RCTs evaluating the utility of bridge therapy for reducing the liver transplantation waiting list drop-out rate, limit the conclusions that can be drawn.
      i. Bridge therapy later noted as "can be considered for patients with HCC to decrease tumor progression and the dropout rate from the liver transplantation waiting list"
   c. Downstaging therapy: prospective studies have demonstrated that downstaging prior to transplant with various therapies including Y90 improves outcomes such as DFS and recurrence following transplant. However…further validation is needed to define the endpoints for successful downstaging prior to transplant
2) **AASLD 2018**, HCC guideline https://www.aasld.org/sites/default/files/guideline_documents/HCC%20Guideline%202018.pdf
   a. Question 4: SHOULD ADULTS WITH CHILD-PUGH CLASS A CIRRHOSIS AND EARLY-STAGE HCC (T1 OR T2) BE TREATED WITH RESECTION OR LOCOREGIONAL THERAPY (LRT)?
      i. The AASLD suggests that adults with Child- Pugh class A cirrhosis and resectable T1 or T2 HCC undergo resection over radiofrequency ablation.
         1. Quality/Certainty of Evidence: Moderate
         2. Strength of Recommendation: Conditional
      ii. Direct comparative studies of resection versus other types of LRT—such as transarterial radioembolization (TARE) and transarterial chemoembolization (TACE) or other forms of ablative therapy, such as radiation and microwave—are not available, though indirect evidence favors resection
   b. Question7 SHOULD ADULTS WITH CIRRHOSIS AND OPTN T2 HCC AWAITING LIVER TRANSPLANTATION UNDERGO TRANSPLANT ALONE OR TRANSPLANT WITH BRIDGING THERAPY WHILE WAITING?
      a. The AASLD suggests bridging to transplant in patients listed for liver transplantation within OPTNT2 (Milan) criteria to decrease progression of disease and subsequent dropout from the waiting list.
         1. Quality/Certainty of Evidence: Very Low
         2. Strength of Recommendation: Conditional
         3. Bridging is defined as the use of LRT—such as TACE, yttrium-90 (Y90), ablative therapy, or a combination of different types of LRT such as TACE and ablation—to induce tumor death and deter tumor progression beyond the Milan criteria.

   b. The AASLD does not recommend one form of liver-directed therapy over another for the purposes of bridging to liver transplantation for patients within OPTN T2 (Milan) criteria.
      ii. Quality/Certainty of Evidence: Very Low
      iii. Strength of Recommendation: Conditional
c. Question 8 SHOULD ADULTS WITH CIRRHOSIS AND HCC BEYOND MILAN CRITERIA (T3) BE TRANSPLANTED FOLLOWING DOWNSTAGING TO WITHIN MILAN CRITERIA?
   a. The AASLD suggests that patients beyond the Milan criteria (T3) should be considered for liver transplantation after successful downstaging into the Milan criteria.
      i. Quality/Certainty of Evidence: Very Low
      ii. Strength of Recommendation: Conditional
      iii. The optimal form of liver-directed therapy for the purposes of downstaging cannot be determined based on the available data.
d. Question 9 SHOULD ADULTS WITH CIRRHOSIS AND HCC (T2 OR T3, NO VASCULAR INVOLVEMENT) WHO ARE NOT CANDIDATES FOR RESECTION OR TRANSPLANTATION BE TREATED WITH TACE, TARE, OR EXTERNAL RADIATION?
   a. The AASLD recommends LRT (locoregional therapy) over no treatment in adults with cirrhosis and HCC (T2 or T3, no vascular involvement) who are not candidates for resection or transplantation.
      i. Quality/Certainty of Evidence:
         1. TACE: Moderate
         2. Transarterial Bland Embolization: Very Low
         3. TARE: Very Low
         4. External Radiation: Very Low
      ii. Strength of Recommendation: Strong
   b. The AASLD does not recommend one form of LRT over another.
      iii. Quality/Certainty of Evidence: Very low
      iv. Strength of Recommendation: Conditional
e. Question 10 SHOULD ADULTS WITH CHILD-PUGH CLASS A/B CIRRHOSIS AND ADVANCED HCC WITH MACROVASCULAR INVASION AND/OR METASTATIC DISEASE BE TREATED WITH SYSTEMIC THERAPY OR LRT OR NO THERAPY?
   a. The AASLD recommends the use of systemic therapy over no therapy for patients with Child-Pugh class A cirrhosis or well-selected patients with Child- Pugh class B cirrhosis plus advanced HCC with macrovascular invasion and/or metastatic disease.
      i. Quality/Certainty of Evidence: Moderate
      ii. Strength of Recommendation: Strong
      iii. It was not possible to make a recommendation for systemic therapy over LRT, because there was inadequate evidence to inform the balance of benefit versus harm.

3) **ESMO 2018**, HCC guideline https://academic.oup.com/annonc/article-pdf/29/Supplement_4/iv238/25899715/mdy308.pdf
   a. Early and intermediate stage HCC
      i. Selective internal radiation therapy (SIRT, including Y90) is not recommended as first-line therapy for HCC patients in intermediate and advanced stage [Level of evidence I, strong evidence against efficacy E].

ii. in exceptional circumstances, for patients with liver-confined disease and preserved liver function in whom neither TACE nor systemic therapy is possible, SIRT may be considered.
iii. Additionally, SIRT may be considered instead of TACE for the treatment of small tumours in patients waiting for liver transplantation, in an attempt to avoid drop-out from the list due to tumour progression

b. Advanced disease
   i. SIRT not mentioned as a treatment option

4) **NICE 2016** SIRSpheres for inoperable HCC
https://www.nice.org.uk/advice/mib63/resources/sirspheres-for-treating-inoperable-hepatocellular-carcinoma-pdf-63499285313989
   a. SIR-Spheres can be used to treat inoperable hepatocellular carcinoma (HCC). It may be an alternative or adjunct to conventional transarterial chemoembolisation (TACE), drug-eluting bead TACE (DEB-TACE) or systemic drugs to control tumour size, extend life, reduce symptoms or to shrink tumours for resection or transplantation.
      i. 11 studies (n=1089 patients). Three were non-randomised comparative, 3 were randomised comparative and 5 were non-comparative. The studies compared SIR-Spheres with conventional TACE, DEBTACE, sorafenib either alone or in combination with SIR-Spheres, and with active or supportive care.

5) **NICE 2016**, TheraSphere for inoperable HCC
https://www.nice.org.uk/advice/mib62/resources/therasphere-for-treating-operable-and-inoperable-hepatocellular-carcinoma-pdf-63499283634373
   a. TheraSphere can be used to treat operable and inoperable hepatocellular carcinoma (HCC). It may be an alternative or adjunct to conventional transarterial chemoembolization (TACE) with lipiodol, drug-eluting bead TACE (DEB-TACE) or systemic drugs to control tumour size, extend life or reduce symptoms in people with inoperable tumours, or to shrink tumours for resection or transplantation.
   b. TheraSphere may be a treatment option for patients with portal vein thrombosis, which is an adverse prognostic factor in patients with HCC
   c. Based on review of 11 studies (n=1205 patients). Seven studies were non-randomised comparative studies and 4 were non-comparative studies. Five studies compared TheraSphere with conventional TACE with lipiodol, 1 with doxorubicin DEB-TACE, and 1 with hepatic artery infusion (HAI) of cisplatin

Other payer policies

1) Aetna 2018
   a. Covers Y90 for unresectable, primary HCC; unresectable liver tumors from primary colorectal cancer; Pre-operative use as a bridge to orthotopic liver transplantation for HCC
      i. Additional indications/tumor types are covered in certain circumstances

2) Regence BCBS 2018
   a. Radioembolization may be considered **medically necessary** for treatment of any of the following:
      i. Unresectable primary liver tumors (hepatocellular carcinoma [HCC])
      ii. As a bridge to transplantation in primary HCC
      iii. Additional indications/tumor types are covered in certain circumstances

Yttrium-90 for Hepatocellular Carcinoma
November 2018

HERC staff summary

High level evidence for the use of Yttrium 90 (RCT level evidence) exists only for use of Y90 as first line treatment for HCC or for CRC metastatic to the liver; this evidence does not support its use in this situation. Expert guidelines and local expert opinion also do not recommend Y90 for first line treatment of HCC or CRC metastatic to the liver.

Lower level evidence (cohort studies, case series, expert opinion) does support the use of Y90 in limited clinical situations:

1) Treatment of patients on the liver transplant wait list to reduce the risk of disease progression and loss of eligibility for transplant. The evidence to support this use is 3 cohort studies showing a non-significant trend for decreased drop out rates from all causes with any bridging therapy compared to observation. Expert guidelines (NCCN, AASLD, ESMO) conditionally recommend this use with wording such as "can be considered" and note the very low level of evidence. Local experts do not include this situation in the list of requested uses for Y90.
2) Downsizing tumors in patients who could become eligible for transplant or resection. The evidence to support this use is 3 cohort studies showing a significant increase in 1 year and 5 year survival for patients who received any form of locoregional therapy compared to no downsizing. NCCN notes that studies show improved outcomes with Y90 in this situation, but also notes that further validation is needed. ESMO does not recommend use in this situation. However, AASLD and local experts do recommend Y90 for this clinical situation.
3) Palliative treatment of incurable patients with unresectable or inoperable tumors that are not amenable to ablation therapy with good liver function and performance status, who have either intermediate stage HCC with tumors >5cm or advanced stage HCC with unilateral portal vein tumor thrombus. The evidence supporting this indication include 22 studies (21 cohort, 1 small RCT). NCCN and AASLD recommend some type of locoregional therapy in these situations. ESMO does not mention this as an option.

HERC staff, while researching this topic, discovered that CPT 79440 (Radiopharmaceutical therapy, by intra-articular administration) is on many lines, including liver cancer. Most of these lines are inappropriate; this code could be restricted to lines with joint involved tumors (benign or malignant).

HERC staff recommendations:

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

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

Line 500

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

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

4) Make no change to the entry on line 600/GN173 for non-liver use of Yttrium 90

5) Add a new guideline to line for line 315 CANCER OF LIVER as shown below
    a. Consider not including circumstance #1 below as not requested by local providers

GUIDELINE NOTE XXX, YTTRIUM 90 THERAPY

Line 315

Yttrium 90 therapy is only included on this line for treatment of hepatocellular carcinoma (HCC) and only in the following circumstances:

1) Treatment of patients on the liver transplant wait list to reduce the risk of disease progression and loss of eligibility for transplant, OR
2) Downsizing tumors in patients who could become eligible for curative treatment (transplant, ablation, or resection), OR
3) Palliative treatment of incurable patients with unresectable or inoperable tumors that are not amenable to ablation therapy with good liver function and performance status, who have intermediate stage disease with tumors > 5 cm or advanced stage HCC with unilateral portal vein tumor thrombus.

Pancreas Transplant Alone for Type 1 Diabetes

Question: Should coverage of pancreas transplant alone for Type 1 Diabetes be modified?

Question source: OHA Hearings Division; OHSU and patient

Issue: This issue was raised based on a specific case through OHSU in which OHP denied a pancreas transplant for a patient who has Type 1 diabetes and preserved kidney function. Currently, pancreas transplant is only covered on the Prioritized List when performed simultaneously with kidney transplant, or after kidney transplant. The patient raised the question of why they would need to wait for further kidney damage rather than have the pancreas transplant alone performed earlier, to prevent the kidney damage.

Prioritized List Status:

Line: 84

Condition: DIABETES MELLITUS WITH END STAGE RENAL DISEASE (See Coding Specification Below)

Treatment: SIMULTANEOUS PANCREAS/KIDNEY (SPK) TRANSPLANT, PANCREAS AFTER KIDNEY (PAK) TRANSPLANT

ICD-10: E10.21-E10.29,T86.10-T86.19,T86.850-T86.899,Z48.22,Z48.288

CPT: 48160,48550-48556,50300-50365,76776,86825-86835,93792,93793,96150-96155,98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99449,99468-99480,99487-99490,99495-99498,99605-99607

HCPCS: G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467, G0490,G0508-G0511,G0513,G0514,S2065

SPK included for type I diabetes mellitus with end stage renal disease (E10.2), PAK only included for other type I diabetes mellitus with secondary diagnosis of Z94.0.

Evidence Summary:

Dean, 2017

1. Clinical review of pancreas transplantation
2. Indication for pancreas transplant alone is diabetes complicated by frequent, severe (requiring third party intervention or hospital admission) metabolic complications despite intensive insulin therapy. This problem is often caused by unawareness of hypoglycemia and diabetic ketoacidosis or severe hyperglycemia that requires hospital admission. For such patients, PTA can restore glucose homeostasis and provide freedom from hypoglycemia.

3. The relative disadvantages of PTA are higher rates of technical graft loss and acute cellular rejection compared with SPK transplants and potential deleterious effects on the recipient's native renal function.
4. Perhaps because of the relatively small number of PTAs performed, **no published reports have rigorously studied the efficacy (for example, freedom from hypoglycemia) or quality of life benefits of PTA. This is an area in need of additional study.**
5. In the US, five-year patient survival rates are currently 93% for SPK, 91% for PAK, and 78% for PTA recipients, respectively. Five-year pancreas graft survival rates (based on center reported data) are currently 73% for SPK, 65% for PAK, and 53% for PTA. The Scientific Registry of Transplant Recipients has not reported pancreas graft survival rates in more than two years because of the lack of a consistent definition of graft failure.
6. In the UK for pancreas only transplants, the five-year patient and graft survival rates are 78% (64% to 87%) and 45% (36% to 53%), respectively.
7. There is a survival disadvantage for PTA alone (Venstrome, 2003)
8. There is no survival disadvantage (or advantage) to PTA alone (Gruessner, 2004)

Venstrom, 2003

1. Retrospective observational cohort study conducted at 124 transplant centers in the United States
2. N= 11572 patients with diabetes mellitus on the waiting list for pancreas transplantation (pancreas alone, pancreas after-kidney, or simultaneous pancreas-kidney) at the United Network for Organ Sharing/Organ Procurement and Transplantation Network between January 1, 1995, and December 31, 2000. All patients receiving a multiorgan (other than simultaneous pancreas kidney) transplant were excluded, as were those listed for solitary pancreas transplantation who had a serum creatinine level greater than 2 mg/dL (176.8 µmol/L) at time of listing, or who ultimately received a simultaneous pancreas-kidney transplant.
3. Results: Overall relative risk of all-cause mortality for transplant recipients (compared with patients awaiting the same procedure) over 4 years of follow-up was 1.57 (95% confidence interval [CI], 0.98-2.53; *P*=.06) for pancreas transplant alone, 1.42 (95% CI, 1.03-1.94; *P*=.03) for pancreas-after-kidney transplant, and 0.43 (95% CI, 0.39-0.48) for simultaneous pancreas-kidney transplant.
    a. Transplant patient 1- and 4-year survival rates were
        i. 96.5% and 85.2% for pancreas transplant alone
        ii. 97.6% and 92.1% on the waiting list for PTA
4. Conclusion: From 1995-2000, survival for those with diabetes and preserved kidney function and receiving a solitary pancreas transplant was significantly worse compared with the survival of waiting-list patients receiving conventional therapy

Gruessner, 2004

1. Retrospective cohort study of UNOS waiting lists, 1995-2003
2. 1207 were waitlisted for pancreas transplant alone
    a. Excluded patients with multiple listings at different transplant centers, included a more recent patient cohort, and extended the follow-up period. They also did not exclude patients with abnormal creatinine levels.
3. Results:
    a. On the waiting list, patient survival rates at 1 and 4 years of 96.6% and 87.3%.
    b. Patient survival rates at 1 and 4 years post-transplant were 97.0% and 90.5% ($p > 0.168$).
2. Conclusions: In summary, the mortality for solitary pancreas transplant recipients is not higher than for wait-listed patients.

Choi, 2017

1. Retrospective single center study, February 2000 and December 2015
2. N=89 for pancreas transplant alone compared to N = 116 compared to patients on the waiting list for PTA
3. Waiting list with 4.3% death rate; PTA 4.5% death rate
4. For PTA, the overall relative risk of death following transplantation was 2.145 [95% confidence interval (CI): 0.531 ±8.684; $p = 0.285$). Until the first year, PTA recipients had a 1.86-fold higher risk of death than patients on the waiting list for the same period (95% CI: 0.146 ±23.72; $p = 0.632$). After the first year, they had a relative risk of 2.069 (95% CI: 0.289 ±14.832; $p = 0.049$); however, this association was not statistically significant.
5. PTA can be considered as a treatment option as patient survival was not poor.

Shin, 2018

https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0191421#sec005

1. Retrospective single-center cohort study
2. N = 163 patients with type 1 diabetes and preserved renal function, 79 in transplanted group and 84 in matched nontransplanted group who were candidates for PTA
3. Results:
    a. PTA group – 7 recipients (8.9%) had end-stage renal disease post-transplant whereas only one patient (1.2%) developed end-stage renal disease in the nontransplanted group during their follow-up period (median 12.0, range 6–96 months) ($p = 0.03$).
    b. Furthermore, a composite of severe renal dysfunction and end-stage renal disease (31.6% vs 2.4%) was significantly higher in the transplanted group ($p < 0.001$).
    c. Multivariate Cox regression analysis revealed that a higher level of tacrolimus at six months post-transplant (HR = 1.648, CI = 1.140–2.385,

p = 0.008) was the only significant factor associated with end-stage renal disease.

4. Conclusions: There is a considerable risk for deterioration of renal function in PTA recipients post-transplant compared with non-transplant diabetic patients.

Speight, 2010

1. Systematic review of patient reported outcomes after pancreas transplant
2. 12 studies [including PRO assessment of PAK, PTA, islet-after kidney (IAK) and islet transplant alone (ITA); n = 7–205] used a total of nine specified and two unspecified PRO measures.
3. Results were mixed but identified some benefits which remained apparent up to 36 months post-transplant, including improvements in fear of hypoglycaemia, as well as some aspects of diabetes-specific quality of life (QoL) and general health status. Negative outcomes included short-term pain associated with the procedure, immunosuppressant side effects and depressed mood associated with loss of graft function.
4. Conclusions: Mixed results and full impact of QOL is unknown

Guidelines from Others

CMS, 2006 https://www.cms.gov/medicare-coverage-database/shared/handlers/highwire.ashx?url=https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx@@@NCAId$$$166***ver$$$19***NcaName$$$Pancreas+Transplants+(1st+Recon)***bc$$$BEAAAAAAEAAA******fromdb$$$true&session=5ofiqalkjzjdcnia0eujchzb&kq=1645215058

The Centers for Medicare and Medicaid Services (CMS) has determined that the evidence is adequate to conclude that pancreas transplantation alone (PA) is reasonable and necessary for Medicare beneficiaries in the following limited circumstances:

1. PA will be limited to those facilities that are Medicare-approved for kidney transplantation (Approved centers can be found at: http://www.cms.hhs.gov/ESRDGeneralInformation/02_Data.asp#TopOfPage;
2. Patients must have a diagnosis of type I diabetes;
   - The patient with diabetes must be beta cell autoantibody positive, or
   - The patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting Cpeptide levels will only be considered valid with a concurrently obtained fasting glucose ≤225 mg/dL;
3. Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;

4. Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems;
5. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression;
6. Patients must otherwise be a suitable candidate for transplantation.

NHS, 2016
http://odt.nhs.uk/pdf/pancreas_selection_policy.pdf
Pancreas transplant alone/islet transplant alone

- Patients with severe hypoglycaemic unawareness but normal or near-normal renal function
- Patients listed for pancreas transplant alone/islet transplant alone must also have at least two severe hypoglycaemic episodes, as defined by the American Diabetes Association* (ADA), within the last 24 months and be assessed by a diabetologist to have disabling hypoglycaemia.

Canadian Diabetes Association clinical practice guidelines expert committee, 2013

- Reported graft survival rates of pancreas transplant alone (Waki, 2007) https://www.ncbi.nlm.nih.gov/pubmed/18637455)
    - 1 year 78%
    - 5 years 54%
    - 10 years 28%
    - 15 years 9%
- Recommendation: Individuals with type 1 diabetes with preserved renal function, or who have undergone successful kidney transplantation but have persistent metabolic instability characterized by severe glycemic lability and/or severe hypoglycemia despite best efforts to optimize glycemic control, may be considered for pancreas or islet allotransplantation [Grade D, Consensus].

The American Diabetes Association (ADA) criteria for pancreas transplant alone

- Patients without substantial renal disease are candidates for pancreas transplantation alone if they have a history of frequent, acute, severe metabolic complications (hypoglycemia, marked hyperglycemia, ketoacidosis), incapacitating clinical and emotional problems with exogenous insulin therapy, and consistent failure of insulin-based management to prevent acute complications.

HERC Staff Assessment

There is not good evidence demonstrating the relative benefits and harms of pancreas transplant alone for type 1 diabetes with preserved renal function. Management of type 1 diabetes includes regular insulin injections, or an insulin pump, and while a successful pancreas graft can lead to insulin independence, there may be very high rates of graft failure and this benefit may not be prolonged. However, the immunosuppression would be lifelong and has many associated harms. There is mixed evidence on whether it increases mortality, and a recent study suggesting an increase in end stage renal disease. Overall, there is insufficient evidence suggesting the benefits outweigh the harms.

HERC Staff Recommendations:

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

Amniotic Membrane Transplant for Ocular Conditions

Question: which ocular conditions should be paired with amniotic membrane transplant?

Question source: HSD claims reconsideration

Issue: amniotic membrane transplantation is used for a variety of ocular conditions, including ocular burns, ulcers, and pterygium. Amniotic membranes are also used for repair of surgical wounds. Recently, a case was brought to HERC staff attention involving lack of pairing of amniotic membrane transplantation for repair of the cornea after a neoplasm was removed. On review, it appeared to HERC staff that many ocular conditions did not pair with amniotic membrane transplantation. This procedure was last reviewed as part of the 2010 ICD-10 ophthalmology review, although this procedure was not specifically called out for discussion and no changes were recommended to current line placement.

Alternatives to amniotic membrane transplantation include living and cadaveric cornea transplants, the use of the patients own cornea as a graft, and the use of various tissue substitutes.

Current Prioritized List status:
65778 (Placement of amniotic membrane on the ocular surface; without sutures), 65779 (Placement of amniotic membrane on the ocular surface; single layer, sutured), 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers) are on lines:

56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE
57 BURN, FULL THICKNESS GREATER THAN 10% OF BODY SURFACE
159 TOXIC EPIDERMAL NECROLYSIS AND STAPHYLOCOCCAL SCALDED SKIN SYNDROME; STEVENS-JOHNSON SYNDROME; ERYTHEMA MULTIFORME MAJOR; ECZEMA HERPETICUM
213 BULLOUS DERMATOSES OF THE SKIN
245 ORNEAL ULCER; SUPERFICIAL INJURY OF EYE AND ADNEXA
310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
351 STRABISMUS DUE TO NEUROLOGIC DISORDER
370 AMBLYOPIA
393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN

Evidence

1) **Paolin 2015**, review of outcomes of amniotic membrane transplants
    a. Most common indication for use: corneal ulcers, keratitis, pterygium
    b. 100% success reported with multiple indications
        i. Success defined as resolution of inflammation, relief of symptoms, restoration of regular and stable corneal epithelium, and restoration of the structural integrity of the eye
        ii. Partial success was defined as attainment of only two of the above criteria
        iii. Failure defined as absence of all of the above criteria
    c. this procedure cannot be used in ocular cicatricial pemphigoid or Stevens–Johnson syndrome (bilateral diseases).
2) **Clare 2015**, Cochrane review of amniotic membrane transplant (AMT) for treatment of ocular burns
    a. N=1 RCT with 68 included participants

i. AMT vs medical therapy alone
ii. High risk of bias
iii. In the moderate category, 13/20 control eyes and 14/16 treatment eyes had complete epithelialisation by 21 days. The RR of failure of epithelialization by day 21 was 0.18 in the treatment group (95% confidence interval (CI) 0.02 to 1.31; P = 0.09). Mean LogMAR final visual acuities were 0.06 (standard deviation (SD) 0.10) in the treatment group and 0.38 (SD 0.52) in the control group, representing aMD of -0.32 (95% CI -0.05 to -0.59). In the severe category, 1/17 treatment and 1/15 control eyes were epithelialised by day 21. The RR of failure of epithelialisation in the treatment group was 1.01 (95% CI 0.84 to 1.21; P = 0.93). Final visual acuity was 1.77 (SD 1.31) in the treated eyes and 1.64 (SD 1.48) in the control group (MD 0.13; 95% CI -0.88 to 1.14). The risks of performance and detection biases.
iv. **Authors' conclusions** Conclusive evidence supporting the treatment of acute ocular surface burns with AMT is lacking. Heterogeneity of disease presentation, variations in treatment, undefined criteria for treatment success and failure, and non-uniform outcome measures are some of the factors complicating the search for clear evidence regarding this treatment.

3) **Clearfield 2016**, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011349.pub2/epdf/full
Cochrane review of amniotic membrane transplant for pterygium
a. N=20 studies (1947 eyes of 1866 participants)
b. Overall risk of bias was unclear
c. The risk ratio for recurrence of pterygium using conjunctival autograft versus amniotic membrane transplant was 0.87 (95%confidence interval (CI) 0.43 to 1.77) and 0.53 (95%CI 0.33 to 0.85) at 3 months and 6 months, respectively.
d. For participants with primary pterygia, the risk ratio was 0.92 (95% CI 0.37 to 2.30) and 0.58 (95% CI 0.27 to 1.27) at 3 months and 6 months, respectively.
e. We were only able to estimate the recurrence of pterygia at 6 months for participants with recurrent pterygia, and the risk ratio comparing conjunctival autograft with amniotic membrane transplant was 0.45 (95% CI 0.21 to 0.99).
f. We did not analyze data on the need for repeat surgery, vision-related quality of life, and direct and indirect costs of surgery due to an insufficient number of studies reporting these outcomes.
g. Adverse events that occurred in more than one study were granuloma and pyogenic granuloma and increased intraocular pressure.
h. **Authors' conclusions** In association with pterygium excision, conjunctival autograft is associated with a lower risk of recurrence at six months after surgery than amniotic membrane transplant. Participants with recurrent pterygia, in particular, have a lower risk of recurrence when they receive conjunctival autograft surgery compared with amniotic membrane transplant. There are few studies comparing the two techniques with respect to visual acuity outcomes, and we identified no studies that reported on vision-related quality of life or direct or indirect costs. Comparison of these two procedures in such outcome measures bears further investigation. There were an insufficient number of studies that used adjunctive mitomycin C to estimate the effects on pterygium recurrence following conjunctival autograft or amniotic membrane transplant.

HERC staff recommendations:

1) Remove ocular amniotic membrane transplant CPT codes [65778 (Placement of amniotic membrane on the ocular surface; without sutures), 65779 (Placement of amniotic membrane on the ocular surface; single layer, sutured), 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers)] from the following lines:
    a. 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE
        i. No appropriate diagnoses
    b. 159 TOXIC EPIDERMAL NECROLYSIS AND STAPHYLOCOCCAL SCALDED SKIN SYNDROME; STEVENS-JOHNSON SYNDROME; ERYTHEMA MULTIFORME MAJOR; ECZEMA HERPETICUM
        i. Not effective for this type of condition
    c. 213 BULLOUS DERMATOSES OF THE SKIN
        i. Cicatricial pemphigoid (ICD10 L12.1) is on this line; AMT is not effective for this condition
2) Add ocular amniotic membrane transplant CPT codes [65778 (Placement of amniotic membrane on the ocular surface; without sutures), 65779 (Placement of amniotic membrane on the ocular surface; single layer, sutured), 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers)] to the following lines:
    a. 113 CANCER OF EYE AND ORBIT
    b. 470 KERATOCONJUNCTIVITIS
    c. 493 ECTROPION AND BENIGN NEOPLASM OF EYE
3) Do not pair with pterygium (line 652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY)
4) Keep AMT on lines
    a. 245 ORNEAL ULCER; SUPERFICIAL INJURY OF EYE AND ADNEXA
    b. 310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
    c. 351 STRABISMUS DUE TO NEUROLOGIC DISORDER
    d. 370 AMBLYOPIA
    e. 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN

code	long_code_description	Comments	Placement	subworksheet
10004	Fine needle aspiration biopsy, without imaging guidance; each additional lesion (List separately in addition to code for primary procedure)	10021 (Fine needle aspiration biopsy, without imaging guidance; first lesion) is on the Diagnostic	Diagnostic Procedures File	Straightforward
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	Replacing 10022 (Fine needle aspiration; with imaging guidance). Changed to include bundling with the imaging service.	Diagnostic Procedures File	Straightforward
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File	Straightforward
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	see above	Diagnostic Procedures File	Straightforward
10008	Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion (List separately in addition to code for primary	see above	Diagnostic Procedures File	Straightforward
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	see above	Diagnostic Procedures File	Straightforward
10010	Fine needle aspiration biopsy, including CT guidance; each additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File	Straightforward
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	see above	Diagnostic Procedures File	Straightforward
10012	Fine needle aspiration biopsy, including MR guidance; each additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File	Straightforward

code	long_code_description	Comments	Placement	subworksheet
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	Replacing 11100 and 11101 (Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; single lesion/each additional lesion) to provide more specificity. 11100 and 11101 were on the Diagnostic Procedures File	Diagnostic Procedures File	Straightforward
11103	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); each separate/additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File	Straightforward
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	see above	Diagnostic Procedures File	Straightforward
11105	Punch biopsy of skin (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File	Straightforward
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	see above	Diagnostic Procedures File	Straightforward
11107	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File	Straightforward
20932	Allograft, includes templating, cutting, placement and internal fixation, when performed; osteoarticular, including articular surface and contiguous bone (List separately in addition to code for primary procedure)	See issues document	Ancillary Procedures File	Issues

code	long_code_description	Comments	Placement	subworksheet
20933	Allograft, includes templating, cutting, placement and internal fixation, when performed; hemicortical intercalary, partial (ie, hemicylindrical) (List separately in addition to code for primary procedure)	See issues document	Ancillary Procedures File	Issues
20934	Allograft, includes templating, cutting, placement and internal fixation, when performed; intercalary, complete (ie, cylindrical) (List separately in addition to code for primary procedure)	See issues document	Ancillary Procedures File	Issues
27369	Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography	Replacing CPT 27370 (Injection of contrast for knee arthrography) which was on the Diagnostic Procedures File	Diagnostic Procedures File	Straightforward
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Issues
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Issues
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming	Requires Diagnostic Guideline D2 edits	Diagnostic Procedures File	Issues

code	long_code_description	Comments	Placement	subworksheet
33286	Removal, subcutaneous cardiac rhythm monitor		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	Issues
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed	Requires edit to the GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Issues
33440	Replacement, aortic valve; by translocation of autologous pulmonary valve and transventricular aortic annulus enlargement of the left ventricular outflow tract with valved conduit replacement of pulmonary valve (Ross-Konno procedure)	CPT 33412 (Konno procedure) and 33413 (Ross procedure) are on lines 69,82,106,186,189,224,285,366	82 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 106 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 186 RHEUMATIC MULTIPLE VALVULAR DISEASE 189 CHRONIC ISCHEMIC HEART DISEASE 224 DISEASES AND DISORDERS OF AORTIC VALVE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 366 ALLERGIC BRONCHOPULMONARY ASPERGILLOSIS	Straightforward

code	long_code_description	Comments	Placement	subworksheet
33866	Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)	Similar CPT 33860-33864 (Ascending aorta graft) are on lines 284,325	284 DISSECTING OR RUPTURED AORTIC ANEURYSM 325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE	Straightforward
36572	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age	CPT 36568 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; younger than 5 years of age) is Ancillary	Ancillary Procedures File	Straightforward
36573	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older	CPT 36569 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; age 5 years or older) is Ancillary	Ancillary Procedures File	Straightforward
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	Several exisitng codes are Diagnostic: 38525 (Biopsy or excision of lymph node(s); open, deep axillary node(s)) and 38520 (Biopsy or excision of lymph node(s); open, internal mammary node(s))	Diagnostic Procedures File	Straightforward
43762	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract	Placement of gastrostomy tube, percutaneous (CPT 49440) is Ancillary	Ancillary Procedures File	Straightforward

code	long_code_description	Comments	Placement	subworksheet
43763	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract	Placement of gastrostomy tube, percutaneous (CPT 49440) is Ancillary	Ancillary Procedures File	Straightforward
50436	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, with postprocedure tube placement, when performed;	Replacing CPT 50395 (Introduction of guide into renal pelvis and/or ureter with dilation to establish nephrostomy tract, percutaneous) which was on lines 180,231,352	180 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER 231 URINARY FISTULA 352 URINARY SYSTEM CALCULUS	Straightforward
50437	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, with postprocedure tube placement, when performed; including new access into the renal collecting system	See 50436	180 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER 231 URINARY FISTULA 352 URINARY SYSTEM CALCULUS	Straightforward
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Issues
76391	Magnetic resonance (eg, vibration) elastography		199 CHRONIC HEPATITIS; VIRAL HEPATITIS	Issues

code	long_code_description	Comments	Placement	subworksheet
76978	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Issues
76979	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection (List separately in addition to code for primary procedure)	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Issues
76981	Ultrasound, elastography; parenchyma (eg, organ)		199 CHRONIC HEPATITIS; VIRAL HEPATITIS	Issues
76982	Ultrasound, elastography; first target lesion		199 CHRONIC HEPATITIS; VIRAL HEPATITIS	Issues
76983	Ultrasound, elastography; each additional target lesion (List separately in addition to code for primary procedure)		199 CHRONIC HEPATITIS; VIRAL HEPATITIS	Issues
77046	Magnetic resonance imaging, breast, without contrast material; unilateral		Diagnostic Procedures File	Issues
77047	Magnetic resonance imaging, breast, without contrast material; bilateral		Diagnostic Procedures File	Issues
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral	May require modification to Diagnostic Guideline D6	Diagnostic Procedures File	Issues

code	long_code_description	Comments	Placement	subworksheet
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral	May require modification to Diagnostic Guideline D6	Diagnostic Procedures File	Issues
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis	GAP review	Diagnostic Procedures File	Genetics
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	GAP review	Diagnostic Procedures File	Genetics
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis	GAP review	Diagnostic Procedures File	Genetics
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	GAP review	Diagnostic Procedures File	Genetics
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	GAP review	Diagnostic Procedures File	Genetics
81171	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	GAP review Updates needed to the non-prenatal genetic testing and the prenatal genetic testing guidelines	Diagnostic Procedures File	Genetics

code	long_code_description	Comments	Placement	subworksheet
81172	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)	GAP review Updates needed to the non-prenatal genetic testing and the prenatal genetic testing guidelines	Diagnostic Procedures File	Genetics
81173	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence	GAP review	Diagnostic Procedures File	Genetics
81174	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant	GAP review	Diagnostic Procedures File	Genetics
81177	ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81178	ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81179	ATXN2 (ataxin 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81180	ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81181	ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics

code	long_code_description	Comments	Placement	subworksheet
81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81183	ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence	GAP review	Diagnostic Procedures File	Genetics
81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant	GAP review	Diagnostic Procedures File	Genetics
81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81188	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81189	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; full gene sequence	GAP review	Diagnostic Procedures File	Genetics
81190	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; known familial variant(s)	GAP review	Diagnostic Procedures File	Genetics

code	long_code_description	Comments	Placement	subworksheet
81204	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)	GAP review	Diagnostic Procedures File	Genetics
81233	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)	Oncology	418 CHRONIC LEUKEMIAS WITH POOR PROGNOSIS	Oncology
81234	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence	Oncology	Diagnostic Procedures File	Oncology
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Oncology
81239	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)	GAP review	Diagnostic Procedures File	Genetics
81271	HTT (huntingtin) (eg, Huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81274	HTT (huntingtin) (eg, Huntington disease) gene analysis; characterization of alleles (eg, expanded size)	GAP review	Diagnostic Procedures File	Genetics

code	long_code_description	Comments	Placement	subworksheet
81284	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81285	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)	GAP review	Diagnostic Procedures File	Genetics
81286	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence	GAP review	Diagnostic Procedures File	Genetics
81289	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; known familial variant(s)	GAP review	Diagnostic Procedures File	Genetics
81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant	Oncology	Diagnostic Procedures File	Oncology
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)	GAP review Add entry to guideline note 173	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Genetics
81312	PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)	Oncology	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Oncology

code	long_code_description	Comments	Placement	subworksheet
81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed	GAP review Change entry to prenatal genetic testing guideline	Diagnostic Procedures File	Genetics
81333	TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)	GAP review	Diagnostic Procedures File	Genetics
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence	GAP review	Diagnostic Procedures File	Genetics
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)	GAP review	Diagnostic Procedures File	Genetics
81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81344	TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	GAP review	Diagnostic Procedures File	Genetics
81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)	Oncology	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Oncology

code	long_code_description	Comments	Placement	subworksheet
81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)	GAP review See separate issues document	Diagnostic Procedures File	Genetics
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy	Oncology	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Oncology
81596	Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver	Also requires modification to GN 76	199 CHRONIC HEPATITIS; VIRAL HEPATITIS	Issues
82642	Dihydrotestosterone (DHT)	Tested to determine if 5-alpha-reductase deficiency is present	Diagnostic Procedures File	Straightforward

code	long_code_description	Comments	Placement	subworksheet
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	Also requires modification to GN 173	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Issues
90689	Influenza virus vaccine, quadrivalent (IIV4), inactivated, adjuvanted, preservative free, 0.25 mL dosage, for intramuscular use	Flu shots are included on line 3	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	Straightforward
92273	Electroretinography (ERG), with interpretation and report; full field (ie, ffERG, flash ERG, Ganzfeld ERG)		Diagnostic Procedures File	Issues
92274	Electroretinography (ERG), with interpretation and report; multifocal (mfERG)		Diagnostic Procedures File	Issues
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	Requires edit to the GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Issues
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days	Implantation of brain neurostimulators (e.g. CPT 61870, 61886) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	Straightforward

code	long_code_description	Comments	Placement	subworksheet
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	Implantation of neurostimulators for cranial nerves (e.g. CPT 61885) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	Straightforward
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	Implantation of neurostimulators for cranial nerves (e.g. CPT 61885) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	Straightforward

code	long_code_description	Comments	Placement	subworksheet
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	Implantation of brain neurostimulators (e.g. CPT 61870, 61886) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	Straightforward
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)	Implantation of brain neurostimulators (e.g. CPT 61870, 61886) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	Straightforward

code	long_code_description	Comments	Placement	subworksheet
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour	Psychological testing review	Diagnostic Procedures File	Psychological testing
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)	Psychological testing review	Diagnostic Procedures File	Psychological testing
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)	Psychological testing review	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Psychological testing

code	long_code_description	Comments	Placement	subworksheet
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	Psychological testing review	Diagnostic Procedures File	Psychological testing
96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)	Psychological testing review	Diagnostic Procedures File	Psychological testing
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	Psychological testing review	92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 173 POSTTRAUMATIC STRESS DISORDER 193 AUTISM SPECTRUM DISORDERS 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS	Psychological testing

code	long_code_description	Comments	Placement	subworksheet
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)	Psychological testing review	92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 173 POSTTRAUMATIC STRESS DISORDER 193 AUTISM SPECTRUM DISORDERS 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS	Psychological testing
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes	Psychological testing review	Diagnostic Procedures File	Psychological testing
96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)	Psychological testing review	Diagnostic Procedures File	Psychological testing
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes	Psychological testing review	Diagnostic Procedures File	Psychological testing
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)	Psychological testing review	Diagnostic Procedures File	Psychological testing
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only	Psychological testing review	Diagnostic Procedures File	Psychological testing

code	long_code_description	Comments	Placement	subworksheet
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan	CPT 0359T-0374T (Behavior identification, adaptive behavior treatment, etc.) are on line 193 AUTISM SPECTRUM DISORDERS and line 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER. The new CPT code series 97151-97158 are crosswalked directly to the previous 0359T-0374T series of codes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.	ABA
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes	See 97151	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.	ABA
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes	See 97151	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.	ABA

code	long_code_description	Comments	Placement	subworksheet
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes	See 97151	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.	ABA
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes	See 97151	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.	ABA
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes	See 97151	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.	ABA
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes	See 97151	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.	ABA

code	long_code_description	Comments	Placement	subworksheet
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	See 97151	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.	ABA
99451	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time	Similar codes 99446-99449 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional) are on all lines with E&M codes	All lines with E&M codes	Straightforward
99452	Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes	See 99451	All lines with E&M codes	Straightforward
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment	See issues document	Ancillary Procedures File	Issues

code	long_code_description	Comments	Placement	subworksheet
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	See issues document	Ancillary Procedures File	Issues
99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month	See issues document	Ancillary Procedures File	Issues
99491	Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.	Similar codes 99487-99490 (Complex chronic care management services) are currently on all lines with E&M codes	All lines with E&M codes	Straightforward

code	long_code_description	Comments	Placement
10004	Fine needle aspiration biopsy, without imaging guidance; each additional lesion (List separately in addition to code for primary procedure)	10021 (Fine needle aspiration biopsy, without imaging guidance; first lesion) is on the Diagnostic Procedures File	Diagnostic Procedures File
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	Replacing 10022 (Fine needle aspiration; with imaging guidance). Changed to include bundling with the imaging service. 10022 was on the Diagnostic Procedures File	Diagnostic Procedures File
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	see above	Diagnostic Procedures File
10008	Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	see above	Diagnostic Procedures File
10010	Fine needle aspiration biopsy, including CT guidance; each additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	see above	Diagnostic Procedures File
10012	Fine needle aspiration biopsy, including MR guidance; each additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File

code	long_code_description	Comments	Placement
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	Replacing 11100 and 11101 (Biopsy of skin, subcutaneous tissue and/or mucous membrane (including simple closure), unless otherwise listed; single lesion/each additional lesion) to provide more specificity. 11100 and 11101 were on the Diagnostic Procedures File	Diagnostic Procedures File
11103	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); each separate/additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	see above	Diagnostic Procedures File
11105	Punch biopsy of skin (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	see above	Diagnostic Procedures File
11107	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)	see above	Diagnostic Procedures File
27369	Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography	Replacing CPT 27370 (Injection of contrast for knee arthrography) which was on the Diagnostic Procedures File	Diagnostic Procedures File

code	long_code_description	Comments	Placement
33440	Replacement, aortic valve; by translocation of autologous pulmonary valve and transventricular aortic annulus enlargement of the left ventricular outflow tract with valved conduit replacement of pulmonary valve (Ross-Konno procedure)	CPT 33412 (Konno procedure) and 33413 (Ross procedure) are on lines 69,82,106,186,189,224,285,366	82 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 106 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 186 RHEUMATIC MULTIPLE VALVULAR DISEASE 189 CHRONIC ISCHEMIC HEART DISEASE 224 DISEASES AND DISORDERS OF AORTIC VALVE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 366 ALLERGIC BRONCHOPULMONARY ASPERGILLOSIS
33866	Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)	Similar CPT 33860-33864 (Ascending aorta graft) are on lines 284,325	284 DISSECTING OR RUPTURED AORTIC ANEURYSM 325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE

code	long_code_description	Comments	Placement
36572	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age	CPT 36568 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; younger than 5 years of age) is Ancillary	Ancillary Procedures File
36573	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older	CPT 36569 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; age 5 years or older) is Ancillary	Ancillary Procedures File
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	Several exisitng codes are Diagnostic: 38525 (Biopsy or excision of lymph node(s); open, deep axillary node(s)) and 38520 (Biopsy or excision of lymph node(s); open, internal mammary node(s))	Diagnostic Procedures File
43762	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract	Placement of gastrostomy tube, percutaneous (CPT 49440) is Ancillary	Ancillary Procedures File
43763	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract	Placement of gastrostomy tube, percutaneous (CPT 49440) is Ancillary	Ancillary Procedures File

code	long_code_description	Comments	Placement
50436	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, with postprocedure tube placement, when performed;	Replacing CPT 50395 (Introduction of guide into renal pelvis and/or ureter with dilation to establish nephrostomy tract, percutaneous) which was on lines 180,231,352	180 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER 231 URINARY FISTULA 352 URINARY SYSTEM CALCULUS
50437	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, with postprocedure tube placement, when performed; including new access into the renal collecting system	See 50436	180 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER 231 URINARY FISTULA 352 URINARY SYSTEM CALCULUS
82642	Dihydrotestosterone (DHT)	Tested to determine if 5-alpha-reductase deficiency is present	Diagnostic Procedures File
90689	Influenza virus vaccine, quadrivalent (IIV4), inactivated, adjuvanted, preservative free, 0.25 mL dosage, for intramuscular use	Flu shots are included on line 3	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days	Implantation of brain neurostimulators (e.g. CPT 61870, 61886) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

code	long_code_description	Comments	Placement
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	Implantation of neurostimulators for cranial nerves (e.g. CPT 61885) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	Implantation of neurostimulators for cranial nerves (e.g. CPT 61885) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

code	long_code_description	Comments	Placement
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	Implantation of brain neurostimulators (e.g. CPT 61870, 61886) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)	Implantation of brain neurostimulators (e.g. CPT 61870, 61886) are on lines 174,250,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

code	long_code_description	Comments	Placement
99451	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time	Similar codes 99446-99449 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional) are on all lines with E&M codes	All lines with E&M codes
99452	Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes	See 99451	All lines with E&M codes
99491	Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.	Similar codes 99487-99490 (Complex chronic care management services) are currently on all lines with E&M codes	All lines with E&M codes

code	long_code_description	Discussion	Placement
81233	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)	See oncology issues document	418 CHRONIC LEUKEMIAS WITH POOR PROGNOSIS
81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence	See oncology issues document	Diagnostic Procedures File
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)	See oncology issues document Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant	See oncology issues document	Diagnostic Procedures File
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)	See oncology issues document	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)	See oncology issues document	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

code	long_code_description	Discussion	Placement
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy	See oncology issues document	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

2019 CPT Codes
Oncology Issues

1) Genetic testing in chronic lymphocytic leukemia
    a. **CPT 81233** (BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F))
    b. **CPT 81320** PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)
    c. Definition:
        i. BTK is an enzyme that in humans is encoded by the *BTK* gene. BTK is a kinase that plays a crucial role in B-cell development. Oncology drugs that target BTK are ibrutinib and acalabrutinib (only FDA approved for mantel cell lymphoma). This gene test is for mutations that confer resistance to ibrutinib.
        ii. PLCG2 is another gene involved in CLL. Mutations may confer ibrutinib resistance.
    d. Expert input: Dr. John Godwin, Providence oncology
        i. BTK:
            1. Not routinely done prior to therapy and rare. CLINICAL utility small
            2. While BTK/PLCG2 mutations have characteristics suggesting that they can drive ibrutinib resistance, this conclusion remains formally unproven until specific inhibition of such mutations is shown to cause regression of ibrutinib-resistant CLL. Data suggest that alternative mechanisms of resistance do exist in some patients.
        ii. PLCG2:
            1. UNCLEAR if useful. Simply change therapy if ibrutinib is failing.
            2. While BTK/PLCG2 mutations have characteristics suggesting that they can drive ibrutinib resistance, this conclusion remains formally unproven until specific inhibition of such mutations is shown to cause regression of ibrutinib-resistant CLL. Data suggest that alternative mechanisms of resistance do exist in some patients.
    e. **NCCN 2018**, lymphocytic leukemia:
        i. CGP-stimulated karyotype is useful to identify high-risk patients, particularly for…BTK inhibitor therapy
        ii. Acalabrutinib has no activity against CLL cells with BTK C481S mutations and should not be administered to patients with ibrutinib-refractory disease who have this mutation present in their tumor cells.
        iii. Testing for BTK and PLCG2 mutations may be useful in patients receiving ibrutinib and suspected of having progression. BTK and PLCG2 mutation status alone is not an indication to change treatment.
        iv. …testing for [BTK and PLCG2 mutations] may be helpful to confirm ibrutinib resistance. Testing for mutations as screening for resistance is not currently recommended.
    f. HERC staff summary: BTK and PLCG2 gene tests do not appear to have wide clinical use. BTK gene testing is recommended by NCCN prior to acalabrutinib therapy, and may be useful to confirm ibrutinib resistance. Expert input is that this test has limited clinical utility. PLCG2 gene testing appears to have less utility than BTK, and expert input is that therapy can simply be changed based on clinical indications.
    g. HERC staff recommendations:

i. Add **CPT 81233** (BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)) to line 418 CHRONIC LEUKEMIAS WITH POOR PROGNOSIS
ii. Add **CPT 81320** PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F) to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
iii. Add the following entry to GN173

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

Line 660

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

Procedure Code	**Intervention Description**	**Rationale**	**Last Review**
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)	Insufficient evidence of effectiveness	November 2018

2) EZH2 gene analysis
   a. **81236** EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence
   b. **81237** EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)
   c. Definition: Mutation or over-expression of EZH2 has been linked to many forms of cancer. EZH2 inhibits genes responsible for suppressing tumor development, and blocking EZH2 activity may slow tumor growth
   d. Similar codes:
      i. CPT 81450 and 81455 (Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1)) are on the Diagnostic Procedures File
   e. Expert input: Dr. John Godwin, Providence oncology
      i. For MDS: This mutation conveys poor prognosis and could mean a treatment change. This test is useful. EZH2 INHIBITORS IN TRIAL – more potential uses in future
      ii. For B cell lymphomas: EZH2 INHIBITORS IN TRIAL – so could be useful for approved drugs

f. **NCCN 2018**, Myelodysplastic Syndrome:
    i. EZH2 mutation present in 5-10% of MDS patients. Independently associated with a poor prognosis in MDS and myeloproliferative patients
g. **NCCN 2018**, B cell lymphomas
    i. EZH2 mutation not mentioned under testing
    ii. EZH2 inhibitors not mentioned under treatment
h. HERC staff summary: Testing for EZH2 mutations appears to be useful by NCCN and expert recommendation for myelodysplastic syndrome. However, the specific codon 646 mutation mentioned for B cell lymphomas is not part of the NCCN guideline for that disease.
i. HERC staff recommendations:
    i. Add **CPT 81236** (EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence) to the Diagnostic Procedures File
    ii. Add **CPT 81237** (EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646) to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    iii. Add the following entry to GN173

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)	Insufficient evidence of effectiveness	November 2018

3) **81305** MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant
    a. Definition: Mutation in MYD88 at position 265 leading to a change from leucine to proline have been identified in many human lymphomas including ABC subtype of diffuse large B-cell lymphoma and Waldenstrom's macroglobulinemia
    b. Expert input: Dr. John Godwin, Providence oncology
        i. Important distinction from Waldenstroms' and other lymphomas. Useful.
    c. **NCCN 2019**: Waldenstrom's macroglobulinemia

i. Testing for MYD88 L265P in the bone marrow is an essential part of the workup. These mutations are present in >90% of patients with Waldenstroms' macroglobulinemia. Testing for the allele specific mutation is helpful in distinguishing Waldenstrom's macroglobulinemia from B cell and plasma cell lymphomas.

d. HERC staff recommendation:
   i. Add CPT **81305** (MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant) to the Diagnostic Procedures File

4) **81345** TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)
   a. Definition: Telomerase activity is associated with the number of times a cell can divide, playing an important role in the immortality of cell lines, such as cancer cells. The enzyme complex acts through the addition of telomeric repeats to the ends of chromosomal DNA. This generates immortal cancer cells.
   b. NCCN:
      a. **NCCN 2018** Thyroid Carcinoma guideline
         i. not mentioned
      b. **NCCN 2018** CNS Cancers
         i. Testing for TERT mutation is recommended but not required for gliomas
         ii. TERT mutations in diffusely infiltrative gliomas are associated with a reduced overall survival
   c. HERC staff summary: testing for TERT mutations has some utility in gliomas, but is not required testing under NCCN. There is no mention of such testing for thyroid carcinoma.
   d. HERC staff recommendation:
      i. Add CPT **81345** (TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)) to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
      ii. Add the following entry to GN173

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis,	Insufficient evidence of effectiveness	November 2018

	targeted sequence analysis (eg, promoter region)		

5) **81518** Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy
    a. Similar codes are on line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
        i. 81519 Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score
            1. This code is used for Oncotype Dx
        ii. 81520 Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score
            1. This code is used for Prosigna
        iii. 81521 Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis
            1. This code is used for Mammaprint
    b. Breast cancer algorithmic tests were reviewed in an HTAS coverage guidance in May, 2018. CPT 81518 appears to represent a test called the Breast Cancer Index. The Breast Cancer Index test analyzes the activity of seven genes to help predict the risk of node-negative, hormone-receptor-positive breast cancer coming back 5 to 10 years after diagnosis. The test is designed to help women and their doctors decide if extending hormonal therapy 5 more years (for a total of 10 years of hormonal therapy) would be beneficial. The 7 genes listed by the industry website for Breast Cancer Index indicate that these 7 genes are "content" genes; no mention is made of housekeeping genes. The coverage guidance recommended that the Breast Cancer Index not be covered (weak recommendation).
    c. HERC staff recommendation:
        i. Add CPT **81518** (Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy) to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
        ii. Add the entry shown below to GN173 and modify the existing entry
        iii. Edit Guideline Note 148 as shown below

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy	Insufficient evidence of effectiveness	November 2018 Coverage Guidance May 2018
Breast Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999, S3854)	• Mammostrat • Oncotype DX Breast DCIS Score • ~~Breast Cancer Index~~ • IHC4	Unproven intervention	May 2018 Coverage Guidance Blog

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

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

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

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

- Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.
- EndoPredict (using CPT 81599) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.

- MammaPrint (using CPT 81521 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

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

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

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

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

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

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

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

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

2019 CPT codes
Psychologicial Testing

Code	Code description	See also	Placement
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour	Psychological testing review	Diagnostic Procedures File
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)	Psychological testing review	Diagnostic Procedures File
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)	Psychological testing review	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	Psychological testing review	Diagnostic Procedures File

2019 CPT codes
Psychologicial Testing

Code	Code description	See also	Placement
96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)	Psychological testing review	Diagnostic Procedures File
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	Psychological testing review	92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 173 POSTTRAUMATIC STRESS DISORDER 193 AUTISM SPECTRUM DISORDERS 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)	Psychological testing review	92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 173 POSTTRAUMATIC STRESS DISORDER 193 AUTISM SPECTRUM DISORDERS 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

2019 CPT codes
Psychologicial Testing

Code	Code description	See also	Placement
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes	Psychological testing review	Diagnostic Procedures File
96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)	Psychological testing review	Diagnostic Procedures File
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes	Psychological testing review	Diagnostic Procedures File
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)	Psychological testing review	Diagnostic Procedures File
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only	Psychological testing review	Diagnostic Procedures File

2019 CPT Code Review
Psychological Testing

CMS is replacing the current psychological testing codes, 96101-96103, 96111 and 96118-96120. These tests will be replaced with 96112-96146. The new codes differentiate technician administration of psychological testing and neuropsychological testing from physician/psychologist administration and assessment of testing. The American Psychological Association has come up with crosswalks for these codes. The new codes will require multiple codes to be used in place of one of the deleted codes: one CPT code for the professional test interpretation and one code for the test administration. Additionally, CPT 96116 (Neurobehavioral status exam) will have a companion code added to allow billing for additional time.

2019 CPT codes

Code	Code Description
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes

2019 CPT Code Review
Psychological Testing

96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only

2019 CPT Code Review
Psychological Testing

Code Crosswalk

Deleted CPT Code	Code Description	Current Placement	Replacement code(s)	Replacement Code description
96101	Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI, Rorschach, WAIS), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report	Diagnostic Procedures File	96130, 96131 With 96136 and 96137	Psychological testing evaluation services Psychological or neuropsychological test administration and scoring, physician or professional
96102	…with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face	Diagnostic Procedures File	96130, 96131 With 96138 and 96139	Psychological testing evaluation services Psychological or neuropsychological test administration and scoring, technician
96103	Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI), administered by a computer, with qualified health care professional interpretation and report	Diagnostic Procedures File	96130, 96131 With 96146	Psychological testing evaluation services Psychological or neuropsychological test administration, electronic platform
96111	Developmental testing, (includes assessment of motor, language, social, adaptive, and/or cognitive functioning by standardized developmental instruments) with interpretation and report	Diagnostic Procedures File	96112, 96113	Developmental test administration
96116	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities), per hour of the psychologist's or physician's time, both face-to-face time with the patient and time interpreting test results and preparing the report	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT	96121 (add on new code)	***96116 not being deleted*** Neurobehavioral status exam …each additional hour

2019 CPT Code Review
Psychological Testing

Deleted CPT Code	Code Description	Current Placement	Replacement code(s)	Replacement Code description
		BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS		
96118	Neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report	92,173,193,202	96132, 96133 With 96136 and 96137	Neuropsychological testing evaluation services Psychological or neuropsychological test administration and scoring, physician or professional
96119	Neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face	92,173,193,202	96132, 96133 With 96138 and 96139	Neuropsychological testing evaluation services Psychological or neuropsychological test administration and scoring, technician
96120	Neuropsychological testing (eg, Wisconsin Card Sorting Test), administered by a computer, with qualified health care professional interpretation and report	92,173,193,202	96132, 96133 With 96146	Neuropsychological testing evaluation services Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only

2019 CPT Code Review
Psychological Testing

HERC staff recommendation

1) Place the following codes on the Diagnostic Procedures File
    a. CPT **96112** and **96113** Developmental test administration
    b. CPT **96130** and **96131** Psychological testing evaluation services
    c. CPT **96136-96139**, **96146** Psychological or neuropsychological test administration and scoring
        i. Includes neuropsychological testing that should be on the lines in #2 below, but can no longer distinguish from psychological testing
2) Place CPT **96132, 96133** (Neuropsychological testing evaluation services) on the following lines
    a. 92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
    b. 173 POSTTRAUMATIC STRESS DISORDER
    c. 193 AUTISM SPECTRUM DISORDERS
    d. 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS
3) Place CPT **96121** (Neurobehavioral status exam; each additional hour) on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS to match CPT 96116
    a. Modify the entry to GN173 as shown below

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

Line 660

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

96116 96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities)		November 2018

Code	Code description		Placement
20932	Allograft, includes templating, cutting, placement and internal fixation, when performed; osteoarticular, including articular surface and contiguous bone (List separately in addition to code for primary procedure)		Ancillary Procedures File
20933	Allograft, includes templating, cutting, placement and internal fixation, when performed; hemicortical intercalary, partial (ie, hemicylindrical) (List separately in addition to code for primary procedure)		Ancillary Procedures File
20934	Allograft, includes templating, cutting, placement and internal fixation, when performed; intercalary, complete (ie, cylindrical) (List separately in addition to code for primary procedure)		Ancillary Procedures File
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming	Requires Diagnostic Guideline D2 edits	Diagnostic Procedures File
33286	Removal, subcutaneous cardiac rhythm monitor		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

Code	Code description		Placement
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed	Requires edit to the GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
76391	Magnetic resonance (eg, vibration) elastography		199 CHRONIC HEPATITIS; VIRAL HEPATITIS
76978	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
76979	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection (List separately in addition to code for primary procedure)	Requires GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
76981	Ultrasound, elastography; parenchyma (eg, organ)		199 CHRONIC HEPATITIS; VIRAL HEPATITIS
76982	Ultrasound, elastography; first target lesion		199 CHRONIC HEPATITIS; VIRAL HEPATITIS

Code	Code description		Placement
76983	Ultrasound, elastography; each additional target lesion (List separately in addition to code for primary procedure)		199 CHRONIC HEPATITIS; VIRAL HEPATITIS
77046	Magnetic resonance imaging, breast, without contrast material; unilateral		Diagnostic Procedures File
77047	Magnetic resonance imaging, breast, without contrast material; bilateral		Diagnostic Procedures File
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral	May require modification to Diagnostic Guideline D6	Diagnostic Procedures File
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral	May require modification to Diagnostic Guideline D6	Diagnostic Procedures File
81596	Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver	Requires modification to GN 76	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	Requires modification to GN 173	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
92273	Electroretinography (ERG), with interpretation and report; full field (ie, ffERG, flash ERG, Ganzfeld ERG)		Diagnostic Procedures File
92274	Electroretinography (ERG), with interpretation and report; multifocal (mfERG)		Diagnostic Procedures File

Code	Code description		Placement
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	Requires edit to the GN173 entry	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment		Ancillary Procedures File
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days		Ancillary Procedures File
99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month		Ancillary Procedures File

2019 CPT Code Review
General Issues

1) Structural allograft codes
    a. Codes
        i. CPT **20932** Allograft, includes templating, cutting, placement and internal fixation, when performed; osteoarticular, including articular surface and contiguous bone (List separately in addition to code for primary procedure)
        ii. CPT **20933** Allograft, includes templating, cutting, placement and internal fixation, when performed; hemicortical intercalary, partial (ie, hemicylindrical) (List separately in addition to code for primary procedure)
        iii. CPT **20934** Allograft, includes templating, cutting, placement and internal fixation, when performed; intercalary, complete (ie, cylindrical) (List separately in addition to code for primary procedure)
    b. Definition: These codes are to be used as add on codes only, which must be secondary to the primary procedure. These codes are noted in AMA materials to be facility-only codes. Allografts are used for various orthopedic surgery procedures.
    c. Similar codes
        i. Various CPT codes for allograft procedures for various joints are on multiple covered and uncovered lines
    d. <u>HERC staff recommendation</u>:
        i. Add CPT **20932, 20933, and 20934** to the Ancillary Procedures File

2) Leadless pacemakers
    a. Codes
        i. CPT **33274** Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
        ii. CPT **33275** Transcatheter removal of permanent leadless pacemaker, right ventricular
    b. Definition: Leadless pacemakers, also known as intracardiac or transcatheter pacemakers, are pacemakers in which the components are combined into a single device implanted directly within the heart, without any subcutaneous pocket or tunneling. This is in contrast to traditional transvenous pacemakers that require a subcutaneous generator plus transvenous/epicardial lead(s).
    c. Evidence
        i. **NICE 2018**, review of leadless pacemakers for bradyarrythmias https://www.nice.org.uk/guidance/ipg626/evidence/overview-final-pdf-6533758045
            1. Evidence on the safety of leadless cardiac pacemaker implantation for bradyarrhythmias shows that there are serious but well-recognised complications.
            2. The evidence on efficacy is inadequate in quantity and quality:

a. For people who can have conventional cardiac pacemaker implantation, leadless pacemakers should only be used in the context of research.
b. For people in whom a conventional cardiac pacemaker implantation is contraindicated following a careful risk assessment by a multidisciplinary team, leadless cardiac pacemakers should only be used with special arrangements for clinical governance, consent and audit or research.

3. The evidence included 6 case series and 2 retrospective matched case-control studies
4. Acceptable pacing performance reported in 80-100% of cases up to 24 months
5. Multiple complications reported
    a. Death, permanent loss of device function as a result of mechanical or electrical dysfunction, hospitalization, prolongation of hospitalization by at least 48 hours, system revision, cardiac perforation, vascular complications, device dislodgement and migration
    b. Deaths were reported in 3-11% of patients in case series within 30 days to 16 months

d. Other coverage:
    i. **CMS 2017** NCD
        1. CMS will provide coverage for leadless pacemakers when procedures are performed:
            a. In an FDA-approved post approval study (PAS) such as the Micra Transcatheter Pacing System Post-Approval Study (PAS); or
            b. In a prospective longitudinal study for leadless pacemakers that have either an associated ongoing FDA-approved PAS; or completed an FDA PAS.
    ii. **Aetna 2018**: experimental
e. HERC staff summary: Trusted sources do not recommend use due to high reported complication rates and lack of evidence of effectiveness.
f. <u>HERC staff recommendation</u>:
    i. Add **33274** and **33275** to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    ii. Add an entry to GN173 as shown below

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
33274 33275	Leadless cardiac pacemakers	Insufficient evidence of effectiveness; evidence of harm	November, 2018

3) Subcutaneous cardiac rhythm monitor
    a. Codes
        i. CPT **33285** Insertion, subcutaneous cardiac rhythm monitor, including programming
        ii. CPT **33286** Removal, subcutaneous cardiac rhythm monitor
    b. Subcutaneous cardiac rhythm monitors are also known as implantable loop recorders. These are devices used to monitor cardiac rhythms for 30 days or longer to try to diagnose atrial fibrillation or similar arrhythmias when such arrhythmias have not been detected on testing such as Holter monitors.
    c. These new codes are replacing 2 existing codes
        i. 33282 (Implantation of patient-activated cardiac event recorder) is on the Diagnostic Procedure File
        ii. 33284 (Removal of an implantable, patient-activated cardiac event recorder) is on line 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
    d. Previous review: implantable loop recorders were reviewed in August, 2016 by VBBS/HERC
        i. HERC staff summary: The use of implantable loop recorders (ICLRs) appears to have evidence to support, and expert recommendations for, use for evaluation of recurrent transient loss of consciousness in patients in whom a comprehensive evaluation including noninvasive ambulatory monitoring did not demonstrate a cause of the TLoC or lead to specific treatment, and in whom a cardiac cause is suspected, and in whom an event is expected to recur within the battery life of the ICLR. The use of ICLRs for evaluation for possible atrial fibrillation as the cause of cryptogenic stroke appears to be an area of active research and controversy.
        ii. HERC staff recommendation was to add coverage for the use of implantable cardiac loop recorders (ICLRs) for the evaluation of recurrent transient loss of consciousness in selected patients. Do not add coverage for other indications due to their experimental nature.
            1. Advise HSD to add CPT 33282 (Implantation of patient-activated cardiac event recorder) to the Diagnostic Procedures File and remove from the Services Recommended for Non-Coverage Table
            2. Adopt a new Diagnostic Guideline Note regarding implantable cardiac loop recorders
    e. <u>HERC staff recommendations</u>:
        i. Add CPT **33285** to the Diagnostic Procedure File

ii. Add CPT **33286** to line 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
iii. Modify Diagnostic Guideline D2 as shown below

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

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

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

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

4) Updated CardioMEMS CPT codes
   a. CPT **33289** Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
   b. CPT **93264** Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional
   c. CardioMEMs was reviewed at the October, 2018 VBBS/HERC meetings. This procedure was found to have insufficient evidence of effectiveness and was added to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and Guideline Note 173. At the October 2018 review, only HCPCS codes existed specific to this procedure. It is unclear whether these codes are being deleted.

HCPCS Level II Codes		
C9741	Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report	660
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components	660

d. HERC staff recommendations:
   i. Add CPT **33289** and **93264** to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
   ii. Modify the GN173 entry for CardioMEMS as shown below

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
33289, 93264 C2624, C9741	CardioMEMS™ – Implantable wireless pulmonary artery pressure monitor for heart failure monitoring	Insufficient evidence of effectiveness	October, 2018 Coverage guidance

5) Radiofrequency water vapor transurethral destruction of prostate tissue
   a. CPT **53854** Transurethral destruction of prostate tissue; by radiofrequency generated water vapor
   b. Definition: A minimally invasive treatment for lower urinary tract symptoms (LUTS) using steam energy to coagulate part of the prostate to decrease its size. This technique is known as the Rezum© system.
   c. CPT 53854 replaces HCPCS code C9748 (Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy to treat BPH) effective January 1, 2019. C9748 was added to line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION in May 2018 as part of the HCPCS "C" code review. The staff discussion during that review was that it was suggested for addition to line 327 "To match CPT 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy), which was reviewed as part of the alternatives to TURP in March, 2015." During that review, no evidence review of effectiveness was conducted.
   d. Similar codes are on line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
      i. CPT 53850 Transurethral destruction of prostate tissue; by microwave thermotherapy
      ii. CPT 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy)

e. Previous review: Alternatives to transurethral resection of the prostate (TURP) for lower urinary tract symptoms (LUTS) was reviewed in March, 2015 as a coverage guidance by VBBS/HERC. At that time, TUNA (Transurethral Needle Ablation of Prostate) was added for coverage. CPT 53852 is used for TUNA. The new CPT 53854 now allows separation of TUNA from the radiofrequency generated water vapor procedure. This procedure was not reviewed in the alternatives to TURP coverage guidance process. During the Alternatives to TURP review, TUMP (coded with CPT 53850) was also added for coverage.

f. From the American Urological Association: The primary difference between each of these codes [53852 and 53850 and 53854] is the energy source used to destroy or shrink prostate tissue: 53852 uses radiofrequency energy, 53854 (Rezum) uses radiofrequency generated water vapor thermotherapy, while 53850 uses microwave energy. Otherwise, the procedures and resources used in these procedures are all very similar.

g. Evidence
    i. **Magistero 2017,** https://www.europeanurology.com/article/S0302-2838(17)30583-3/pdf review of emerging minimally invasive procedures for LUTS
        1. Reported on 2 trials: pilot study of 30 patients, RCT of 197 men
        2. Conclusion: The first clinical experience suggests that this novel technique of prostatic ablation is able to provide rapid and meaningful relief of LUTS without compromising sexual function. Further RCTs are needed to confirm these promising first clinical results and to evaluate mid-term and long-term efficacy and safety of the Rezum system.
    i. **Aoun 2015**, https://www.dovepress.com/minimally-invasive-devices-for-treating-lower-urinary-tract-symptoms-i-peer-reviewed-fulltext-article-RRU review of minimally invasive procedures for LUTS
        3. Pilot study of 30 subjects
        4. One other study with 3 months duration published
        5. At present, this system is considered to be an investigational device, and there is one prospective, randomized, controlled, single-blind clinical trial underway in the USA (ClinicalTrials.gov identifier NCT01912339) evaluating the efficacy and safety of the Rezum system and assessing its effect on urinary symptoms secondary to BPH. The estimated study completion date is in June 2019.

h. HERC staff summary: The Rezum system appears to be promising, and is similar to two covered procedures for LUTS. However, the literature to date indicates that this is still an experimental procedure, with further studies expected within in the next year.

i. HERC staff recommendation:
    i. Add CPT **53854** to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    ii. Add an entry to GN173 as shown below

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor	Insufficient evidence of effectiveness	November 2018

6) Magnetic resonance elastography
    a. CPT codes
        i. **76391** Magnetic resonance (eg, vibration) elastography
    b. Definition: Magnetic resonance elastography is a phase-contrast-based magnetic resonance imaging (MRI) technique that can directly visualize and quantitatively measure propagating acoustic strain waves in tissue subjected to harmonic mechanical excitation. The data acquired allows the calculation of local quantitative values of shear modulus and the generation of images that depict tissue elasticity or stiffness. MR elastography has mostly been studied in liver disease, although sporadic reports of evaluation of other conditions were found in the literature.
    c. Similar code CPT 91200 (Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report) is on line 199 CHRONIC HEPATITIS; VIRAL HEPATITIS
    d. Evidence
        i. **Singh 2017,** https://www.gastrojournal.org/article/S0016-5085(17)30325-6/pdf technical review of elastography for evaluation of liver disease
            1. MR elastography (MRE) vs vibration-controlled transient elastography (VCTE)
                a. Key Question 11. In adults with chronic HCV, is the overall diagnostic performance of MRE superior to VCTE for detection of cirrhosis?
                    i. Key message. In adults with HCV, MRE has little to no increased diagnostic accuracy in identifying cirrhosis in patients who truly have cirrhosis over VCTE, but has lower diagnostic accuracy in ruling out cirrhosis in patients who do not have cirrhosis, over VCTE (Very low quality of evidence).
                b. Question 12. In adults with non-alcoholic fatty liver disease (NAFLD), is the overall diagnostic performance of MRE superior to VCTE for detection of cirrhosis?

i. Key message. In adults with NAFLD, MRE has little to no increased diagnostic accuracy in identifying cirrhosis in patients who truly have cirrhosis over VCTE, but has considerably higher diagnostic accuracy in ruling out cirrhosis in patients who do not have cirrhosis, over VCTE (Very low quality of evidence).
ii. The technical report notes that there is limited consensus on when fibrosis assessment (regardless of modality) should be performed in patients suspected of having NAFLD, as there are very limited treatment options available to favorably modify the natural history of patients with NAFLD.

ii. **Singh 2015**, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4333001/pdf/nihms638933.pdf systematic review and meta analysis of MR elastography for staging liver fibrosis
1. N=12 retrospective studies (607 patients)
2. Mean AUROC values (and 95% confidence intervals) for diagnosis of any (≥stage 1), significant (≥stage 2), or advanced fibrosis (≥stage 3), and cirrhosis, were 0.84 (0.76–0.92), 0.88 (0.84–0.91), 0.93 (0.90–0.95), and 0.92 (0.90–0.94), respectively. Similar diagnostic performance was observed in stratified analysis based on sex, obesity, and etiology of CLD. The overall rate of failure of MRE was 4.3%.
3. Conclusion—Based on pooled analysis of data from individual participants, MRE has high accuracy for diagnosis of significant or advanced fibrosis and cirrhosis, independent of BMI and etiology of CLD. Prospective studies are warranted to better understand the diagnostic performance of MRE.

e. HERC staff summary: MR elastography does not add to the accuracy of standard liver elastography for the detection of cirrhosis in patients with hepatitis C. Based on very low quality of evidence, MR elastography may be superior to standard liver elastography for ruling out cirrhosis in non-alcoholic fatty liver disease, but there is no standard recommendation to conduct a fibrosis assessment in NAFLD as there is no effective treatment for that condition at this time. However, GN76, based on the hepatitis C coverage guidance, includes limited coverage for MR elastrography of the liver.

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

Line 199

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

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

- Shear wave elastography (SWE) (Aixplorer®)

Blood tests (only if imaging tests are unavailable):

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

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

Imaging tests:

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

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

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

- Real time tissue elastography
- Hepascore (FibroScore)

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

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

f. **HERC staff recommendation**:
   i. Place CPT **76391** (Magnetic resonance (eg, vibration) elastography) on line 199 CHRONIC HEPATITIS; VIRAL HEPATITIS

7) Elastography
   a. CPT codes
      i. **76981** Ultrasound, elastography; parenchyma (eg, organ)
      ii. **76982** Ultrasound, elastography; first target lesion
      iii. **76983** Ultrasound, elastography; each additional target lesion
   b. Definition: Elastography refers to the measurement of elastic properties of tissues and is based on the principle that malignant tissue is harder than benign tissue. There are 3 main types of US elasticity imaging: 1) elastography that tracks tissue movement during compression to obtain an estimate of strain, 2) sonoelastography that uses color Doppler to generate an image of tissue movement in response to external vibrations, and 3) tracking of shear wave propagation through tissue to obtain the elastic modulus.
      i. Elastography has been used to measure the stiffness of the liver to assist in diagnoses the fibrosis stage in liver cirrhosis. Elastography has also been reported as a method of detecting breast malignancies. Literature review finds

studies examining elastography for evaluation of a variety of diseases, such as uterine fibroids and adenomyosis, carotid artery disease, evaluation of salivary glands, cervical lymph nodes in thyroid cancer, skeletal muscle disease, the neonatal brain, kidney rejection after transplantation, as well as multiple other conditions.

c. Similar code CPT 91200 (Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report) is on line 199 CHRONIC HEPATITIS; VIRAL HEPATITIS
    i. 91200 does not include ultrasound imaging. If ultrasound imaging of the liver (to look for masses, etc.), then CPT 0346T (Ultrasound, elastography) is used. 0346T is not currently on the Prioritized List or other HERC list, and is being replaced by the new CPT codes for 2019
d. Evidence
    i. A wide variety of small trials and case series are published for a variety of uses of elastography. The best delineated literature for non-liver elastography is for breast evaluation
        1. **Liu 2016,** https://www.umbjournal.org/article/S0301-5629(15)00638-9/pdf systematic review and meta analysis of elastography for evaluation of breast lesions
            a. N=33 studies (5838 lesions in 5397 patients)
            b. Summary sensitivity and specificity for distinguishing malignant from benign lesions were 0.886 (95% confidence interval [CI], 0.858–0.909) and 0.866 (95% CI, 0.833–0.894), respectively. The pooled diagnostic odds ratio was 50.410 (95% CI, 34.972–72.664). And the area under the receiver operating characteristic curve of SWE was 0.94 (95% CI, 0.91–0.96).
            c. When analysis confined to 9 studies evaluated the diagnostic performance of combination SWE and conventional ultrasound, the area under the curve was 0.96 (95% CI, 0.94–0.97), yielding a sensitivity of 0.971 (95% CI, 0.941–0.986) and specificity of 0.801 (95% CI, 0.733–0.856).
            d. Conclusions: SWE seems to be a good quantitative method for differentiating breast lesions, with promise for integration into routine imaging protocols.
        2. Expert guidelines: breast elastography is not mentioned in the American College of Radiology appropriateness criteria for evaluation of breast masses
e. HERC staff summary: Non-liver elastography appears to be an emerging field, with a variety of possible applications. No specific application appears to have a robust evidence base at this time, other than breast elastography. Breast elastography appears to be promising, but not yet ready for routine clinical application. As each application of elastography develops support for its use and is brought up for possible addition to the Prioritized List, the HERC should consider each on an individual basis.

i. Liver elastography with ultrasound imaging (i.e. elastography done with imaging to look for liver masses or lesions) is included within the new CPT code series and has restrictions on its use as outlined in Guideline Note 76 (see MR elastography above)

f. HERC staff recommendations:
   i. Place CPT **76981-76983** on line 199 CHRONIC HEPATITIS; VIRAL HEPATITIS

8) Ultrasound bubble studies of non-cardiac organs
   a. CPT codes
      i. **76978** Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion
      ii. **76979** Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection (List separately in addition to code for primary procedure)
   b. Definition: Contrast-enhanced ultrasound (CEUS) is the application of ultrasound contrast medium to traditional medical sonography. This may be the surface of a small air bubble or a more complex structure. Commercially available contrast media are gas-filled microbubbles that are administered intravenously to the systemic circulation. Microbubbles have a high degree of echogenicity (the ability of an object to reflect ultrasound waves). There is a great difference in echogenicity between the gas in the microbubbles and the soft tissue surroundings of the body. Thus, ultrasonic imaging using microbubble contrast agents enhances the ultrasound backscatter (reflection) of the ultrasound waves, to produce a sonogram with increased contrast due to the high echogenicity difference. Contrast-enhanced ultrasound can be used to image blood perfusion in organs, measure blood flow rate in the heart and other organs, and for other applications. Targeting ligands that bind to receptors characteristic of intravascular diseases can be conjugated to microbubbles, enabling the microbubble complex to accumulate selectively in areas of interest, such as diseased or abnormal tissues. This form of molecular imaging, known as targeted contrast-enhanced ultrasound, will only generate a strong ultrasound signal if targeted microbubbles bind in the area of interest. Targeted contrast-enhanced ultrasound may have many applications in both medical diagnostics and medical therapeutics. However, the targeted technique has not yet been approved by the FDA for clinical use in the United States. Targeted microbubbles are under preclinical development. They retain the same general features as untargeted microbubbles, but they are outfitted with ligands that bind specific receptors expressed by cell types of interest, such as inflamed cells or cancer cells. Current microbubbles in development are composed of a lipid monolayer shell with a perflurocarbon gas core. The lipid shell is also covered with a polyethylene glycol (PEG) layer. PEG prevents microbubble aggregation and makes the microbubble more non-reactive. It temporarily “hides” the microbubble from the immune system uptake, increasing the amount of circulation time, and hence, imaging time. In addition to the PEG layer, the shell is modified with molecules that allow for the attachment of ligands that bind certain receptors. These ligands are attached to the microbubbles using carbodiimide, maleimide, or biotin-streptavidin coupling.

c. From the FDA: Ultrasound Contrast (US): The device is cleared for general US non-contrast imaging in several areas of the body and for contrast enhanced echocardiography using FDA approved US imaging drugs in accordance with their labeling. The imaging drug (microbubble) is approved for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.
    i. FDA expects that the US device will have different technological characteristics when using the US imaging device and microbubble in different areas of the body… These technological differences raise different safety and effectiveness questions as compared to the predicate device which include: interactions of the device megahertz energy that may rupture the microbubbles that may lead to adverse events, new clinical endpoints, new patient populations, and different benefits/risks ratio analysis. [the FDA is requiring in this section that non-cardiac uses must be submitted to the FDA for approval rather than just relying on cardiac bubble study results]
    ii. Most imaging drug classes (e.g., gadolinium, microbubbles, and radiopharmaceuticals) have a Black Box Warning regarding different types of serious adverse events
d. Evidence review: multiple articles were found looking at various uses of microbubbles such as treatment of stroke, delivery of chemotherapy agents, imaging of the pelvic organs, etc.
e. HERC staff summary: ultrasound with microbubbles appears to only have FDA approval for cardiac use. Cardiac bubble studies have separate CPT codes and are explicitly excluded from these new codes. As each new application of this technology is developed and brought to the HERC for consideration for coverage, the HERC should review that specific application for evidence of effectiveness.
f. <u>HERC staff recommendation</u>:
    i. Add CPT **76978 and 76979** to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    ii. Add an entry to GN173 as shown below

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
76978 76979	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac)	Insufficient evidence of effectiveness	November 2018

9) Breast MRI without/with contrast and with/without computer-aided detection (CAD)
    a. CPT codes
        i. CPT **77046** Magnetic resonance imaging, breast, without contrast material; unilateral
        ii. CPT **77047** Magnetic resonance imaging, breast, without contrast material; bilateral
        iii. CPT **77048** Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
        iv. CPT **77049** Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral
    b. Similar codes: these new codes are replacing 77058 and 77059 (Magnetic resonance imaging, breast, without and/or with contrast material(s)), which were on Diagnostic Procedures File. There are two guidelines on the Prioritized List that mention breast MRI, but these GNs do not include CPT codes.
    c. Definition: Computer-aided detection has been used to aid radiologists' interpretation of contrast-enhanced MRI of the breast. The use of CAD may also reduce the time needed to interpret breast MRI images, which currently takes much longer than reading mammograms. Contrast material may be used in MRI imaging of the breast as part of the standard test protocol.
    d. Previous evidence reviews: Breast MRI for screening above average risk women was reviewed as a coverage guidance in 2017, but MRI with CAD was not part of that review. Breast MRI was recommended for coverage with a new guideline based on that review. There was also an earlier coverage guidance regarding breast MRI of the contralateral breast as part of breast cancer staging/work up, which recommended non-coverage and also resulted in a guideline note. This coverage guidance also did not mention use of CAD with breast MRI.
    e. Evidence
        i. **Dorrius 2015**, systematic review and meta-analysis of CAD in breast MRI
            1. N=10 good quality studies (895 patients, 1264 total breast lesions)
                a. These studies appeared to be retrospective (7) and prospective (3) cohort studies
            1. Experienced radiologists reached comparable pooled sensitivity and specificity before and after using CAD (sensitivity: without CAD: 89%; 95% CI: 78–94%, with CAD: 89%; 95%CI: 81–94%) (specificity: without CAD: 86%; 95% CI: 79–91%, with CAD: 82%; 95% CI: 76–87%). For residents the pooled sensitivity increased from 72% (95% CI: 62–81%) without CAD to 89% (95% CI: 80–94%) with CAD, however, not significantly. Concerning specificity, the results were similar (without CAD: 79%; 95% CI: 69–86%, with CAD: 78%; 95% CI: 69–84%).

2. Conclusions: CAD in breast MRI has little influence on the sensitivity and specificity of experienced radiologists and therefore their interpretation remains essential. However, residents or inexperienced radiologists seem to benefit from CAD concerning breast MRI evaluation.

ii. **Fischer 2018**, breast MRI with CAD for detection of breast lesions in asymptomatic women
1. N=789 women, prospective cohort study
2. Brest MRI alone: sensitivity 90.6%
3. Sensitivity of CAD was 62.5% (specificity, 84.4%; PPV, 5.2%).
4. Digital mammography sensitivity, 56.3%; specificity, 98.4%; PPV, 32.1%
5. Conclusions: The exclusive use of quality-assured breast MRI allows the early detection of breast cancer with a high sensitivity and specificity. The CAD analysis of MRI does not give additional information but shows results comparable with digital mammography.

f. HERC staff summary: breast MRI was previously reviewed and included on the Prioritized List for screening of high risk women and excluded from the Prioritized List for use in perioperative evaluation of women with breast cancer. Contrast material appears to be a standard variation of the breast MRI. Addition of CAD to MRI does not appear to improve the sensitivity or specificity of the test.

g. HERC staff recommendations**:**
i. Add CPT **77046-77049** (Magnetic resonance imaging, breast, with/without contrast material; with/without computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis)) to the Diagnostic Procedure File
ii. Consider modifying Diagnostic Guideline D6 as shown below
1. Specifies that CAD is not covered with MRI; however, CAD use may not be distinguishable based on CPT codes as the CAD codes are also to be use for MRI with contrast
iii. Make no changes to Diagnostic Guideline D9

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

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

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

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

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

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

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

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

DIAGNOSTIC GUIDELINE D9, MRI FOR BREAST CANCER DIAGNOSIS
In women with recently diagnosed breast cancer, preoperative or contralateral MRI of the breast is not a covered service.

10) ActiTest for hepatitis C
    a. Codes
        i. CPT **81596** Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver
    b. Definition: ActiTest is a patented panel of six components including ALT, total bilirubin (Bili) and four other components of FibroTest [6,7]: apolipoprotein-A1 (ApoA1), haptoglobin (HAPTO), alpha-2 macroglobulin (A2M) and gamma-glutamyl transpeptidase (GGT).
    c. Previous review: ActiTest was reviewed as part of the 2016 Coverage Guidance on Non-Invasive Testing for Liver Fibrosis in Patients with Chronic Hepatitis C. It was mentioned only briefly as being similar to FibroTest. FibroTest was recommended for non-coverage in the Coverage Guidance. However, FibroTest was included as covered in certain situations in GN76 DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE TREATMENT OF HEPATITIS C IN NON-CIRRHOTIC PATIENTS.
    d. Similar codes: There is no CPT code for FibroTest. The components of the test (i.e. haptoglobin, GGT, etc.) are all on the Diagnostic Procedures File.
    e. HERC staff recommendations:
        i. Place CPT **81596** on line 199 CHRONIC HEPATITIS; VIRAL HEPATITIS
        ii. Modify GN76 as shown below

GUIDELINE NOTE 76, DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE TREATMENT OF HEPATITIS C IN NON-CIRRHOTIC PATIENTS
Line 199
Given that a fibrosis score of ≥F2 is the threshold for antiviral treatment of Hepatitis C, the following are included on this line:
Imaging tests:
- Transient elastography (FibroScan®)
- Acoustic radiation force impulse imaging (ARFI) (Virtual Touch™ tissue quantification, ElastPQ)

- Shear wave elastography (SWE) (Aixplorer®)

Blood tests (only if imaging tests are unavailable):

- Enhanced Liver Fibrosis (ELF™)
- Fibrometer™
- FIBROSpect® II
- FibroSure® (FibroTest®) or ActiTest®

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

Imaging tests:

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

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

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

- Real time tissue elastography
- Hepascore (FibroScore)

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

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

11) Small dense LDL cholesterol
    a. CPT **83722** Lipoprotein, direct measurement; small dense LDL cholesterol
    b. Definition: LDL consists of several subclasses of particles with different sizes and densities, including large buoyant (lb) and intermediate and small dense (sd) LDLs. It has been well documented that sdLDL has a greater atherogenic potential than that of other LDL subfractions and that sdLDL cholesterol (sdLDL-C) proportion is a better marker for prediction of cardiovascular disease than that of total LDL-C
    a. Evidence
        a. **Ivanova 2017**, review article on small dense LDL
            i. The results of recent studies demonstrate that LDL fractions have different atherogenicity, with sdLDL being more atherogenic than larger LDL subfractions
            ii. Study of the sdLDL role in the development of atherosclerosis and CVD is hindered by significant variations in LDL fractionation results obtained by different methods
            iii. Statins and other lipid-lowering drugs were reported to have beneficial effects on LDL profile correction, but more studies are necessary to

draw clear guidelines for sdLDL lowering in CVD prevention and treatment.

iv. Conclusion: Further studies are needed to establish guidelines for sdLDL evaluation and correction in clinical practice.

a. HERC staff recommendation:
    a. Add CPT **83722** to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    b. Add an entry to GN173 as shown below

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	Insufficient evidence of effectiveness	November 2018

12) Electroretinopathy
    a. New codes
        i. CPT **92273** Electroretinography (ERG), with interpretation and report; full field (ie, ffERG, flash ERG, Ganzfeld ERG)
        ii. CPT **92274** Electroretinography (ERG), with interpretation and report; multifocal (mfERG)
    b. Definition: Electroretinography measures the electrical responses of various cell types in the retina, including the photoreceptors (rods and cones), inner retinal cells (bipolar and amacrine cells), and the ganglion cells. Electrodes are placed on the skin near the eye for EOG type testing. During a recording, the patient's eyes are exposed to standardized stimuli and the resulting signal is displayed showing the time course of the signal's amplitude (voltage). Clinically, the electroretinogram (ERG) is used for the diagnosis of various retinal diseases. It can be used to distinguish retinal from optic nerve disease.
        i. Multi-focal electroretinography (mfERG) is a higher resolution form of ERG, enabling assessment of ERG activity in small areas of the retina
    c. Similar code: The two new codes are replacing CPT 92275 (Electroretinography with interpretation and report) which was on 50+ ophthalmology lines. The new codes breakout multifocal ERG (mfERG).
    d. ERG and diagnosis/monitoring of glaucoma: most major insurers specifically exclude electroretinography for diagnosis or evaluation of glaucoma; currently, the old code

92275 is on the glaucoma lines. The American Academy of Ophthalmology does not list electroretinography in their practice guideline for evaluation of open or closed angle glaucoma (AAO 2015). CMS has various local coverage determinations which find the use of ERG for diagnosis or monitoring of glaucoma to not be medically necessary.

e. Evidence for mfERG:
    i. **Dettoraki 2016**, review of mfERG for detection of drug toxicity
        1. mfERG is widely used for the evaluation of drug-induced retinopathy. It is particularly useful for the diagnosis of retinal toxicity limited to the central retina, as full-field ERG is usually normal in these cases.
f. Coding for drug-induced retinopathy: ICD-10 H35.00 (Unspecified background retinopathy) Diagnostic Workup File, coded with ICD-10 Z79.899 (Other long term (current) drug therapy), also on the Diagnostic Workup File
g. Cost: CPT 92275 is reimbursed at $105.82 per day of service
h. Expert input: Dr. Pennesi from Casey Eye Institute agreed with ERG placement as proposed by staff. However, he did not agree with staff recommendation of limiting mfERG to diagnosis of drug toxicity. A full field ERG gives information about the entire retina, but does not give information about the macula. To determine if the macula is involved requires mfERG. mfERG is used for workup of inherited macular disease, evaluation of drug toxicity, etc. In some cases, both ERG and mfERG needs to be done to fully evaluate the retina. ERG is a two-hour long test that requires a skilled technician. Only OHSU Casey Eye Institute can do this test in Oregon. They charge private insurers approximately $600 (versus $100 for OHP). This is a low volume test (100-200 per year for all insurers and includes non-Oregon residents).
i. HERC staff summary: electroretinography appears to be a standard test for evaluation of retinal disease. However, it is not recommended for the diagnosis of evaluation of glaucoma. Additionally, the current ERG code appears on many lines with no retinal diagnoses. Multifocal ERG appears to have best evidence to support its use in evaluation of retinal drug toxicity, but expert input recommends use for evaluation of most retinal disease. These tests are low cost and low volume.
j. <u>HERC staff recommendations:</u>
    i. Add CPT **92273** (ERG) and CPT **92274** (mfERG) to the Diagnostic Procedures File

13) Remote monitoring of physiologic parameters
    a. New codes
        i. CPT **99453** Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
        ii. CPT **99454** Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
        iii. CPT **99457** Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care

professional time in a calendar month requiring interactive communication with the patient/caregiver during the month

b. Issue: CMS is expanding the ability of providers to monitor patient physiologic measurements, such as blood pressure or weight. This type of data might be used in a variety of ways, such as monitoring weight as part of a congestive heart failure management program. The new 2019 codes do not require a physician or qualified healthcare professional to complete the service; a registered nurse or other clinical staff could complete the service.
c. Similar codes:
    i. 90990 (Analysis of clinical data stored in computers (eg, ECGs, blood pressures, hematologic data)) is deleted as of 2019. This code was on the "Services Recommended for Non-coverage File" which appeared to be due to the requirement that it be bundled with other services
    ii. 90991 (Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time) is on the Ancillary Procedures File
d. <u>HERC staff recommendation</u>:
    i. Add the following CPT codes to the Ancillary Procedures File
        1. CPT **99453** Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
        2. CPT **99454** Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days
        3. CPT **99457** Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month

2019 CDT codes

CDT Code	Code description	Proposed Placement	Comments
D0412	blood glucose level test – in-office using a glucose meter	Diagnostic Procedures File	D0411 (HbA1c in-office point of service testing) was added to the Diagnostic Procedures File with the 2018 CDT code review. However, the dental board has said that D0411 is not in dental scope of practice. D0411 coverage is currently on hold by HSD as not allowed to cover procedures that are not in scope of practice. HSD recommends coverage pending dental board review and possible legislative action.
D1516	space maintainer – fixed – bilateral, maxillary	53 PREVENTIVE DENTAL SERVICES	
D1517	space maintainer – fixed – bilateral, mandibular	53 PREVENTIVE DENTAL SERVICES	
D1526	space maintainer – removable – bilateral, maxillary	53 PREVENTIVE DENTAL SERVICES	
D1527	space maintainer – removable – bilateral, mandibular	53 PREVENTIVE DENTAL SERVICES	
D5282	removable unilateral partial denture – one-piece cast metal (including clasps and teeth), maxillary	588 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH)	Replaces D5281 (Removable unilateral partial denture-one piece cast metal (including clasps and teeth)) which was on line 588
D5283	removable unilateral partial denture – one-piece cast metal (including clasps and teeth), mandibular	588 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH)	Replaces D5281 (Removable unilateral partial denture-one piece cast metal (including clasps and teeth)) which was on line 588
D5876	add metal substructure to acrylic full denture (per arch)	451 DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE)	See issues document
D9130	temporomandibular joint dysfunction – non-invasive physical therapies	547 TMJ DISORDER	See issues document

2019 CDT codes

CDT Code	Code description	Proposed Placement	Comments
D9613	infiltration of sustained release therapeutic drug – single or multiple sites	Excluded File	See issues document
D9944	occlusal guard – hard appliance, full arch	644 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT	Occlusal guards currently on line 644
D9945	occlusal guard – soft appliance, full arch	644 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT	See D9944 above
D9946	occlusal guard – hard appliance, partial arch	644 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT	See D9944 above
D9961	duplicate/copy patient's records	Excluded File	Not a covered service: OAR 410-120-1200-Exclusions, (2) The Division of Medical Assistance Programs (Division) shall make no payment for any expense incurred for any of the following services or items that are: (l) For copying or preparing records or documents, except those Administrative Medical Reports requested by the branch offices or the Division for casework planning or eligibility determinations
D9990	certified translation or sign-language services – per visits	Ancillary Procedures File	For managed care, this is included in the capitation rate. Unsure about how FFS handles this. Coverage of this is being reviewed by OHA.

2019 CDT Code Issues

1) **D5876** (add metal substructure to acrylic full denture (per arch))
    a. Definition: According to the ADA, "This procedure…applies to fabrication of a new denture. It is not intended as a repair procedure…this code is an additional service when the prothesis is being fabricated."
    b. From the OHA dental group review:
        i. Unclear what this code represents; it may be a mesh structure. Definitely appropriate for some patients. Repairs D5511-12 (Repair broken complete denture base) are on line 451 DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE). However, this code appears to refer to a new denture, and may refer to a specialized form of a denture. Needs OHAP discussion.
    c. OHAP discussion: Used to strengthen dentures. Already being done in certain cases in dental practice. Adds cost up front but may save cost in repairs downstream. OHA could make rules about when this procedure is covered. Decision was to place on line 451 DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE) and have OHA dental group look at rules around this procedure.
    d. <u>OHAP/HERC staff recommendation</u>:
        i. Add D5876 to 451 DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE)

2) **D9130** (temporomandibular joint dysfunction – non-invasive physical therapies)
    a. Definition: Therapy including but not limited to massage, diathermy, ultrasound, or cold application to provide relief from muscle spasms, inflammation or pain intending to improve freedom of motion and joint function. This should be reported on a per session basis.
    b. From the OHA dental group review*:* PT codes are on neither of the TMJ lines currently. There was discussion of an evidence review. There may be an impact on opioid utilization and on comorbid conditions such as migraines. TMJ is historically a non-covered diagnosis (below the line on the Prioritized List). Recommended discussing with OHAP. Depending on line placement, HSD recommends coverage to avoid other non-desirable treatment, e.g. opioid use.
    c. OHAP discussion: Austin reports that specific massage can be effective, but no way to determine if this code is being used for actual effective massage. TMJ is historically non-covered. Adding a service for TMJ would require HERC to re-evaluate the prioritization of TMJ as a condition. Decision was line 547 TMJ DISORDER
    d. <u>OHAP/HERC staff recommendation</u>:
        i. Add CDT D9130 to line 547 TMJ DISORDER

3) D9613 (infiltration of sustained release therapeutic drug – single or multiple sites)

a. Definition: Infiltration of a sustained release pharmacologic agent for long acting surgical site pain control. Not for local anesthesia purposes.
b. HSD dental group discussion: New code added at the request of oral and maxillofacial surgeons, due to demand for non-narcotic alternatives. There was discussion about this code being similar to D9610 and D9612 (Therapeutic parenteral drug), which are on line 54 DENTAL CONDITIONS (E.G., INFECTION, PAIN, TRAUMA). The HSD felt that coverage of this code would follow along with opioid prescribing workaround. HSD recommends coverage, depending on prioritized list line placement.
c. From the ADA: One code addition approved at the most recent meeting of the Code Maintenance Committee of particular interest, according to Drs. Steven I. Snyder and Christopher Bulnes — the chair and vice chair, respectively, of the ADA Council of Dental Benefit Programs — was the inclusion of a code requested by the American Association of Oral and Maxillofacial Surgeons. It is a code for "infiltration of a sustained release therapeutic drug — single or multiple site." Dr. Bulnes said with the increased focus on the use of opioids and the problems associated with their use, patients are requesting non-narcotic alternatives for post-operative pain control. Dentists are now increasingly utilizing a sustained-release pharmacologic agent infiltrated at the surgical site to reduce the use of narcotic pain medicine in their pain management protocol, he said.
d. OHAP discussion: cannot be used for short acting local anesthetic. May be used for dental blocks. Question about whether this could be used in the ED for dental pain. Question about whether to cover separately from the procedure. Concern that this might be abused. These are not expensive drugs. Discussion about covering long acting anesthetic rather than corticosteroids. Many private plans roll this into the procedure as a bundle. Concern with unbundling and increasing cost. OHAP wanted to get further input from commercial plans to see how they are handling this code. HERC staff will contact Karen Nolan to get commercial plan into. OHAP needs information on whether this is bundled with the procedure. Also, need input on whether this could be billed as a second visit if a patient returns later for the injection. Return visit might also be bundled with the procedure, so concern for extra cost as a separate code. Concern that this should be done when appropriate, and already being done without extra payment now. Medicaid already pays high fees for oral surgery; concern for adding cost. OHAP decided to not cover, unless feedback from the commercial plans indicates that coverage will be standard among commercial payers. Currently, D9610 is being used for this type of injection, which is on line 54 DENTAL CONDITIONS (E.G., INFECTION, PAIN, TRAUMA). Later input from Karen Nolan indicated that commercial plans are not covering this as a separate procedure unless a group requires it in its contract. If it is in a contract, it will only be paid on the date of service and when paired with dental extraction codes (D7220-D7241). Decision was Excluded File.
e. <u>OHAP/HERC staff recommendation</u>:
    i. Add D9613 to the Excluded File

4) D9990 (certified translation or sign-language services – per visit)
    a. HSD dental group discussion: For managed care, this is included in the cap rate. Coverage by FFS is being reviewed by HSD. This topic needs discussion with OHAP.
    b. From the ADA: Certified translation or sign-language services are required services under many federal or state laws, programs, or benefit plans. This new code allows a practitioner to report the use of a certified interpreter or translator. Federal or state laws may specify what may be charged…
    c. OHAP discussion: this should be covered, but unclear how OHA will cover it. It is bundled for CCOs. Decision was to make Ancillary and have OHA work on rules.
    d. <u>OHAP/HERC staff recommendation</u>:
        i. Add CDT D9990 (certified translation or sign-language services – per visits) to the Ancillary Services File
        ii. OHA to make rules regarding reimbursement

code	long_code_description	Comments	Placement
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis		Diagnostic Procedures File
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)		Diagnostic Procedures File
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis		Diagnostic Procedures File
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)		Diagnostic Procedures File
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)		Diagnostic Procedures File
81171	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Updates needed to the non-prenatal genetic testing and the prenatal genetic testing guidelines	Diagnostic Procedures File
81172	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)	See above	Diagnostic Procedures File
81173	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence		Diagnostic Procedures File
81174	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant		Diagnostic Procedures File
81177	ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81178	ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File

81179	ATXN2 (ataxin 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81180	ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81181	ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81183	ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence		Diagnostic Procedures File
81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant		Diagnostic Procedures File
81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81188	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81189	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; full gene sequence		Diagnostic Procedures File
81190	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; known familial variant(s)		Diagnostic Procedures File

81204	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)		Diagnostic Procedures File
81234	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles		Diagnostic Procedures File
81239	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)		Diagnostic Procedures File
81271	HTT (huntingtin) (eg, Huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81274	HTT (huntingtin) (eg, Huntington disease) gene analysis; characterization of alleles (eg, expanded size)		Diagnostic Procedures File
81284	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles		Diagnostic Procedures File
81285	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)		Diagnostic Procedures File
81286	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence		Diagnostic Procedures File
81289	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; known familial variant(s)		Diagnostic Procedures File
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)	Add entry to guideline note 173	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81312	PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File

81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed	Change entry to prenatal genetic testing guideline	Diagnostic Procedures File
81333	TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)		Diagnostic Procedures File
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence		Diagnostic Procedures File
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)		Diagnostic Procedures File
81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81344	TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles		Diagnostic Procedures File
81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)	See separate issue summary on expanded carrier testing and recommended edits to the prenatal genetic testing guideline	Diagnostic Procedures File

2019 Genetic CPT Code Review

1) CPT **81163-81167** BRCA1/2 testing changes
    a. Definition: BRCA genes test for breast cancer genetic defects. Various BRCA testing (CPT 81211, 81213, and 81214) codes are being replaced and several are being revised (CPT 81162, 81212, and 81215-81217).
    b. Current Prioritized List status: All BRCA codes are on the Diagnostic Procedures File
    c. GAP discussion: the staff placement recommendation is appropriate
    d. GAP/HERC staff recommendation:
        i. Place 81163-81167 on the Diagnostic Procedures File
            1. Revise the Non-Prenatal Genetic Testing Guideline to reflect updated codes

2) CPT **81171-81172** (AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis)
    a. Definition: Mutations in the *AFF2* gene cause fragile XE syndrome, a condition characterized by mild intellectual disability and learning difficulties
    b. Current Prioritized List status: The current fragile X gene analysis codes are on the Diagnostic Procedures File and included in the Non-Prenatal Genetic Testing Guideline
        i. 81243 FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
        ii. 81244 FMR1 (Fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; characterization of alleles (eg, expanded size and methylation status)
    c. GAP discussion: the staff placement recommendation is appropriate
    d. GAP/HERC staff recommendation:
        i. Place 81171-81172 on the Diagnostic Procedures File
            1. Revise the Non-Prenatal Genetic Testing Guideline and the Prenatal Genetic Testing Guideline to reflect updated codes

3) CPT **81173, 81174 and 81204** (AR (androgen receptor)) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis)
    a. Definition: The *AR* gene provides instructions for making a protein called an androgen receptor. Androgens are hormones (such as testosterone) that are important for normal male sexual development before birth and during puberty. Androgen receptors allow the body to respond appropriately to these hormones. Spinal and bulbar muscular atrophy, a disorder of specialized nerve cells that control muscle movement (motor neurons), results from an expansion of the CAG trinucleotide repeat in the *AR* gene. Kennedy Disease is a form of spinal muscular atrophy.
    b. Current Prioritized List status: currently, spinal muscular atrophy genetic tests are coded with a generic CPT code
    c. GAP discussion: the staff placement recommendation is appropriate
    d. GAP/HERC staff recommendation:

i. Add CPT 81173, 81174 and 81204 (AR (androgen receptor)) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis) to the Diagnostic Procedures File

4) CPT **81177** (ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis)
   a. Definition: Dentatorubral-pallidoluysian atrophy (DRPLA) is a rare autosomal dominant neurodegenerative disorder characterized by ataxia, choreoathetosis, dementia, and psychiatric disturbance in adults and ataxia, myoclonus, seizures, and progressive intellectual deterioration in children. DRPLA is caused by an expansion of the CAG trinucleotide repeat in the *ATN1* (*DRPLA*) gene. Gene analysis is used for 1) molecular confirmation of a diagnosis of dentatorubral-pallidoluysian atrophy (DRPLA) for symptomatic patients and 2) predictive testing for individuals with a family history of DRPLA and a documented expansion in the *ATN1* gene in an affected family member
   b. Current Prioritized List status: no current similar code
   c. GAP discussion: the staff placement recommendation is appropriate. This condition is on the differential for Huntington like syndromes.
   d. <u>GAP/HERC staff recommendation</u>:
      i. Add CPT 81177 (ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis) to the Diagnostic Procedures File

5) CPT **81178-81183** (ATXN1-ATXN10 (eg, spinocerebellar ataxia) gene analysis)
   a. Definition: The *ATXN* genes provides instructions for making proteins called ataxins. This protein is found throughout the body, but its function is unknown for most types. Mutations in the ATXN gene family result in various types of spinocerebellar ataxia, conditions characterized by progressive problems with movement.
   b. Current Prioritized List status: no current similar code
   c. GAP discussion: the staff placement recommendation is appropriate
   d. <u>GAP/HERC staff recommendation</u>:
      i. Add to CPT 81178-81183 (ATXN1-ATXN10 (eg, spinocerebellar ataxia) gene analysis) to the Diagnostic Procedures File

6) CPT **81184-81186** (CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis)
   a. Definition: The *CACNA1A* gene belongs to a family of genes that provide instructions for making calcium channels. Several genetic illnesses are associated with gene mutations, including episodic atoaxia and spinocerebellar ataxia type 6. The major features of SCA6 include progressive ataxia, nystagmus, and impaired speech (dysarthria), most often beginning in a person's forties or fifties.
   b. Current Prioritized List status: no current similar code
   c. GAP discussion: the staff placement recommendation is appropriate
   d. <u>GAP/HERC staff recommendation:</u>

i. Add CPT 81184-81186 (CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis) to the Diagnostic Procedures File

7) CPT **81187** (CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis)
   a. Definition: The CNBP protein is found in many of the body's tissues, but it is most abundant in the heart and in muscles used for movement (skeletal muscles). Although the exact function of this protein is unclear, it appears to regulate the activity of other genes. Type 2 myotonic dystrophy results from a mutation in the *CNBP* gene known as a tetranucleotide repeat expansion.
   b. Current Prioritized List status: no current similar code
   c. GAP discussion: the staff placement recommendation is appropriate. This is a less common form of myotonic dystrophy, with adult onset.
   d. <u>GAP/HERC staff recommendation:</u>
      i. Add CPT 81187 (CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis) to the Diagnostic Procedures File

8) CPT **81188-81190** (CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis)
   a. Definition: Mutations in the *CSTB* gene cause Unverricht-Lundborg disease. The *CSTB* gene provides instructions for making a protein called cystatin B. This protein reduces the activity of enzymes called cathepsins. Cathepsins help break down certain proteins in the lysosomes (compartments in the cell that digest and recycle materials). Unverricht-Lundborg disease is a rare inherited form of epilepsy. Affected individuals usually begin showing signs and symptoms of the disorder between the ages of 6 and 15. Eventually people with Unverricht-Lundborg disease may develop problems with balance and coordination (ataxia), involuntary rhythmic shaking called intention tremor because it worsens during movement, difficulty speaking (dysarthria), depression, and a slow, mild decline in intellectual functioning.
   b. Current Prioritized List status: no current similar code
   c. GAP discussion: the staff placement recommendation is appropriate
   d. <u>GAP/HERC staff recommendation</u>:
      i. Add CPT 81188-81190 (CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis) to the Diagnostic Procedures File

9) CPT **81234 and 81239** (DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis)
   a. Definition: The *DMPK* gene provides instructions for making a protein called myotonic dystrophy protein kinase. Although the specific function of this protein is unknown, it appears to play an important role in muscle, heart, and brain cells. Type 1 myotonic

dystrophy results from a mutation in the *DMPK* gene known as a trinucleotide repeat expansion.

b. Current Prioritized List status: no current similar code
c. GAP discussion: the staff placement recommendation is appropriate. This is a more common variety of myotonic dystrophy
d. GAP/HERC staff recommendation:
    i. Add CPT 81234 and 81239 (DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis) to the Diagnostic Procedures File

10) CPT **81271, 81274** (HTT (huntingtin) (eg, Huntington disease) gene analysis)
    a. Definition: The *HTT* gene provides instructions for making a protein called huntingtin. Although the exact function of this protein is unknown, it appears to play an important role in nerve cells (neurons) in the brain and is essential for normal development before birth. The inherited mutation that causes Huntington disease is known as a CAG trinucleotide repeat expansion. This mutation increases the size of the CAG segment in the *HTT* gene. People with Huntington disease have 36 to more than 120 CAG repeats. People with 36 to 39 CAG repeats may or may not develop the signs and symptoms of Huntington disease, while people with 40 or more repeats almost always develop the disorder.
    b. Current Prioritized List status: no current similar code
    c. GAP discussion: the staff placement recommendation is appropriate. Update for newer technique for test
    d. GAP/HERC staff recommendation:
        i. Add CPT 81271, 81274 (HTT (huntingtin) (eg, Huntington disease) gene analysis) to the Diagnostic Procedures File

11) CPT **81271-81279** (FXN (frataxin) (eg, Friedreich ataxia) gene analysis)
    a. Definition: The *FXN* gene provides instructions for making a protein called frataxin. This protein is found in cells throughout the body, with the highest levels in the heart, spinal cord, liver, pancreas, and muscles used for voluntary movement (skeletal muscles). Within cells, frataxin is found in energy-producing structures called mitochondria. Although its function is not fully understood, frataxin appears to help assemble clusters of iron and sulfur molecules that are critical for the function of many proteins, including those needed for energy production. Friedreich ataxia results from an increased number of copies (expansion) of the GAA trinucleotide repeat in the *FXN* gene. In people with this condition, the GAA segment is abnormally repeated 66 to more than 1,000 times. The length of the GAA trinucleotide repeat appears to be related to the age at which the symptoms of Friedreich ataxia appear. People with GAA segments repeated fewer than 300 times tend to have a later appearance of symptoms (after age 25) than those with larger GAA trinucleotide repeats.
    b. Current Prioritized List status: no current similar code

c. GAP discussion: the staff placement recommendation is appropriate. Rare recessive disorder. This new code is breaking out the testing for the missense mutation
d. GAP/HERC staff recommendation:
    i. Add CPT 81271-81279 (FXN (frataxin) (eg, Friedreich ataxia) gene analysis) to the Diagnostic Procedures File

12) CPT **81306** (NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis)
    a. Definition: This gene encodes an enzyme that belongs to the Nudix hydrolase superfamily. Members of this superfamily catalyze the hydrolysis of nucleoside diphosphates, including substrates like 8-oxo-dGTP, which are a result of oxidative damage, and can induce base mispairing during DNA replication, causing transversions. The encoded enzyme is a negative regulator of thiopurine activation and toxicity. Mutations in this gene result in poor metabolism of thiopurines, and are associated with thiopurine-induced early leukopenia. This genetic test is useful for predicting potential for toxicity to thiopurine drugs (6-mercaptopurine, 6-thioguanine, and azathioprine). The US Food and Drug Administration, the Clinical Pharmacogenetics Implementation Consortium, and some professional societies recommend consideration of *TPMT* genotype or TPMT erythrocyte testing prior to the initiation of therapy with thiopurine drugs. There is substantial evidence linking *TPMT* genotype to phenotypic variability. Dose adjustments based upon *TPMT* genotype have reduced thiopurine-induced adverse effects without compromising desired antitumor and immunosuppressive therapeutic effects in several clinical settings. Rare variants may be present that could lead to false-negative or false-positive results. This test will not detect all *TPMT* or *NUDT15* genetic variants. A negative result does not rule out the possibility of toxicity if thiopurines are used, since multiple factors (eg, other genetic factors, drug-drug interactions) are known to play a role.
    b. Evidence
        i. **Yin 2017**, systematic review and meta-analysis of the impact of NUDT15 polymorphisms on thiopurine intolerance
            1. N=7 studies (1752 patients)
                a. All cohort studies
            2. Variant allele of rs116855232 contributes 7.86-fold ($P < 0.00001$, 95% CI: 6.13–10.08) higher risk to develop leucopenia with high specificity (91.74%) and sensitivity (43.19%), and lower thiopurines intolerance dose ($P < 0.00001$).
            3. In conclusion, genetic polymorphisms in *NUDT15* are strongly associated with adverse drug reaction (ADR) of thiopurines, although more evidence is needed to determine values of all functional *NUDT15* polymorphisms for clinical regimen, rs116855232 should be considered as a highly credible pharmacogenetic indicator for thiopurines use, especially in Asians.

c. Current Prioritized List status: all other drug metabolism genetic tests are on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
d. GAP discussion: The impact of gene analysis not clear. Sue Richards sent recommendations that this not be covered and GAP members felt she had the most expertise in this area.
e. GAP/HERC staff recommendation:
    i. Add CPT 81306 (NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis) to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
        1. There is no evidence that genetic analysis leads to clinical decision changes or improves patient outcomes; data to date is only that positive tests are correlated with higher risk of adverse outcomes. There is no evidence that testing will prevent overall adverse outcomes. The test is not listed in NCCN guidelines as recommended prior to use of thiopurines in oncology
    ii. Add the following entry to GN173

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis	Insufficient evidence of effectiveness	November 2018

13) CPT **81312** (PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis)
    a. Definition: The *PABPN1* gene provides instructions for making a protein that plays an important role in processing molecules called messenger RNAs (mRNAs). At least 20 different mutations in the *PABPN1* gene have been found to cause oculopharyngeal muscular dystrophy. This condition is characterized by muscle weakness that begins in adulthood and largely affects the eyelids, throat, shoulders, hips, and legs. The extent and number of mutations affects the age of onset of the condition and severity of symptoms.
    b. Current Prioritized List status: no current similar codes
    c. GAP discussion: the staff placement recommendation is appropriate.
    d. GAP/HERC staff recommendation:

i. Add 81312 (PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis) to the Diagnostic Procedures File

14) CPT **81329, 81336, 81337** (SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis)
    a. Definition: The *SMN1* gene provides instructions for making the survival motor neuron (SMN) protein. The SMN protein is found throughout the body, with high levels in the spinal cord. This protein is particularly important for the maintenance of specialized nerve cells called motor neurons, which are located in the spinal cord and the part of the brain that is connected to the spinal cord (the brainstem). Motor neurons control muscle movement. About 95 percent of individuals with spinal muscular atrophy have mutations that delete a section called exon 7 in both copies of the *SMN1* gene in each cell. As a result, little or no SMN protein is made. In about 5 percent of people with this disorder, one copy of the *SMN1* gene has a deletion of exon 7, and the other copy has a different mutation that disrupts the production or function of the SMN protein. Researchers have identified at least 65 mutations in the *SMN1* gene that cause spinal muscular atrophy.
    e. Current Prioritized List status: no current similar codes
    f. GAP discussion: the staff placement recommendation is appropriate. Should be covered test as treatments are available for this condition. CPT 81329 is a prenatal test and should be added to the prenatal genetic testing guideline.
    g. <u>GAP/HERC staff recommendation</u>:
        i. Add 81329, 81336, 81337 (SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis) to the Diagnostic Procedures File

15) CPT **81333** (TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q))
    a. Definition: This gene encodes a protein involved in cell adhesion. Mutations of the gene cause several forms of corneal dystrophies
    h. Current Prioritized List status: no current similar codes
    i. GAP discussion: the staff placement recommendation is appropriate
    j. <u>GAP/HERC staff recommendation</u>:
        i. Add 81343 (PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis) to the Diagnostic Procedures File

16) CPT **81343** (PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis)
    a. Definition: This gene encodes a beta isoform of the regulatory subunit B55 subfamily. Defects in this gene cause autosomal dominant spinocerebellar ataxia 12 (SCA12), a disease caused by degeneration of the cerebellum, sometimes involving the brainstem and spinal cord, resulting in poor coordination of speech and body movements.
    k. Current Prioritized List status: no current similar codes

l. GAP discussion: agreed with staff rec
m. GAP/HERC staff recommendation:
    i. Add 81343 (PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis) to the Diagnostic Procedures File

17) CPT **81344** (TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis)
    a. Definition: The TATA-binding protein (TBP) is a general transcription factor that binds specifically to a DNA sequence called the TATA box. Mutations that expand the number of CAG repeats encoding this polyglutamine tract, and thus increase the length of the polyglutamine string, are associated with spinocerebellar ataxia 17, a neurodegenerative disorder classified as a polyglutamine disease
    b. Current Prioritized List status: no current similar codes
    c. GAP discussion: the staff placement recommendation is appropriate
    d. GAP/HERC staff recommendation:
        i. Add 81344 (TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis) to the Diagnostic Procedures File

Panel Tests for Carrier Screening

Question: should expanded carrier screening panel tests be included in the prenatal genetic screening guideline?

Question source: GAP

Issue: There is a new code for expanded carrier screening, which the GAP members felt should be added to the Diagnostic Procedures File. Expanded carrier screening tests for many different heritable conditions (150+ in some panels) in one test, rather than testing for single or a small range of heritable conditions.

> CPT **81443** (Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes)

The prenatal genetic testing guideline explicitly limits such expanded carrier screening testing. This restriction is based on a 2014 coverage guidance. The Coverage Guidance found no evidence for or against expanded carrier screening. However, there was concern about the risk of cascade testing and the finding of clinically unimportant results. It was noted that expanded carrier screening was much less expensive than screening for individual genetic disorders. There was thought to be high variability in values and preferences. The recommendation was expanded carrier screening only for conditions found to be beneficial to screen for in the same coverage guidance, such as cystic fibrosis or spinal muscular atrophy.

Currently, there is coverage for CPT 81412 for Ashkenazi Jewish carrier testing panel and CPT 81220 for CF panel testing. The non-prenatal genetic testing guideline contains clauses expressly addressing such limited carrier panel testing.

At the October 2018 Genetics Advisory Panel meeting, the GAP recommended expanded carrier panel testing for prenatal or preconception counseling/testing. Panel tests used now have 170+ genes. The new code was noted to be allowed for use for any panel 15 genes or larger. The reason this CPT code was added was that the same code is to be used for any panel with one rate of reimbursement. All GAP members felt that this was reasonable to cover. Often the cost for this expanded carrier panel is the same as the cost for a single gene test.

Public testimony was heard at the GAP meeting in favor of coverage of expanded panel testing. It was noted that ACOG guidelines include such expanded panel testing. Over ½ of all screening in US is now done with expanded panel tests. ACOG has specific criteria for prenatal panel tests, requiring that the genes in a panel must be for diseases with a childhood onset, there should be a 1 in 100 carrier frequency, etc. This can be found in ACOG committee opinions 690 and 691. The purpose of this new code is to prevent code stacking. The industry representative suggested considering coverage for a limited group of patients (adopted, unexplained family history, h/o repeated miscarriages).

Expert guidelines

1) **ACOG** 2017 committee opinion **690** **https://www.acog.org/-/media/Committee-Opinions/Committee-on-Genetics/co690.pdf?dmc=1&ts=20181029T1555151910**
    a. Ethnic-specific, panethnic, and expanded carrier screening are acceptable strategies for prepregnancy and prenatal carrier screening.
    b. The disorders selected for inclusion should meet several of the following consensus-determined criteria: have a carrier frequency of 1 in 100 or greater, have well-defined phenotype, have a detrimental effect on quality of life, cause cognitive or physical impairment, require surgical or medical intervention, or have an onset early in life. Additionally, screed conditions should be able to be diagnosed prenatally and may afford opportunities for antenatal intervention to improve outcomes, changes to delivery management to optimize newborn and infant outcomes, and education of the parents about special needs after birth.
    c. Carrier screening panels should not include conditions primarily associated with a disease of adult onset
    d. Carrier screening panels have largely replaced more specific screening because of its efficacy and economy
2) **ACOG 2017 committee opinion 691** **https://www.acog.org/-/media/Committee-Opinions/Committee-on-Genetics/co691.pdf?dmc=1&ts=20170808T1020526802**
    a. The cost of carrier screening for an individual condition may be higher than the cost of testing through commercially available expanded carrier screening panels

GAP/HERC staff recommendation:

1) Add CPT **81443** (Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes) to the Diagnostic Procedures File
2) Modify the prenatal genetic testing guideline as shown below to remove wording excluding these types of panel tests
    a. Consider additional entry to specify that CPT 81443 is only allowed once in a lifetime and only for pre-conception or prenatal testing

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

The following types of prenatal genetic testing and genetic counseling are covered for pregnant women and the other parent:

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

c. unexplained early onset intellectual disability
d. fragile X intellectual disability
e. unexplained autism through the pregnant woman's maternal line
f. CPT 81243, 81244, 81171, 81172, Fragile X genetic testing

N) Screening for spinal muscular atrophy (CPT ~~81401~~ 81329) once in a lifetime
O) Screening those with Ashkenazi Jewish heritage for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255). Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
P) ~~Expanded carrier screening only for those genetic conditions identified above~~

The following genetic screening tests are not covered:

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

Non-Prenatal Genetic Testing Guideline

Issue: various changes are suggested by GAP for Diagnostic Guideline D1, NON-PRENATAL GENETIC TESTING GUIDELINE

1) Routine guideline updates:
    a. NCCN guideline version updates
        i. It was pointed out by stakeholders that the NCCN guideline for PTEN syndrome was mistakenly the colon cancer genetic guideline when it should be the breast cancer genetic guideline. This change was not noted until after the GAP meeting and was not reviewed by GAP members. On staff review, PTEN is mentioned in both the colon and breast cancer genetic risk NCCN guidelines. The staff recommendation is to add the breast cancer genetic risk NCCN guideline to that portion of the new hereditary cancer genetic guideline and leave in the colon cancer genetic testing guideline.
    b. The American College of Genomics and Genetics cystic fibrosis carrier screening link requires an update
2) Updates needed for 2019 CPT codes:
    a. BRCA genetic test CPT codes revisions/changes
    b. Fragile X genetic testing additional CPT codes
    c. Adding spinal muscular atrophy screening for non-pregnant patients to mirror changes done to the prenatal genetic testing guideline
3) Changes recommended based on stakeholder input:
    a. Hereditary cancer testing
        i. GAP recommends removing the section on hereditary cancer testing from the non-prenatal genetic testing guideline and making it its own diagnostic guideline. The non-prenatal genetic testing guideline is becoming too long and unwieldy. The section on hereditary cancer testing should not fall under the requirement to have a 10% change of a genetic abnormality prior to authorizing the test; rather, testing should be done according to NCCN guidelines. The hereditary cancer section was removed and made into a separate guideline.
        ii. Within the new hereditary cancer genetic testing, the GAP agreed that the section on breast and ovarian cancer syndrome genetic testing for patients with a history of cancer should have “women” changed to “patient” to include men with a history of breast or associated cancers. The section for patients without a personal history of cancer should be changed to include other associated cancers which are included in NCCN guidelines.
        iii. The GAP members modified the section on panel testing for hereditary cancer syndromes. They removed the restriction to genes in the breast/ovarian or colon cancer NCCN genetic testing guidelines, as they felt that other cancer syndromes could require panel testing. They approved removing the section requiring the panel to have at least 5 genes mentioned in the NCCN breast/ovarian or colon cancer guidelines and remove the limit of “a reasonable number of genes.” GAP member noted that they routinely use panel testing rather than single or a few gene tests, and that these panels are more cost effective. Many of these panels have 150+ genes.

1. Myriad Genetics submitted a request after the GAP meeting to change the GAP suggested wording change to something similar to: "…panels… should be provided as a substitute for individual gene testing for any of the hereditary cancer genes listed in a) through d), using the criteria for testing for those genes in the relevant NCCN or USPSTF guidelines listed in a) through d)." Myriad felt that the GAP suggested wording change was too broad and difficult to interpret.

iv. Regarding who can provide genetic counseling for hereditary cancer testing
   1. For the new hereditary cancer guideline, the GAP suggested taking out the wording specifying the type of provider. However, this wording should be left in the general non-prenatal genetic testing guideline. If this suggestion is not acceptable to the HERC, the GAP suggests convening a work group on genetic counseling, with hereditary cancer testing separated from cancer testing and other types of genetic testing. This workgroup should balance access with appropriateness of services.

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

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

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

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

~~D) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history.~~
   ~~1) Services are provided according to the Comprehensive Cancer Network Guidelines.~~
      ~~a) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as~~

defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) V3.2017 (10/10/17). www.nccn.org.

b) Breast and ovarian cancer syndrome genetic testing services (CPT 81162 81167, 81211-81217 81212, 81215-81217) for women without a personal history of breast, ovarian and other associated cancers should be provided to high risk women as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and ovarian. V2.2019 (7/30/18) V1.2018 (10/3/17). www.nccn.org.

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

d) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Colorectal Screening. V1.2018 (7/12/18) V3.2017 (10/10/17). www.nccn.org.

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

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

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

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

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

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

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

5) Hereditary breast cancer-related disorders genomic sequence analysis panels (CPT 81432, 81433, 81479) are only included if the panel test

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

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

D) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70

on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:

1) CPT 81228, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
2) CPT 81229, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities; plus cytogenetic constitutional microarray analysis for single nucleotide polymorphism (SNP) variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder; only if (a) consanguinity and recessive disease is suspected, or (b) uniparental disomy is suspected, or (c) another mechanism is suspected that is not detected by the copy number variant test alone.
3) CPT 81243, 81244, 81171, 81172, Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
4) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.

E) Related to other tests with specific CPT codes:
   1) Certain genetic tests have not been found to have proven clinical benefit. These tests are listed in Guideline Note 173, INTERVENTIONS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN INTERVENTIONS
   2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
      a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
      b) Diagnostic testing for cystic fibrosis (CF)
         i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
      c) Carrier testing for cystic fibrosis

i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered once in a lifetime.

d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.

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

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

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

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

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

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

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

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

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

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

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

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

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

DIAGNOSTIC GUIDELINE DX, HEREDITARY CANCER GENETIC TESTING

A) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history.

1) Services are provided according to the Comprehensive Cancer Network Guidelines.

a) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) ~~V3.2017 (10/10/17)~~. www.nccn.org.

b) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, ~~81211-81217~~ 81212, 81215-81217) for ~~women~~ patients without a personal history of breast, ovarian and other associated cancers should be provided to high risk ~~women~~ patients as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and ovarian. V2.2019 (7/30/18) ~~V1.2018 (10/3/17)~~. www.nccn.org.

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

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

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

a) Pre and post-test genetic counseling should be covered when provided by a suitable trained health professional with expertise and experience in cancer genetics. Genetic

counseling is recommended for cancer survivors when test results would affect cancer screening.

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

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

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

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

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

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

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

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

Prenatal Genetic Testing Guideline

The GAP recommends various changes to Diagnostic Guideline D17, PRENATAL GENETIC TESTING

1) Add the 2019 CPT codes regarding Fragile X genetic testing to section "M" as shown below
2) Add the 2019 CPT code for spinal muscular atrophy testing to section "N" as shown below [CPT 80401 is non specific code and should be deleted, CPT 81329 is now the specific code for this type of carrier testing]
    i. Note: an addition for this type of testing was made in the non-prenatal genetic testing guideline for non-pregnant patients for preconception counseling or testing of a partner of a women who is pregnant and a carrier
3) Adding additional CPT codes for completeness
    i. Add the following CPT codes for serum genetic tests to section "E."
        1. 81512 Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score
        2. 82105 Alpha-fetoprotein (AFP); serum
        3. 82677 Estriol
    ii. Add the following genetic analysis CPT codes to the amniocentesis/CVS section (section "H")
        1. 76945 Ultrasonic guidance for chorionic villus sampling, imaging supervision and interpretation
        2. 76946 Ultrasonic guidance for amniocentesis, imaging supervision and interpretation
        3. 88261 Chromosome analysis; count 5 cells, 1 karyotype, with banding
        4. 88262 Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding
        5. 88263 Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding
        6. 88264 Chromosome analysis; analyze 20-25 cells
        7. 88283 Chromosome analysis; additional specialized banding technique (eg, NOR, C-banding)
        8. 88289 Chromosome analysis; additional high resolution study
        9. 88291 Cytogenetics and molecular cytogenetics, interpretation and report
    iii. Add the following additional CPT codes to section "J" regarding FISH testing
        1. 88272 Molecular cytogenetics; chromosomal in situ hybridization, analyze 3-5 cells (eg, for derivatives and markers)
        2. 88274 Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells
4) Changes removing restrictions on panel testing for genetic diseases, pending the outcome of the VBBS/HERC discussion on new CPT code 81443
    i. Highlighted wording to be deleted

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

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

The following genetic screening tests are not covered:

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

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

Cell Free Fetal DNA Non-Invasive Prenatal Screening

Question: Should cell free fetal DNA non-invasive prenatal screening coverage be broadened to include average risk women?

Question source: Coalition for Access to Prenatal Screening (CAPS), an industry group representing the 6 leading genetic testing companies in the US

Issue: Cell free fetal DNA non-invasive prenatal screening (NIPS) is a test to determine a woman's risk of having an infant affected by various chromosomal aneuploidies. If a screening test is positive, a woman should be offered definitive testing such as amniocentesis. Cell free fetal DNA testing involves taking a maternal blood sample and isolating fetal DNA for testing. It does not carry any risk to the fetus.

Currently, cell free fetal DNA screening is only available in the prenatal genetic testing guideline to high risk women (maternal age >34, family history or elevated risk based on screening). The Coalition for Access to Prenatal Screening (CAPS) has requested consideration of expanding coverage of cell free fetal DNA screening to average risk women (see CAPS letter). This request is based on their claim of lower false positive screening rates and the 2018 ACOG guideline which CAPS feels recommends screening with NIPS be available to women of any risk level.

Several alternative testing modalities are currently available to both high and average risk women in the prenatal genetic testing guideline, including blood tests such as the triple or quad screen, and fetal nuchal translucency.

Current Prioritized List status:

1) CPT 81420 (Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21) is on line 1 PREGNANCY
2) CPT 81507 (Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy) is on line 1 PREGNANCY

Excerpt from Diagnostic Guideline D17

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

5. Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency] (CPT 76813, 76814, 81508-81511)
6. Cell free fetal DNA testing (CPT 81420, 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).

Evidence

1) **Badeau 2017**, Cochrane review on cell free fetal DNA screening
    a. N=65 studies of 86,139 pregnant women (3141 aneuploids and 82,998 euploids) were included.
        i. 42 enrolled pregnant women at high risk
        ii. five recruited an unselected population
        iii. 18 recruited cohorts with a mix of prior risk of fetal aneuploidy
        iv. Among the 65 studies, 44 evaluated massively parallel shotgun sequencing (MPSS) and 21 evaluated targeted massively parallel sequencing (TMPS)
    b. gNIPT assay failure rate ranged between 0% and 25% for MPSS, and between 0.8% and 7.5% for TMPS.
    c. In the population of unselected pregnant women, MPSS was evaluated by only one study; the study assessed T21, T18 and T13. TMPS was assessed for T21 in four studies involving unselected cohorts; three of the studies also assessed T18 and 13.
    d. In pooled analyses (88 T21 cases, 22 T18 cases, eight T13 cases and 20,649 unaffected pregnancies (non T21, T18 and T13)), the clinical sensitivity (95% confidence interval (CI)) of TMPS was 99.2% (78.2% to 100%), 90.9% (70.0% to 97.7%) and 65.1% (9.16% to 97.2%) for T21, T18 and T13, respectively. The corresponding clinical specificity was above 99.9% for T21, T18 and T13.
    e. We were unable to perform meta-analyses of gNIPT for 47,XXX, 47,XXY and 47,XYY because there were very few or no studies in one or more risk groups.
    f. Authors' conclusions: These results show that MPSS and TMPS perform similarly in terms of clinical sensitivity and specificity for the detection of fetal T31, T18, T13 and sex chromosome aneuploidy (SCA). The accuracy of gNIPT as a prenatal screening test has been mainly evaluated as a second-tier screening test to identify pregnancies at very low risk of fetal aneuploidies (T21, T18 and T13), thus avoiding invasive procedures. Genomics-based non-invasive prenatal testing methods appear to be sensitive and highly specific for detection of fetal trisomies 21, 18 and 13 in high-risk populations. There is paucity of data on the accuracy of gNIPT as a first-tier aneuploidy screening test in a population of unselected pregnant women. With respect to the replacement of invasive tests, the performance of gNIPT observed in this review is not sufficient to replace current invasive diagnostic tests. We conclude that given the current data on the performance of gNIPT, invasive fetal karyotyping is still the required diagnostic approach to confirm the presence of a chromosomal abnormality prior to making irreversible decisions relative to the pregnancy outcome. However, most of the gNIPT studies were prone to bias, especially in terms of the selection of participants.

1) **Gil 2017**, meta-analysis of cell free fetal DNA
https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1002/uog.17484
    a. N= 35 articles
        i. 9 "routine" population
        ii. 6 "mixture" population
        iii. 20 "high risk" population
        iv. Various laboratory techniques
    b. Trisomy 21: detection rate (DR) 99.7% (95% CI, 99.1–99.9%), false positive rate (FPR) 0.04% (95% CI, 0.02–0.07%)
    c. Trisomy 18: detection rate (DR) 97.9% (95% CI, 94.9–99.1%), false positive rate (FPR) 0.04% (95% CI, 0.03–0.07%)

   d. Trisomy 13: detection rate (DR) 99.0% (95% CI, 65.8–100%), false positive rate (FPR) 0.04% (95% CI, 0.02–0.07%)
   e. Monosomy X: detection rate (DR) 95.8% (95% CI, 70.3–99.5%) false positive rate (FPR) 0.14% (95% CI, 0.05–0.38%)
   f. Conclusions: Screening by analysis of cfDNA in maternal blood in singleton pregnancies could detect >99% of fetuses with trisomy 21, 98% of trisomy 18 and 99% of trisomy 13 at a combined FPR of 0.13%.

2) **TEC Assessment 2013,** noninvasive prenatal cell free fetal DNA screening for trisomy 21
   a. The sensitivity and specificity estimates of sequencing-based testing for trisomy 21 were uniformly high, ranging from 99.1% to 100%, and from 99.7% to 100%, respectively. Negative predictive values, whether calculated for average (pregnant women electing screening) or high-risk (age >35) populations, were uniformly high, near or at 100% as is desirable for a screening test. Positive predictive values were 83% and 55% for high- and average-risk populations, respectively, using point estimates for test sensitivity and specificity.

1) **TEC Assessment 2014**, noninvasive prenatal cell free fetal DNA screening for aneuploidies other than trisomy 21
   a. Examined trisomy 18 (T18), trisomy 13 (T13) and sex chromosome aneuploidies (SCA)
   b. N=29 articles
      i. T13 (N=16,927 patients screened), T18 (N=32,554 patients screened), monosomy X (N=8994 patients screened), and other SCA (N=6449 patients screened)
      ii. Maternal study populations were described or we inferred them to be: high risk for fetal aneuploidies in 21 of 29 (72%) studies; average risk in 6 (21%); mixed risk in 1 (3.5%); and not reported in 1 (3.5%). Among studies of T13 screening, 15 reported results in women deemed high risk for fetal aneuploidy (n=13,680) and 3 reported results in average-risk women (n=2144). For T18, 16 studies included women at high risk (n=16,694), and 6 included average-risk women (n=14,757).
   c. The detection rates for T13 ranged from 76% to 92%; for T18, they ranged from 91% to 97%. The pooled specificity for either T13 or T18 was nearly 100%. The detection rates for the SCA ranged from 77% to 91%, with specificity nearly 100%.
   d. Among average risk women, probability after a positive test was 0.011 for T13 and 0.037 for T18
   e. Conclusions:
      i. In general, assays from all companies currently offering fetal trisomy screening by sequencing cell-free fetal DNA in maternal plasma show high sensitivity and specificity for T13, T18, and SCA. False-positive rates were relatively consistent across the prevalence rates for the aneuploidies. Calculated post-test probabilities for a negative T13 or T18 test were exceedingly small.
      ii. Our findings indicate that for pregnant women undergoing aneuploidy screening, a strategy of using a cell-free fetal DNA–based screening test followed by confirmation of positive test results with an invasive procedure (amniocentesis or CVS) to determine fetal karyotype detected an equivalent or larger proportion of fetal T13 or T18 and missed fewer cases than a strategy employing the traditional integrated screen followed by amniocentesis or CVS diagnosis. Given that T13 and T18 cell-free fetal DNA–based tests will be performed along with T21 testing, the number of invasive procedures and

miscarriages secondary to an invasive diagnostic procedure will be reduced with the cell-free fetal DNA–based strategy (based on the conclusions of the 2012 TEC Assessment examining T21).

Economic analysis

1) **Nshimyumukiza 2017**, systematic review of economic evaluations https://onlinelibrary.wiley.com/doi/epdf/10.1111/cge.13155
    a. N=16 studies
        i. Conducted in a variety of countries/health care systems
            1. 8 studies in the US (7 with authors with conflicts of interest due to funding or being an employee of a laboratory conducting these tests)
        ii. In 12 studies, NIPT was considered as a universal test. In 13 studies, NIPT was evaluated as a contingent test.
        iii. The overall quality of the studies included was fair
    b. Compared to conventional (current) screening practice, universal NIPT was found not to be cost-effective in the majority of studies. However, it was dominant in 4 studies that included directs and indirect lifetime costs of management of aneuploidies. It was dominated in 1 study that considered QALY as the health outcome. It was possibly cost-effective in 2 studies depending on the willingness to pay threshold adopted. Contingent NIPT was found to be the dominant option in 3 studies, cost-neutral or cost-effective in 9 studies, and dominated or not cost-effective in 2 studies.
    c. Conclusion: At current level of NIPT prices, contingent NIPT provide the best value for money, especially for publicly funded screening programs. NIPT as first-line test was found not cost-effective in the majority of studies. The NIPT unit cost, the risk cut-offs for current screening practice, the screening uptake rates (first- and second-line screening) as well as the costs and uptake rates of invasive diagnostic screening were the most common uncertain variables. Considering a possible drop in prices and an ongoing NIPT expansion to include other chromosomes abnormalities other than T21, T18, T13 and sex chromosomes aneuploidies, future research are needed to examine the potential cost-effectiveness of implementing NIPT as first-line test.

Expert guidelines

1) **ACOG/Society for Maternal Fetal Medicine 2018**, practice guideline on screening for fetal aneuploidy https://s3.amazonaws.com/cdn.smfm.org/publications/224/download-491f0e6962960848d2097447ab57a024.pdf
    a. Recommend some type of fetal aneuploidy screening for all pregnant women
    b. Cell free fetal DNA advantages
        i. Highest detection rate for Down Syndrome (98%)
        ii. Can be performed at any gestational age after 10 weeks
        iii. Low false positive rate in high risk women
    c. Cell free fetal DNA disadvantages
        i. Negative and positive predictive values not clearly reported
        ii. Higher false positive rate in women at low risk for Down Syndrome
            1. Positive predictive value for all risk women is 93%
        iii. Lower detection rate for other trisomies such as 13 and 18
            1. Positive predictive value for trisomy 13 is 44%

2. Positive predictive value for trisomy 18 is 64%
3. Positive predictive value for sex chromosome aneuploidy is 39%

iv. Results do not always represent a fetal DNA result
v. There may be a "no call" result (unable to find enough fetal DNA) which may delay screening/definitive testing if needed
1. In one study of 1,000 analyzed samples, 8% failed to return a result

d. Results in average risk woman
i. To date, 5 studies have been done on average risk population, with similar detection rates as for high risk women, but lower positive predictive values due to lower prevalence of aneuploidies in this population; therefore there are more false positives
e. All women with a positive cell free DNA test should have a diagnostic procedure such as an amniocentesis prior to irreversible action, such as pregnancy termination
f. Cell free DNA screening tests for microdeletions have not been validated clinically and are not recommended at this time

2) **National Society of Genetic Counselors 2016**:
a. The National Society of Genetic Counselors supports prenatal cell-free DNA (cfDNA) screening, also known as NIPT or NIPS, as an option for pregnant patients.

<u>Cost data:</u>
Reimbursement rates for FFS:
81420 $531.34.
81507 $556.50

<u>Other coverage policies</u>:
1) **Aetna 2018**: covers non invasive prenatal genetic screening only for high risk women
2) **Premara BCBS 2018**: covers non invasive prenatal genetic screening for all singleton pregnancies
3) **Healthnet 2018**: covers non invasive prenatal genetic screening for only high risk women

Many state Medicaid programs are currently covering non invasive prenatal genetic screening only for high risk women; others are covering for all pregnant women

<u>Expert input</u>
Dr. Leo Pereira, Chair OHSU Perinatalogy

I'm a big fan of cfDNA in low risk women (but in the minority at present). My thoughts on it are that compared to the standard screening that we offer low risk women (quad screen or first trimester screening) cfDNA has higher sensitivity and lower false positive rates. It is true that cfDNA does not perform as well in low risk women compared to high risk women, but that is true for all the screening tests we have.

The cost-benefit studies for cfDNA in low risk women are mixed and depend on if you include life time costs from undetected chromosome anomalies – most of which would have been terminated – or not. So that may be the one reasonable argument for not offering it universally at this

time. However, if the cost of the test comes down then it is a no brainer for me because it is better than current screening.

GAP discussion

The GAP discussed that ACOG is expected to be coming out soon with a new guideline recommending universal NIPS screening (high and low risk women). There is concern about use of NIPS to determine the gender of the baby. The GAP members did feel that it was a better screening test for trisomies that traditional screening tests. There is a newer form of NIPS that can also give a pre-eclampsia risk which could allow for treatment with aspirin in pregnancy to lower the risk of pre-eclampsia. GAP members noted that NIPS is a rapidly changing field.

It was noted by an audience member that the ACOG guideline says that any type of screening is appropriate, but does not say that NIPS should be restricted to high risk women. Therefore, the current ACOG opinion could be interpreted to indicate that ACOG feels that NIPS is appropriate for all risk women. Far more women have false positive tests with traditional screening methods, causing increase invasive testing and expense.

Ashley Allen from Roche Diagnostics noted that NIPS is a more sensitive and specific test that traditional screening, and will reduce the number of women requiring invasive procedures such as amniocentesis, which lowers cost and adverse outcomes. She states that most private payers in Oregon (Premara, Regence, Anthem) cover all risk women for NIPS. Not covering for OHP causes disparities.

The GAP decision was to make no change in the current restriction of NIPS to high risk women. HERC staff will monitor for the new ACOG statement expected to come out in favor of universal NIPS screening. If ACOG publishes such an opinion, GAP would be in favor of changing the prenatal genetic testing guideline to allow use for low and high risk women. Such a change can be made prior to the next GAP meeting or can be taken up at the 2019 GAP meeting

HERC staff summary:

Cell free fetal DNA screening for aneuploidies is highly sensitive and specific among high risk women. It is significantly less sensitive and specific among average risk women, particularly for aneuploidies other than trisomy 21. A recent economic meta-analysis did not find it cost effective as first line screening among average risk women. ACOG recommends some type of aneuploidy screening for average risk women, but does not specify the recommended testing modality. Private insurer policies vary on coverage of non-invasive prenatal genetic screening.

GAP/HERC staff recommendation:

1) Make no change in the current prenatal genetic testing guideline regarding restricting cell free fetal DNA testing to high risk women
    a. Revisit for 2019 GAP meeting if new ACOG guidelines are published

Appendix A

Disposition of submitted literature

1) Benn 2015: included in Nshimyumukiza 2017
2) Bianchi 2018: clinical review
3) Fairbrother 2015: included in Nshimyumukiza 2017
4) Nazareth 2018: not scientific literature
5) Society for Maternal-Fetal Medicine 2017: did not address the question

iStent for Glaucoma with Cataract Removal

Question: Should iStent® (CPT 0191T) be added to the Prioritized List for treatment of glaucoma?

Question source: Holly Jo Hodges, CCO medical director

Issue: At the October, 2018 VBBS meeting, iStent was discussed and the evidence regarding its effectiveness was reviewed. The procedure was found to be effective at reducing intraocular pressure and the amount of glaucoma medications requires. Trusted sources such as NICE recommend utilization. iStent is only FDA approved when done in conjunction with cataract removal. It was noted at the October meeting that CMS required that iStent be billed with cataract removal in a bundle. VBBS generally agreed with the staff recommendation for coverage but wanted to ensure that iStent was bundled with cataract removal so as not to cause a large cost increase. HERC staff was charged with working with HSD to determine if there was any HSD rule requiring OHP to following CMS billing/bundling requirements.

HSD has reviewed the iStent CPT code (CPT 0191T) and found that it is a utilization management requirement to bundle payment, not a CMS rule. OHP was following CMS payment models, including bunding, but this code appears to not fall under a CMS bundle. HSD staff noted that HERC guidelines would suffice to require a bundled payment.

HERC staff recommendation:

1) Add CPT 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork) to line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
2) Add a new guideline note to line 139 to require bundling iStent with cataract removal

GUIDELINE NOTE XXX ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE INSERTION
Line 139
Anterior segment aqueous drainage device (e.g. iStent©) insertion is only included on this line when done at the same time as cataract removal and when the two procedures are billed together as a bundled service.

Donor Breast Milk Update

Question: For which specific conditions should human donor breast milk be included on the Prioritized List?

Question source: VbBS

Issue: At the October 4, 2018 VbBS/HERC meeting there was a decision to adopt a guideline addressing human donor breast milk in high risk infants. VbBS had asked staff to further investigate which gastrointestinal conditions may be most benefited by human donor breast milk and ensure line placement clearly aligns with the population most expected to benefit from human donor breast milk.

New Prioritized List guideline note

GUIDELINE NOTE XXX DONOR BREAST MILK FOR HIGH RISK INFANTS

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

Donor breast milk is included on these lines for infants up to 6 months of age (adjusted for gestational age) who are low birth weight (<1500g) or have underlying gastrointestinal disease (e.g. gastroschisis) AND where maternal breast milk is not available, appropriate or sufficient to meet the infant's needs, despite lactation support for the mother.

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

Lines considered at the end of the last meeting:

Add T2101 *Human breast milk processing, storage and distribution only* to:

Line 2 BIRTH OF INFANT
Line 16 LOW BIRTH WEIGHT; PREMATURE NEWBORN
Line 18 FEEDING PROBLEMS IN NEWBORNS
Line 34 OTHER CONGENITAL ANOMALIES OF ABDOMINAL STRUCTURES
Line 88 NECROTIZING ENTEROCOLITIS IN FETUS OR NEWBORN
Line 101 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION

Line 2 BIRTH OF INFANT

Code	Code Description
P00.0	Newborn affected by maternal hypertensive disorders
P00.1	Newborn affected by maternal renal and urinary tract diseases
P00.2	Newborn affected by maternal infectious and parasitic diseases
P00.3	Newborn affected by other maternal circulatory and respiratory diseases
P00.4	Newborn affected by maternal nutritional disorders
P00.5	Newborn affected by maternal injury

Code	Code Description
P00.6	Newborn affected by surgical procedure on mother
P00.7	Newborn affected by other medical procedures on mother, not elsewhere classified
P00.81	Newborn affected by periodontal disease in mother
P00.89	Newborn affected by other maternal conditions
P00.9	Newborn affected by unspecified maternal condition
P01.0	Newborn affected by incompetent cervix
P01.1	Newborn affected by premature rupture of membranes
P01.2	Newborn affected by oligohydramnios
P01.3	Newborn affected by polyhydramnios
P01.4	Newborn affected by ectopic pregnancy
P01.5	Newborn affected by multiple pregnancy
P01.6	Newborn affected by maternal death
P01.7	Newborn affected by malpresentation before labor
P01.8	Newborn affected by other maternal complications of pregnancy
P01.9	Newborn affected by maternal complication of pregnancy, unspecified
P02.0	Newborn affected by placenta previa
P02.1	Newborn affected by other forms of placental separation and hemorrhage
P02.20	Newborn affected by unspecified morphological and functional abnormalities of placenta
P02.29	Newborn affected by other morphological and functional abnormalities of placenta
P02.3	Newborn affected by placental transfusion syndromes
P02.4	Newborn affected by prolapsed cord
P02.5	Newborn affected by other compression of umbilical cord
P02.60	Newborn affected by unspecified conditions of umbilical cord
P02.69	Newborn affected by other conditions of umbilical cord
P02.70	Newborn affected by fetal inflammatory response syndrome
P02.78	Newborn affected by other conditions from chorioamnionitis
P02.8	Newborn affected by other abnormalities of membranes
P02.9	Newborn affected by abnormality of membranes, unspecified
P03.0	Newborn affected by breech delivery and extraction
P03.1	Newborn affected by other malpresentation, malposition and disproportion during labor and delivery
P03.2	Newborn affected by forceps delivery
P03.3	Newborn affected by delivery by vacuum extractor [ventouse]
P03.4	Newborn affected by Cesarean delivery
P03.5	Newborn affected by precipitate delivery
P03.6	Newborn affected by abnormal uterine contractions
P03.810	Newborn affected by abnormality in fetal (intrauterine) heart rate or rhythm before the onset of labor
P03.811	Newborn affected by abnormality in fetal (intrauterine) heart rate or rhythm during labor
P03.819	Newborn affected by abnormality in fetal (intrauterine) heart rate or rhythm, unspecified as to time of onset
P03.82	Meconium passage during delivery
P03.89	Newborn affected by other specified complications of labor and delivery

Code	Code Description
P03.9	Newborn affected by complication of labor and delivery, unspecified
P04.0	Newborn affected by maternal anesthesia and analgesia in pregnancy, labor and delivery
P04.11	Newborn affected by maternal antineoplastic chemotherapy
P04.12	Newborn affected by maternal cytotoxic drugs
P04.13	Newborn affected by maternal use of anticonvulsants
P04.14	Newborn affected by maternal use of opiates
P04.15	Newborn affected by maternal use of antidepressants
P04.16	Newborn affected by maternal use of amphetamines
P04.17	Newborn affected by maternal use of sedative-hypnotics
P04.1A	Newborn affected by maternal use of anxiolytics
P04.18	Newborn affected by other maternal medication
P04.19	Newborn affected by maternal use of unspecified medication
P04.2	Newborn affected by maternal use of tobacco
P04.3	Newborn affected by maternal use of alcohol
P04.40	Newborn affected by maternal use of unspecified drugs of addiction
P04.41	Newborn affected by maternal use of cocaine
P04.42	Newborn affected by maternal use of hallucinogens
P04.49	Newborn affected by maternal use of other drugs of addiction
P04.5	Newborn affected by maternal use of nutritional chemical substances
P04.6	Newborn affected by maternal exposure to environmental chemical substances
P04.81	Newborn affected by maternal use of cannabis
P04.89	Newborn affected by other maternal noxious substances
P04.9	Newborn affected by maternal noxious substance, unspecified
P05.00	Newborn light for gestational age, unspecified weight
P05.01	Newborn light for gestational age, less than 500 grams
P05.02	Newborn light for gestational age, 500-749 grams
P05.03	Newborn light for gestational age, 750-999 grams
P05.04	Newborn light for gestational age, 1000-1249 grams
P05.05	Newborn light for gestational age, 1250-1499 grams
P05.06	Newborn light for gestational age, 1500-1749 grams
P05.07	Newborn light for gestational age, 1750-1999 grams
P05.08	Newborn light for gestational age, 2000-2499 grams
P05.09	Newborn light for gestational age, 2500 grams and over
P05.10	Newborn small for gestational age, unspecified weight
P05.11	Newborn small for gestational age, less than 500 grams
P05.12	Newborn small for gestational age, 500-749 grams
P05.13	Newborn small for gestational age, 750-999 grams
P05.14	Newborn small for gestational age, 1000-1249 grams
P05.15	Newborn small for gestational age, 1250-1499 grams
P05.16	Newborn small for gestational age, 1500-1749 grams
P05.17	Newborn small for gestational age, 1750-1999 grams

Code	Code Description
P05.18	Newborn small for gestational age, 2000-2499 grams
P05.19	Newborn small for gestational age, other
P05.2	Newborn affected by fetal (intrauterine) malnutrition not light or small for gestational age
P05.9	Newborn affected by slow intrauterine growth, unspecified
P22.1	Transient tachypnea of newborn
P29.11	Neonatal tachycardia
P29.12	Neonatal bradycardia
P29.2	Neonatal hypertension
P29.4	Transient myocardial ischemia in newborn
P29.81	Cardiac arrest of newborn
P29.89	Other cardiovascular disorders originating in the perinatal period
P29.9	Cardiovascular disorder originating in the perinatal period, unspecified
P39.3	Neonatal urinary tract infection
P92.01	Bilious vomiting of newborn
P92.09	Other vomiting of newborn
P94.1	Congenital hypertonia
P94.2	Congenital hypotonia
P94.8	Other disorders of muscle tone of newborn
P94.9	Disorder of muscle tone of newborn, unspecified
P96.0	Congenital renal failure
P96.3	Wide cranial sutures of newborn
P96.5	Complication to newborn due to (fetal) intrauterine procedure
P96.82	Delayed separation of umbilical cord
P96.83	Meconium staining
P96.89	Other specified conditions originating in the perinatal period
Q27.0	Congenital absence and hypoplasia of umbilical artery
Z05.0	Observation and evaluation of newborn for suspected cardiac condition ruled out
Z05.1	Observation and evaluation of newborn for suspected infectious condition ruled out
Z05.2	Observation and evaluation of newborn for suspected neurological condition ruled out
Z05.3	Observation and evaluation of newborn for suspected respiratory condition ruled out
Z05.41	Observation and evaluation of newborn for suspected genetic condition ruled out
Z05.42	Observation and evaluation of newborn for suspected metabolic condition ruled out
Z05.43	Observation and evaluation of newborn for suspected immunologic condition ruled out
Z05.5	Observation and evaluation of newborn for suspected gastrointestinal condition ruled out
Z05.6	Observation and evaluation of newborn for suspected genitourinary condition ruled out
Z05.71	Observation and evaluation of newborn for suspected skin and subcutaneous tissue condition ruled out
Z05.72	Observation and evaluation of newborn for suspected musculoskeletal condition ruled out
Z05.73	Observation and evaluation of newborn for suspected connective tissue condition ruled out
Z05.8	Observation and evaluation of newborn for other specified suspected condition ruled out
Z05.9	Observation and evaluation of newborn for unspecified suspected condition ruled out
Z38.00	Single liveborn infant, delivered vaginally

Code	Code Description
Z38.01	Single liveborn infant, delivered by cesarean
Z38.1	Single liveborn infant, born outside hospital
Z38.2	Single liveborn infant, unspecified as to place of birth
Z38.30	Twin liveborn infant, delivered vaginally
Z38.31	Twin liveborn infant, delivered by cesarean
Z38.4	Twin liveborn infant, born outside hospital
Z38.5	Twin liveborn infant, unspecified as to place of birth
Z38.61	Triplet liveborn infant, delivered vaginally
Z38.62	Triplet liveborn infant, delivered by cesarean
Z38.63	Quadruplet liveborn infant, delivered vaginally
Z38.64	Quadruplet liveborn infant, delivered by cesarean
Z38.65	Quintuplet liveborn infant, delivered vaginally
Z38.66	Quintuplet liveborn infant, delivered by cesarean
Z38.68	Other multiple liveborn infant, delivered vaginally
Z38.69	Other multiple liveborn infant, delivered by cesarean
Z38.7	Other multiple liveborn infant, born outside hospital
Z38.8	Other multiple liveborn infant, unspecified as to place of birth

Line 16 LOW BIRTH WEIGHT; PREMATURE NEWBORN

Code	Code Description
P07.00	Extremely low birth weight newborn, unspecified weight
P07.01	Extremely low birth weight newborn, less than 500 grams
P07.02	Extremely low birth weight newborn, 500-749 grams
P07.03	Extremely low birth weight newborn, 750-999 grams
P07.10	Other low birth weight newborn, unspecified weight
P07.14	Other low birth weight newborn, 1000-1249 grams
P07.15	Other low birth weight newborn, 1250-1499 grams
P07.16	Other low birth weight newborn, 1500-1749 grams
P07.17	Other low birth weight newborn, 1750-1999 grams
P07.18	Other low birth weight newborn, 2000-2499 grams
P07.20	Extreme immaturity of newborn, unspecified weeks of gestation
P07.21	Extreme immaturity of newborn, gestational age less than 23 completed weeks
P07.22	Extreme immaturity of newborn, gestational age 23 completed weeks
P07.23	Extreme immaturity of newborn, gestational age 24 completed weeks
P07.24	Extreme immaturity of newborn, gestational age 25 completed weeks
P07.25	Extreme immaturity of newborn, gestational age 26 completed weeks
P07.26	Extreme immaturity of newborn, gestational age 27 completed weeks
P07.30	Preterm newborn, unspecified weeks of gestation
P07.31	Preterm newborn, gestational age 28 completed weeks
P07.32	Preterm newborn, gestational age 29 completed weeks
P07.33	Preterm newborn, gestational age 30 completed weeks

Code	Code Description
P07.34	Preterm newborn, gestational age 31 completed weeks
P07.35	Preterm newborn, gestational age 32 completed weeks
P07.36	Preterm newborn, gestational age 33 completed weeks
P07.37	Preterm newborn, gestational age 34 completed weeks
P07.38	Preterm newborn, gestational age 35 completed weeks
P07.39	Preterm newborn, gestational age 36 completed weeks
P83.0	Sclerema neonatorum
P91.60	Hypoxic ischemic encephalopathy [HIE], unspecified

Line 18 FEEDING PROBLEMS IN NEWBORNS

Code	Code Descriptions
P78.2	Neonatal hematemesis and melena due to swallowed maternal blood
P78.83	Newborn esophageal reflux
P92.1	Regurgitation and rumination of newborn
P92.2	Slow feeding of newborn
P92.3	Underfeeding of newborn
P92.4	Overfeeding of newborn
P92.5	Neonatal difficulty in feeding at breast
P92.6	Failure to thrive in newborn
P92.8	Other feeding problems of newborn
P92.9	Feeding problem of newborn, unspecified
Q38.1	Ankyloglossia

Line 34 OTHER CONGENITAL ANOMALIES OF ABDOMINAL STRUCTURES

Code	Description
Q79.0	Congenital diaphragmatic hernia
Q79.1	Other congenital malformations of diaphragm
Q79.2	Exomphalos
Q79.3	Gastroschisis
Q79.4	Prune belly syndrome
Q79.51	Congenital hernia of bladder
Q79.59	Other congenital malformations of abdominal wall

Line 88 NECROTIZING ENTEROCOLITIS IN FETUS OR NEWBORN

Code	Code Description
K55.30	Necrotizing enterocolitis, unspecified
K55.31	Stage 1 necrotizing enterocolitis
K55.32	Stage 2 necrotizing enterocolitis
K55.33	Stage 3 necrotizing enterocolitis
P77.1	Stage 1 necrotizing enterocolitis in newborn

Code	Code Description
P77.2	Stage 2 necrotizing enterocolitis in newborn
P77.3	Stage 3 necrotizing enterocolitis in newborn
P77.9	Necrotizing enterocolitis in newborn, unspecified
Z46.59	Encounter for fitting and adjustment of other gastrointestinal appliance and device

Line 101 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION

Code	Code Description
K31.6	Fistula of stomach and duodenum
P76.0	Meconium plug syndrome
P76.1	Transitory ileus of newborn
P76.2	Intestinal obstruction due to inspissated milk
P76.8	Other specified intestinal obstruction of newborn
P76.9	Intestinal obstruction of newborn, unspecified
P78.1	Other neonatal peritonitis
P78.81	Congenital cirrhosis (of liver)
P78.84	Gestational alloimmune liver disease
P78.89	Other specified perinatal digestive system disorders
Q40.0	Congenital hypertrophic pyloric stenosis
Q41.0	Congenital absence, atresia and stenosis of duodenum
Q41.1	Congenital absence, atresia and stenosis of jejunum
Q41.2	Congenital absence, atresia and stenosis of ileum
Q41.8	Congenital absence, atresia and stenosis of other specified parts of small intestine
Q41.9	Congenital absence, atresia and stenosis of small intestine, part unspecified
Q42.0	Congenital absence, atresia and stenosis of rectum with fistula
Q42.1	Congenital absence, atresia and stenosis of rectum without fistula
Q42.2	Congenital absence, atresia and stenosis of anus with fistula
Q42.3	Congenital absence, atresia and stenosis of anus without fistula
Q42.8	Congenital absence, atresia and stenosis of other parts of large intestine
Q42.9	Congenital absence, atresia and stenosis of large intestine, part unspecified
Q43.0	Meckel's diverticulum (displaced) (hypertrophic)
Q43.1	Hirschsprung's disease
Q43.2	Other congenital functional disorders of colon
Q43.3	Congenital malformations of intestinal fixation
Q43.4	Duplication of intestine
Q43.5	Ectopic anus
Q43.6	Congenital fistula of rectum and anus
Q43.7	Persistent cloaca
Q43.8	Other specified congenital malformations of intestine
Q43.9	Congenital malformation of intestine, unspecified
Q45.0	Agenesis, aplasia and hypoplasia of pancreas
Q45.1	Annular pancreas

Code	Code Description
Q45.2	Congenital pancreatic cyst
Q45.3	Other congenital malformations of pancreas and pancreatic duct
Q45.8	Other specified congenital malformations of digestive system
Q45.9	Congenital malformation of digestive system, unspecified
T86.890	Other transplanted tissue rejection
T86.891	Other transplanted tissue failure
T86.892	Other transplanted tissue infection
T86.898	Other complications of other transplanted tissue
T86.899	Unspecified complication of other transplanted tissue
Z46.59	Encounter for fitting and adjustment of other gastrointestinal appliance and device

Evidence summary (newly identified since last meeting)
MED, 2017 for New York EBBRAC

Key Findings:

- Donor human milk could help to prevent necrotizing enterocolitis (*moderate strength of evidence*), and increase maternal breastfeeding at NICU discharge (*low strength of evidence*), but could also result in slower short-term growth (*low strength of evidence*).
- There is evidence that the use of donor human milk does not significantly change neurodevelopmental outcomes (*moderate strength of evidence*), the risk of death (*low strength of evidence*), or retinopathy of prematurity (*low strength of evidence)*.
- There were no eligible studies to determine the effect of donor human milk on NICU length of stay, costs, or cost-effectiveness.

Guidelines from others
Northwest Mothers Milk Bank

Donor human milk can be prescribed for the treatment of various medical conditions including, but not limited to:

1. Prematurity
2. Malabsorption
3. Feeding Intolerance
4. Immunologic deficiencies
5. Congenital anomalies
6. Post-Operative nutrition
7. Trophic feeds/gut priming

8. Any medically indicated need for infant supplementation

If supplies of banked milk are sufficient, milk may be dispensed by prescription for a large variety of situations, including, but not limited to:

1. Absent of insufficient lactation
2. Adoption or surrogacy
3. Illness in the mother requiring temporary interruption of breastfeeding
4. Health risk to the infant from the milk of the biological mother.
5. Death of the mother.
6. When human milk is required for medical indications, and mother's own milk is insufficient or unavailable.

From highest to lowest priority, based on the following factors, from most critical (1) to least critical (3), and community benefit (CB) to individual benefit/choice (IB):

1. Premature Infants, sick (1,2,3-CB & IB)
2. Premature infants, well (2,3 – CB & IB)
3. Infants less than 12 months old with medical conditions likely to respond to donor human milk therapy (1,2,3 – CB & IB)
4. Individuals more than 12 months old with medical conditions likely to respond to donor human milk therapy (1,2 – CB & IB)
5. Research contracts for clinical use in well-designated studies (1,3 – CB & IB)
6. Individuals more than 12 months old with chronic medical conditions and high normal functioning and low dose need for donor human milk therapy (3 – CB & IB)
7. Individuals more than 12 months old with chronic medical conditions and high normal functioning and high dose need for donor human milk therapy (3 – CB & IB)
8. Individuals more than 12 months old with chronic medical conditions and low level functioning and low dose need for donor human milk therapy (IB)
9. Individuals more than 12 months old with chronic medical conditions and low level functioning and high dose need for donor human milk therapy (3- CB & IB)
10. Infants for short-term use, with no specific medical condition (IB)
11. Laboratory research (milk that cannot be used for human consumption due to drugs used by the donor or lack of complete screening/testing of the donor) (1 – CB)

OHSU Policy, 2015

Indications for use of pasteurized Human Donor Milk (HDM):

1. The following infants will be offered HDM regardless of maternal intent to breastfeed after discharge or previous formula use:
    a. Any infant with birth weight less than 1500 grams
    b. Any critically ill infant with birth weight greater than 1500 grams
    c. Short term use as part of a palliative care plan

2. Healthy infants greater than 1500 grams who are temporarily separated from their mothers or have medical indications for supplementation may be offered HDM when available, if there is a plan to provide breast milk after discharge. Potential medical indications for supplemental feeding include, but are not limited to, hypoglycemia, jaundice, dehydration, excessive weight loss, and prematurity. Other indications may be reviewed with Lactation Services.

AAP, 2016

- Fewer data are available regarding the use of donor human milk in other high-risk infants, including infants with abdominal wall defects, such as gastroschisis or omphalocele, and other conditions, such as congenital heart disease. Nonetheless, some infants with these conditions or other neonatal disorders may benefit from donor human milk either because of a direct effect on intestinal growth or improved feeding tolerance.

Policies from others

NY Medicaid Coverage of Pasteurized Donor Human Milk

Effective July 1, 2017, in accordance with the 2017-18 enacted state budget, pasteurized donor human milk (PDHM) for inpatient use is a covered benefit under the Medicaid program.

In accordance with an amendment to subdivision 2 of section 365-a of the Social Services Law, inpatient use of pasteurized donor human milk (PDHM), with fortifiers as medically indicated, requires a written medical order from a licensed medical practitioner. Medically necessary PDHM is covered for infants who:

- Have a documented birth weight of less than 1500 grams; or
- Have a congenital or acquired condition that places the infant at a high risk of developing necrotizing enterocolitis (NEC) and/or infection; or
- Have other qualifying condition(s) as determined by the Commissioner of Health or his/her designee.

PDHM is covered when infants meet the above criteria and there is a written medical order. Coverage of PDHM is for infants who are medically or physically unable to receive maternal breast milk or participate in breast feeding, or in cases where the mother is medically or physically unable to produce maternal breast milk at all or in sufficient quantities, or is unable to participate in breast feeding despite optimal lactation support.

Medicaid managed care (MMC) plans are required to cover inpatient use of PDHM when medically necessary.

AmeriHealth Caritas (2017)

- Donor human milk is medically necessary for infants at risk of necrotizing enterocolitis, at risk for malabsorption, or for whom the mother's breast milk is contraindicated or otherwise unavailable

HERC Staff Recommendations

There is no specific evidence about which intestinal conditions may best be served by human donor breast milk; however, nonspecific infectious gastroenteritis is significantly improved with breast milk. Children most likely to be susceptible to gastroenteritis with adverse sequelae may be the most impacted. The major focus of who should be eligible for human donor breast milk continues to be inpatient infants who are low birth weight. Line 2 BIRTH OF INFANT is broad enough that more specific diagnoses would need to be indicated, similar to Line 18 FEEDING PROBLEMS IN NEWBORNS

Recommendations:

1) Add a guideline note:
   GUIDELINE NOTE XXX DONOR BREAST MILK FOR HIGH RISK INFANTS

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

   Donor breast milk (T2101) is included on these lines for infants up to 6 months of age (adjusted for gestational age) who meet all of the following criteria:
   - Low birth weight (<1500g) OR with severe underlying gastrointestinal disease
   - Human donor milk was continued through neonatal hospital discharge for a clear medical indication
   - Persistent outpatient medical need for human donor breast milk due to ongoing severe concerns with persistent diarrhea or malabsorption with improvement on breast milk compared to formula
   - When maternal breast milk is not available, appropriate or sufficient to meet the infant's needs, despite lactation support for the mother.

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

2) Delay implementation until October 1, 2019 because a State Plan Amendment (SPA) is necessary.

Section 3.0

Multisector Intervention scope statements

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

Community Health Workers for Patients with Chronic Disease

Population description	Adults or children with at least one of the following: asthma, diabetes, hypertension, heart failure, HIV, serious mental illness. High utilizers *Population scoping notes: Exclude studies from low and middle-income countries, patients with substance use disorders, doulas, prenatal programs*
Intervention(s)	Engagement with a community health worker (CHW) *Intervention exclusions: None*
Comparator(s)	Usual care without a CHW, other methods of patient engagement and activation
Outcome(s) (up to five)	Critical: Disease-specific morbidity measures, ED visits, hospitalizations Important: Medication adherence, harms *Considered but not selected for GRADE Table: Engagement or patient activation scores*
Key questions	1. What is the effectiveness of CHWs for improving health outcomes and reducing health care utilization in adults and children with chronic diseases? 2. Does the effectiveness of CHWs vary by: a. Patient characteristics b. Type of chronic condition(s) being addressed c. Co-morbid conditions d. Characteristics of CHW intervention (intensity, setting, methods of engagement) e. Characteristics of the CHWs 3. What are the harms of CHWs?

CHANGE LOG

Date	Change	Rationale
7/12/2018	Added high utilizers to population; changed substance abuse to substance use.	EbGS discussion

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

Multisector Interventions to Reduce the Frequency of Asthma Exacerbations

Population description	Adults and children with asthma *Population scoping notes: None*
Intervention(s)	Case management programs, school-based interventions, home-based interventions, provider- or pharmacist- directed programs *Intervention exclusions: Clinical interventions that are part of usual care*
Comparator(s)	No intervention, usual care, listed interventions compared to each other, pharmacologic or procedural treatments to reduce asthma exacerbations
Outcome(s) (up to five)	Critical: Frequency and severity of asthma exacerbations, emergency department/hospital utilization, missed school/work days Important: Quality of life, harms *Considered but not selected for GRADE Table: None*
Key questions	1. What is the effectiveness of multisector interventions to reduce the frequency of asthma exacerbations? 2. Does the effectiveness of multisector interventions to reduce the frequency of asthma exacerbations vary by: a. Participant characteristics (demographics) b. History of previous exacerbations c. Adherence to pharmacologic interventions d. Environmental/social factors (parental smoking, pets) e. Delivery setting f. Characteristics of the intervention (type of provider, engagement with parents, provision of services to ameliorate asthma triggers) 3. What are the harms of multisector interventions to reduce the frequency of asthma exacerbations?

CHANGE LOG

Date	Change	Rationale
8/30/2018	Deleted air quality alerts, indoor and outdoor air quality and interventions to reduce diesel exhaust	Lack of interest based on survey responses and other feedback.

Date	Change	Rationale
7/12/18	Clarified that health behavior interventions are excluded. Changed the key questions from nonpharmacologic to multisector.	EbGS discussion

Section 4.0

Out Of Hospital Birth rescan

HERC Staff Assessment

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

Public comment from the out of hospital birth community proposed modifying the consultation criteria (to delete some required consultation criteria such as obesity). It also included submission of studies related to out-of-hospital birth, some of which did not meet the search criteria. It seems unlikely based on the rescan that there would be significant new information to help with modifying those consultation criteria, although there are some updates to guideline from others that may result in minor modifications.

Staff has also received requests related to the timing and implementation of the Oregon Health Plan's prior authorization process; addressing these issues is not within HERC's purview.

Public comment also proposed modifications to add additional exclusion criteria such as additional neonatal transfer criteria. As with the requests above, there may be guideline updates which may result in minor modifications.

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

HERC Staff Recommendation

Do not reopen the Coverage Guidance on Planned Out-of-Hospital Birth

Health Evidence Review Commission (HERC)

Rescanning Summary: Planned Out-of-Hospital Birth

DRAFT for HERC Meeting 11/8/2018

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Evidence Summary

This updated review of evidence published after the 2015 coverage guidance on out-of-hospital birth largely comports with current coverage guidance. The available studies from U.S.-based settings demonstrate that planned home birth is associated with increased likelihood of unassisted vaginal delivery, but carries a small but increased risk of harm to newborns in low-risk situation. In high-risk situations (e.g., malpresentation, prior cesarean delivery, gestational age over 41 weeks) the risk of harm to the newborn is greater. The majority of U.S-based studies rely on birth and death certificate data which do not fully capture maternal risk factors, is at risk for misclassification bias, and may underreport planned home birth in states without licensure for lay midwives.

Scope Statement

Population description	Pregnant women
Intervention(s)	Planned out of hospital birth (home or birth center) *Intervention exclusions: None*
Comparator(s)	Planned birth in a hospital
Outcome(s) (up to five)	Critical outcomes: Delivery mode (cesarean, operative vaginal delivery, spontaneous vaginal delivery), perinatal mortality, serious neonatal morbidity (e.g., seizures, NICU admission, low Apgar's, hypoxic ischemic encephalopathy, sepsis), serious maternal harm (e.g., postpartum hemorrhage, serious infection, mortality) Important outcomes: Breastfeeding *Considered but not selected for GRADE Table: None*
Key questions	1. What is the comparative effectiveness of planned out-of-hospital birth compared to hospital birth? 2. Does the comparative effectiveness of planned out-of-hospital birth vary by: a. Patient characteristics (demographics) b. Risk factors (pregnancy or pre-pregnancy) and comorbidities c. Setting (including home, out-of-hospital birth center) d. Location (U.S. vs non-U.S.) 3. What are the harms of planned out-of-hospital birth compared to hospital birth? 4. Do the harms of planned out of hospital birth vary by: a. Patient characteristics (demographics) b. Risk factors (pregnancy or pre-pregnancy) and comorbidities c. Setting (including home, out-of-hospital birth center) d. Location (U.S. vs non-U.S.)

	e. Provider characteristics
Contextual questions	1. What do applicable guidelines recommend as standards for consultation and referral or transfer of patients planning OOHB? a. What conditions require consultation? b. What conditions require transfer? 2. What systems factors (e.g., coordination of OOHB with consultants, hospitals, and emergency transportation) are associated with differential outcomes in OOHB? 3. What is the rate of expected transfer to a hospital setting with a planned out of hospital birth? 4. What are example coverage criteria from other public and private payers?

Change log

Date	Change	Rationale
10/8/18	Added Key Question 4.a to capture comparative effectiveness variation based on provider characteristics.	Based on public comment
10/8/18	Added Contextual Question 3 to look for information on rate of expected transfer to a hospital setting with a planned out of hospital birth.	Based on public comment

2018 Rescanning Results

Studies reviewed for applicability; methodological quality not assessed.

Oregon-based Studies

Snowden, J. M., Tilden, E. L., Snyder, J., Quigley, B., Caughey, A. B., & Cheng, Y. W. (2015). Planned out-of-hospital birth and birth outcomes. *New England Journal of Medicine, 373*(27), 2642-2653.

This is a retrospective cohort study using Oregon birth certificate data. Adjusted analyses demonstrated increased risk of perinatal death for planned out-of-hospital birth compared to planned in-hospital birth (OR 2.43; 95% CI 1.37 to 4.30). Planned out-of-hospital birth was associated with lower odds of cesarean delivery (OR 0.18; 95% CI 0.16 to 0.22) and increased odds of unassisted vaginal delivery (OR 5.63; 95% CI 4.84 to 6.55). Planned out-of-hospital birth was associated with increased risk of blood transfusion (OR 1.91; 95% CI 1.25 to 2.93). Overall, fetal death was rare: planned-out-of-hospital birth excess risk was less than 1 fetal death per 1,000 deliveries. As was noted in the 2015 coverage guidance on OOHB,

data derived from birth certificates have several limitations, including the completeness and accuracy of reporting.[1,2] This study is unlikely to change the current HERC guidance.

U.S.-based Studies

Grunebaum, A., McCullough, L. B., Arabin, B., Brent, R. L., Levene, M. I., & Chervenak, F. A. (2016). Neonatal mortality of planned home birth in the United States in relation to professional certification of birth attendants. *PLoS ONE* [Electronic Resource], *11*(5), e0155721.

This retrospective cohort study of linked birth and death certificates from 2008 to 2010 observed a higher rate of all-cause neonatal mortality for midwife-attended home births compared to in-hospital midwife-attended births (RR 3.62; 95% CI 3 to 4.4). This increased risk remained in subgroup analyses for all categories of neonatal death compared to in-hospital midwife-attended deliveries. This study did not include any information on common risk factors for women giving birth (e.g., breech, trial of labor after cesarean (TOLAC), other comorbidities). In addition to the limitations of data derived from vital statistics, poor birth outcomes in hospitals that are attended by nurse midwives are underreported because patients who develop complications are generally transferred to physician care. This bias is likely to exaggerate any differences noted between home births attended by midwives and hospital births attended by midwives. This study is unlikely to change the current HERC guidance.

Grunebaum, A., McCullough, L. B., Sapra, K. J., Arabin, B., & Chervenak, F. A. (2017). Planned home births: The need for additional contraindications. *American Journal of Obstetrics & Gynecology, 216*(4), 401.e401-401.e408.

This is a retrospective cohort study of linked birth and neonatal death certificates for infants born from 2009 to 2013. The standardized risk of neonatal death was 12.1 per 10,000 births (118 out of 96,815) for planned home births compared to 3.08 per 10,000 (334 out of 1,077,197) for hospital-attended midwives and 5.09 per 10,000 physician-attended hospital births ($p < 0.1$). The risk of neonatal death was highest for planned home births, which had the following combinations of risk factors: nulliparous women over 35 years (52.33 per 10,000 births; 95% CI 18.25 to 86.42); nulliparous women over 41 weeks gestation (40.34 per 10,000 births; 95% CI 24.61 to 56.07); over 41 weeks gestation and over 35 years (19.89 per 10,000 births; 95% CI 8.17 to 31.60).The equivalent risks for midwife-attended hospital births were 4.22 per 10,000 (1.48 to 6.95); 4.21 (2.93 to 5.50); and 4.09 (1.28 to 6.89) respectively. As stated above, limitations of vital statistics data include accuracy and completeness concerns. Vital statistics are unable to adjust for in-hospital transfers from midwives to obstetric care, potentially exaggerating risks differences between these groups.

Hamlin, L. (2017). Comparison of births by provider, place, and payer in New Hampshire. *Policy, Politics, & Nursing Practice, 18*(2), 95-104.

This study was part of larger study following maternity outcomes after the closure of multiple obstetrical units in rural areas of New Hampshire. This study provided cross-sectional data from vital statistics on newborn outcomes by place of birth without any stratification by risk. Overall, infants born at home or in freestanding birth centers experienced better outcomes than their hospital-born peers (lower rates of very low and low birthweight infants, use of ventilator support, and neonatal intensive care (NICU) admission). This study is unlikely to change the current HERC guidance.

Thornton, P., McFarlin, B. L., Park, C., Rankin, K., Schorn, M., Finnegan, L., & Stapleton, S. (2017). Cesarean outcomes in US birth centers and collaborating hospitals: A cohort comparison. *Journal of Midwifery & Women's Health, 62*(1), 40-48.

This is a prospective cohort study of pregnant women receiving routine prenatal care at freestanding birth centers in 43 U.S. states (n = 25,515) who then self-selected to present to that birth center or hospital upon spontaneous onset of labor. Both groups received midwifery care. To obtain a low-risk sample, 72% of women in the hospital group were excluded compared to 46% of the birth center group, the final sample was 8776 women in the birth center cohort compared to 2527 women in the hospital cohort. The two groups were significantly different in many demographics at the time of presentation in labor. The rates of cesarean section and severe neonatal composite outcomes did not differ by location. Adjusted analyses demonstrated decreased risk of cesarean delivery for freestanding birth center deliveries. Women delivering at the freestanding birth center were more likely to be breastfeeding at discharge than women delivering at the hospital, despite similar clinician groups providing the care (94.5% vs. 72.7%, $p < 0.01$). The authors posited that this difference could reflect different time periods of assessment (4-12 hours at discharge from the birth center vs. 24-48 hours in the hospital) or institutional barriers to assessment or breastfeeding support. Although these findings support the current HERC guidance, they describe a system of freestanding birth centers with established hospital collaboration.

U.S.-based Studies of High-Risk Populations

Grunebaum, A., McCullough, L. B., Arabin, B., & Chervenak, F. A. (2017). Serious adverse neonatal outcomes such as 5-minute Apgar score of zero and seizures or severe neurologic dysfunction are increased in planned home births after cesarean delivery. *PLoS ONE* [Electronic Resource], *12*(3), e0173952.

This is a retrospective cohort study of birth certificate data from 2007 to 2014 for women with a history of one or more previous cesarean deliveries who delivered a term (> 37 week) infant weighing > 2500g. Compared to in-hospital vaginal birth after cesarean (VBAC), planned home VBAC was associated with increased risk of Apgar = 0 (RR 9.04 [95% CI; 4 to 20.39]) and seizures or neurological dysfunction (RR 11.2 [95% CI; 5.14 to 24.42]). Neonatal seizures are poorly reported on birth certificates (sensitivity of 0.182 to 0.226) and there is differential reporting of Apgar scores of 0 by different provider groups, raising questions about the comparability of this comparison.[3,4,5] This study is in alignment with current HERC coverage guidance.

Tilden, E. L., Cheyney, M., Guise, J. M., Emeis, C., Lapidus, J., Biel, F. M., . . . Snowden, J. M. (2017). Vaginal birth after cesarean: Neonatal outcomes and United States birth setting. *American Journal of Obstetrics & Gynecology, 216*(4), 403.e401-403.e408.

This is a retrospective cohort study of linked birth and death certificate data from 2007 to 2010 for U.S. infants born via VBAC at home or a freestanding birth center compared to a hospital. VBAC at home or a freestanding birth center was associated with increased odds of Apgar < 7 (adjusted OR 1.62; 95% CI, 1.35 to 1.96) and neonatal seizures (adjusted OR 8.53; 95% CI, 2.87 to 25.4). Infants born at home or at a freestanding birth clinic demonstrated a decreased odds of admission to an NICU compared to in-

hospital deliveries (adjusted OR 0.4; 95% CI, 0.78 to 1.04). This study uses vital statistics data with similar limitations as those reported above, including concerns over accuracy and completeness, inability to distinguish planned route of delivery for women with a history of prior cesarean delivery from actual.This study is in alignment with current HERC guidance.

Narrative Reviews

Alliman, J., & Phillippi, J. C. (2016). Maternal outcomes in birth centers: An integrative review of the literature. *Journal of Midwifery & Women's Health, 61*(1), 21-51.

This study is an integrative review of U.S. and international studies on birth centers published from 1980 to 2014 that is unlikely to change the current HERC guidance.

Zielinski, R., Ackerson, K., & Kane Low, L. (2015). Planned home birth: Benefits, risks, and opportunities. *International Journal of Women's Health, 7*, 361-377.

This is a narrative review of U.S. and international studies on planned home birth published from 2005 to 2015 that is unlikely to change the prior HERC guidance.

Systematic Reviews

Rossi, A. C., & Prefumo, F. (2018). Planned home versus planned hospital births in women at low-risk pregnancy: A systematic review with meta-analysis. *European Journal of Obstetrics, Gynecology, & Reproductive Biology, 222*, 102-108.

This systematic review of low-risk women cared for by midwives at home or in a hospital did not identify any U.S.-based studies and included several studies (5 of 8) that were in the original HERC guidance.

Scarf, V. L., Rossiter, C., Vedam, S., Dahlen, H. G., Ellwood, D., Forster, D., . . . Homer, C. S. E. (2018). Maternal and perinatal outcomes by planned place of birth among women with low-risk pregnancies in high-income countries: A systematic review and meta-analysis. *Midwifery, 62*, 240-255. doi: 10.1016/j.midw.2018.03.024. Epub 2018 Apr 3.

This systematic review of 28 studies of low-risk pregnant women compared planned births at home or in a birth center to hospital births. The authors identified a single U.S.-based study published since the last HERC guidance (the 2017 study by Thornton et al., reviewed above). All other studies were not based in the U.S., had significant heterogeneity of providers comparisons nad maternal risk, but overall demonstrated similar neonatal and maternal outcomes across home, birth center, and hospital births; home and birth centers had greater odds of vaginal delivery. This review does not add information to the current coverage guidance.

Guidelines

Vedam, S., Leeman, L., Cheyney, M., Fisher, T. J., Myers, S., Low, L. K., & Ruhl, C. (2014). Transfer from planned home birth to hospital: Improving interprofessional collaboration. *Journal of Midwifery & Women's Health, 59*(6), 624-634.

This guideline is a narrative reporting of potential avenues to improve transfers from planned home births to a hospital setting.

American College of Nurse-Midwives. (2016). Midwifery Provision of Home Birth Services. *Journal of Midwifery & Women's Health, 61*(1), 127-133. doi: 10.1111/jmwh.12431

This guideline provides list of increased risk conditions that would indicate planned birth in a hospital (e.g., prior stillbirth or cesarean delivery, preterm labor, malpresentation).

The American College of Obstetricians and Gynecologists. (2017). Planned home birth. Retrieved from https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Planned-Home-Birth

Updated in 2017, this guideline supports women having the right to make medically informed decisions regarding the location of delivery, provided that patients are informed of risk factors and midwife training meets International Confederation of Midwives' Global Standards. The guidelines continues to endorse fetal malpresentation, multiple gestation, or prior cesarean delivery as absolute contraindications to planned home birth.

National Institute for Health Care Excellence. (2017). Intrapartum care for healthy women and babies. Retrieved from https://www.nice.org.uk/guidance/cg190/resources/intrapartum-care-for-healthy-women-and-babies-pdf-35109866447557

Women at low risk of complications should be informed of their options for place of delivery (home, freestanding unit, alongside midwifery unit, obstetric unit). Low-risk multiparous women should be informed of a lower rate of interventions and no difference in outcomes for infant for home, freestanding, or alongside midwifery units.. Low-risk nulliparous women should be informed of lower rate of intervention at a freestanding or alongside midwifery unit with no difference in outcomes for the infant compared to delivery in an obstetric unit, but a small increased risk of harm to the baby for delivery at home.

Practice Standards

College of Midwives of Ontario. (2018). Professional standards for midwives. Retrieved from http://www.cmo.on.ca/wp-content/uploads/2018/06/Professional-Standards.pdf

This document consists of general practice standards for midwives in Ontario, Canada.

American Association of Birth Centers. (2017). Standards for birth centers. Retrieved from https://cdn.ymaws.com/www.birthcenters.org/resource/resmgr/AABC-STANDARDS-RV2017.pdf

These standards recommend ensuring women selecting a birth center meet general eligibility criteria including gestational age 36-42 weeks, singleton pregnancy, cephalic, and absence of other medical or obstetric condition that may impair a safe delivery in a freestanding birth center.

Non-U.S. Studies

Bailey, D. J. (2017). Birth outcomes for women using free-standing birth centers in South Auckland, New Zealand. *Birth, 44*(3), 246-251.

This is a retrospective cohort study of low-risk women in New Zealand (n = 47, 381) who gave birth in freestanding birth centers or hospitals, which demonstrated lower rates of instrumented delivery, cesarean section, and blood transfusion, without increased neonatal complications. This study is unlikely to change current HERC guidance.

de Jonge, A., Peters, L., Geerts, C. C., van Roosmalen, J. J. M., Twisk, J. W. R., Brocklehurst, P., & Hollowell, J. (2017). Mode of birth and medical interventions among women at low risk of complications: A cross-national comparison of birth settings in England and the Netherlands. *PLoS ONE* [Electronic Resource], *12*(7), e0180846.

This study used combined registry data from the UK Birthplace and the National Perinatal Register in the Netherlands to compare outcomes from the two countries. Data from these original studies were included in the original HERC guidance.

Grigg, C. P., Tracy, S. K., Tracy, M., Daellenbach, R., Kensington, M., Monk, A., & Schmied, V. (2017). Evaluating maternity units: A prospective cohort study of freestanding midwife-led primary maternity units in New Zealand-clinical outcomes. *BMJ Open, 7*(8), e016288.

This is a retrospective cohort study conducted in New Zealand that compared outcomes for freestanding birth center and obstetric-led hospital settings. Planned birth center delivery was associated with a greater likelihood of vaginal birth. Cesarean rates and neonatal outcomes were similar across groups. This study is unlikely to change prior HERC guidance.

Hollowell, J., Li, Y., Bunch, K., & Brocklehurst, P. (2017). A comparison of intrapartum interventions and adverse outcomes by parity in planned freestanding midwifery unit and alongside midwifery unit births: Secondary analysis of 'low risk' births in the birthplace in England cohort. *BMC Pregnancy & Childbirth*, *17*(1), 95.

This is a secondary analysis of the U.K. Birthplace Study evaluating outcomes for low-risk births at freestanding birth centers and alongside birth centers, which demonstrated no significant differences in birth outcomes or cesarean delivery rates. Women presenting to freestanding birth centers experienced greater odds of vaginal delivery. The primary study was included in the 2015 HERC guidance and this secondary anaysis is unlikely to change the prior HERC guidance.

Li, Y., Townend, J., Rowe, R., Brocklehurst, P., Knight, M., Linsell, L., . . . Hollowell, J. (2015). Perinatal and maternal outcomes in planned home and obstetric unit births in women at 'higher risk' of complications: secondary analysis of the Birthplace national prospective cohort study. *BJOG: An International Journal of Obstetrics & Gynaecology, 122*(5), 741-753.

This is a subgroup comparison for higher-risk women planning home or obstetrical unit delivery from the Birthplace Study, a prospective cohort study conducted in the UK. The risk of intrapartum-related mortality and morbidity and NICU admission was lower for the planned home birth group than for the planned obstetric unit delivery group (RR 0.50; 95% CI 0.31 to 0.81). When limited to only risk of intrapartum mortality or morbidity, infants of higher-risk women were at a higher but not statistically significant risk in the planned home birth group (RR 1.92; 95% CI 0.97 to 3.80). Despite a national study, the small sample size (N = 8,180) observed few rare events (e.g., neonatal death), which limited the authors' ability to analyze individual outcomes. The primary study was included in the 2015 HERC guidance and this secondary anaysis is unlikely to change the prior HERC guidance.

Rowe, R., Li, Y., Knight, M., Brocklehurst, P., & Hollowell, J. (2016). Maternal and perinatal outcomes in women planning vaginal birth after caesarean (VBAC) at home in England: Secondary analysis of the Birthplace national prospective cohort study. *BJOG: An International Journal of Obstetrics & Gynaecology, 123*(7), 1123-1132.

This is a secondary analysis of Birthplace cohort data from the UK, which compared outcomes for planned home birth and planned obstetric unit delivery for women attempting a trial of labor after cesarean delivery (N = 1436). A third of patients who were planning home delivery transferred to hospital intrapartum or immediately postpartum (37.2%). The adjusted relative risk of vaginal birth was greater for planned home birth (RR 1.15; 95% CI 1.06 to 1.24). Adverse maternal and perinatal outcomes were rare and not statistically significantly different in absolute and adjusted analyses. The study was limited by indirect evidence in a small population. The primary study was included in the 2015 HERC guidance and this secondary anaysis is unlikely to change the prior HERC guidance. This study is unlikely to change current HERC guidance.

van der Kooy, J., Birnie, E., Denktas, S., Steegers, E. A. P., & Bonsel, G. J. (2017). Planned home compared with planned hospital births: mode of delivery and perinatal mortality rates, an observational study. *BMC Pregnancy & Childbirth, 17*(1), 177.

This is a retrospective comparison of pre-post outcomes in the Netherlands after the introduction of an alongside birth center. After the introduction, there was redistribution of risk profiles, with higher risk women (nulliparous, younger, single, late to prenatal care) more likely to present to the birth center than to have a planned home birth. The overall maternal morbidities decreased after introduction (from 8.3% to 7.3%; no analysis provided). This study is unlikely to change current HERC guidance.

van der Kooy, J., e Graaf, J. P., Birnie, D. E., Denktas, S., Steegers, E. A., & Bonsel, G. J. (2016). Different settings of place of midwife-led birth: Evaluation of a midwife-led birth centre. *Springerplus, 5*(1), 786.

This is a retrospective cohort study of the Dutch Perinatal Registry (2000 to 2007) comparing intervention rates (operative vaginal delivery, cesarean delivery) and perinatal mortality (neonatal death within 7 days) for women planning home or hospital births. The study accounts for the "Big 3" risk factors (intrauterine growth restriction, congenital anomalies, preterm birth). Although rates of intervention (assisted vaginal or cesarean delivery) were lower in the planned home birth group (OR

0.77; 95% CI 0.75 to 0.78), perinatal risk was higher for women with intrauterine growth restriction, congenital anomalies, or preterm birth. This study is unlikely to change current HERC guidance.

References

1. Schoendorf KC, Branum AM. The use of United States vital statistics in perinatal and obstetric research. *American Journal of Obstetrics and Gynecology.* 2006; 194(4):911-915.

2. Ananth CV. Perinatal epidemiologic research with vital statistics data: validity is the essential quality. *Am J Obstet Gynecol.* 2005; 193(1):5-6.

3. Piper JM, Mitchel EF, Jr., Snowden M, Hall C, Adams M, Taylor P. Validation of 1989 Tennessee birth certificates using maternal and newborn hospital records. *Am J Epidemiol.* 1993; 137(7):758-768.

4. Reichman NE, Schwartz-Soicher O. Accuracy of birth certificate data by risk factors and outcomes: analysis of data from New Jersey. *Am J Obstet Gynecol.* 2007; 197(1):32.e31-38.

5. Watterberg KL. Policy statement on planned home birth: upholding the best interests of children and families. *Pediatrics.* 2013; 132(5):924-926. doi: 10.1542/peds.2013-2596.

This topic rescan was prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary was prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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Appendix A. Methods

Search Strategy

A MEDLINE® search was conducted to identify systematic reviews, meta-analyses, technology assessments, and comparative studies using the search terms for home birth, birth centers, and out-of-hospital birth. The search was limited to publications in English published since 2015.

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, comparative cohorts, or clinical practice guidelines.

Appendix B. Evidence Sources for 2015 Coverage Guidance

Initial search of trusted sources

Olsen, O., & Clausen, J. A. (2012). Planned hospital birth versus planned home birth. *Cochrane Database of Systematic Reviews, 9*. Retrieved from http://almenpraksis.ku.dk/nyheder/oleolsen/Hjemmef_dsel.pdf

National Institute for Clinical Excellence (2014). *Intrapartum care: care of healthy women and their babies during childbirth. Clinical Guideline 190,* December 2014. Retrieved from https://www.nice.org.uk/guidance/cg190/resources/guidance-intrapartum-care-care-of-healthy-women-and-their-babies-during-childbirth-pdf

Initial search of additional sources

Cochrane, A. L. (2000). 1931-1971: A critical review, with particular reference to the medical profession. *Medicines for the year*, 1-11.

College of Midwives of British Columbia. (2014). *Indications for discussion, consultation, and transfer of care*. Retrieved from http://www.cmbc.bc.ca/pdf.shtml?Registrants-Handbook-12-01-Indications-for-Discussion-Consultation-and-Transfer-of-Care

College of Midwives of Ontario (2015). C*onsultation and transfer of care*. Retrieved from http://www.cmo.on.ca/?page_id=1026

de Jonge, A., van der Goes, B. Y., Ravelli, A. C., Amelink-Verburg, M. P., Mol, B. W., Nijhuis, J. G., et al. (2009). Perinatal mortality and morbidity in a nationwide cohort of 529, 688 low-risk planned home and hospital births. *BJOG: An International Journal of Obstetrics & Gynaecology, 116*(9), 1177-1184.

Dowswell, T., Thornton, J. G., Hewison, J., Lilford, R. J., Raisler, J., MacFarlane, A., et al. (1996). Should there be a trial of home versus hospital delivery in the United Kingdom? *BMJ, 312*(7033), 753.

Hendrix, M., Van Horck, M., Moreta, D., Nieman, F., Nieuwenhuijze, M., Severens, J., et al. (2009). Why women do not accept randomisation for place of birth: Feasibility of a RCT in the Netherlands. *BJOG: An International Journal of Obstetrics & Gynaecology, 116*(4), 537-544.

Hodnett E.D., Stremler R., Weston J.A., & Mckeever P. Reconceptualizing the hospital labor room: The Place (Pregnant and Laboring in an Ambient Clinical Environment) pilot trial. (2009). *Birth, 36*(2), 159–66.

Hutton, E. K., Reitsma, A. H., & Kaufman, K. (2009). Outcomes associated with planned home and planned hospital births in low-risk women attended by midwives in Ontario, Canada, 2003–2006: A retrospective cohort study. *Birth, 36*(3), 180-189.

Janssen, P. A., Saxell, L., Page, L. A., Klein, M. C., Liston, R. M., & Lee, S. K. (2009). Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife or physician. *Canadian Medical Association Journal, 181*(6-7), 377-383.

Netherlands Ministry of Health, Welfare, and Sport. (n.d). *Final report of the obstetric working group of the national health insurance board of the Netherlands (abridged version)*. The Hague, NL: Government of the Netherlands. Retrieved from http://blog.lib.umn.edu/kuli0015/studygroup/Dutch%20OB%20Indications.doc

Oregon Health Authority. (2013). *Oregon birth outcomes by planned birth place and attendant*. Retrieved from https://public.health.oregon.gov/BirthDeathCertificates/VitalStatistics/birth/Documents/PlannedBirthPlaceandAttendant.pdf

Wax, J. R., Lucas, F. L., Lamont, M., Pinette, M. G., Cartin, A., & Blackstone, J. (2010). Maternal and newborn outcomes in planned home birth vs planned hospital births: A meta-analysis. *American Journal of Obstetrics and Gynecology, 203*(3), 243-e1.

Zeitlin, J., Mohangoo, A., Alexander, S., Barros, H., Blondel, B., Bouvier-Colle, et al. (n.d). *Health and care of pregnant women and babies in Europe in 2010*. Retrieved from http://www.europeristat.com/images/doc/Peristat%202013%20V2.pdf

Update search (requested by EbGS at April 2, 2015 meeting): included studies

Birthplace in England Collaborative Group; Brocklehurst, P., Hardy, P., Hollowell, J., Linsell, L., Macfarlane, A., McCourt, C. … Stewart, M. (2011). Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: The Birthplace in England national prospective cohort study. *BMJ, 343*, d7400. Retrieved from http://www.bmj.com/content/343/bmj.d7400.full.pdf+html

Catling-Paull, C., Coddington, R. L., Foureur, M. J., Homer, C. S.; Birthplace in Australia Study; National Publically-funded Homebirth Consortium. (2013). Publically funded homebirth in Australia: A review of maternal and neonatal outcomes over 6 years. *Medical Journal of Australia, 198*(11), 616-20. Retrieved from https://www.mja.com.au/system/files/issues/198_11_170613/cat11665_fm.pdf

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Cheyney, M., Bovbjerg, M., Everson, C., Gordon, W., Hannibal, D., & Verdam, S. (2014). Outcomes of care for 16,924 planned home births in the United States: The Midwives Alliance of North America Statistics Project, 2004-2009. *Journal of Midwifery & Women's Health, 59*(1), 17-27. Retrieved from http://onlinelibrary.wiley.com/doi/10.1111/jmwh.12172/epdf

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Section 5.0

EbGS-HTAS Topic Prioritization

EbGS/HTAS Topic Prioritization

Question: EbGS/HTAS Topic Prioritization

Question source: HERC Staff

Issue: EbGS has had some new topics proposed; they need to be reprioritized. HTAS may need a topic retired.

Topic	Description/Status	Staff recommendation
Community Health Workers (CHWs) for Patients with Chronic Disease	This is a multisector interventions topic. Goal would be to promote most effective deployment of CHWs.	Prioritize
Multisector Interventions to Reduce the Frequency of Asthma Exacerbations	This is a multisector interventions topic. Goal would be to promote most effective deployment of health related services (HRS) among CCOs for this condition.	Prioritize
Out-Of-Hospital Birth	Only if rescan recommended	Depends on earlier rescan discussion. Drop or prioritize
Extracorporeal Membrane Oxygenation	Recommend dropping this topic due to need for individualized decisions in heterogenous populations and settings. Scored as a 17 in March.	Drop topic
Interventional Treatments for Lower Extremity Chronic Venous Disease	Scored as a 16 in March. These might result in some unfunded conditions being moved above the funding line for OHP and guide commercial coverage criteria.	Consider priority vis a vis MSI topics
Intermittent Pneumatic Compression Devices for the Treatment of Lymphedema	Scored as a 13 in March. These are currently covered as durable medical equipment in OHP with criteria (but no prior authorization) for more complex devices. Low utilization in OHP, mostly for lower extremity disease and more complex pumps.	Consider priority vis a vis MSI topics Consider sending to VBBS without a coverage guidance
Liposuction for the Treatment of Lymphedema	Scored as 11 in March. No OHP claims found for this service in 2017.	Consider dropping this topic

HTAS topics:

Ambulatory Surgery Centers and Extended Stay Centers	Legislative mandate	
Spinal cord stimulators for chronic back pain	Score 17	
Acellular Dermal Matrix for post-mastectomy breast reconstruction	Score 12	Recommend dropping the Coverage Guidance topic, Dr. Smits plans to review at VbBS.
Hepatic artery infusion pumps	Score 12	
Sacral Nerve Stimulation for non-obstructive urinary Retention	Score 11	