Health Evidence Review Commission's Value-based Benefits Subcommittee

January 18, 2024

8:00 AM - 1:00 PM

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

Join online meeting here

Section 1.0

Call to Order

Agenda
Value-based Benefits Subcommittee (VbBS)
January 18, 2024

8:00 am–1:00pm

Online meeting

All agenda items are subject to change and times listed are approximate.

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

	Time	Topic
I.	8:00 AM	**Call to Order, Roll Call, Approval of Minutes**
		New Discussion Topic A. Vulvodynia (draft done, Gyn experts need as close to 8AM as possible. Pinged experts on 11/29 for more literature)
II.	8:35 AM	**Staff report**
III.	8:40 AM	**Straightforward/Consent Agenda** Consent table Straightforward guideline note changes
IV.	x:00 AM	**2026 Biennial Review** A. X B. X
V.	x:00 AM	**Previous Discussion Topics** A. PANDAS/PANS guideline updates (sent for expert input 11/16) B. Guideline for acute nasal fractures (draft done) C. Lipoprotein testing (draft done, need claims review) D. Coronary lithotripsy (draft done, await expert reply to 11/22 email. Also need claims review on 0715T)
VI.	x:00 AM	**New Discussion Topics** A. Hepatic metastases (tabled from November)—check for NCCN version updates! B. Rectal sensation testing (done)

	Time	Topic
		C. Esophageal balloon dilation distention testing (done) D. Peristeen anal irrigation (done) E. Reflectance confocal microscopy (draft done, waiting for expert to get back with clarified question) F. Pulmonary artery pressure monitoring re-review (done) G. DISE for sleep apnea (draft done, emailed Lam 11/22—delay to March or May) H. Intraocular steroids for uveitis (draft started, need experts reply) I. PSA for prostate cancer screening (draft done) J. POTS review (notes in folder) K. Alopecia areata
VII.	x:00 AM	**Topics** A. X B. X C. X
VIII.	x:00 AM	**Topics** A. X B. X C. X x
XI.	12:25 PM	**Public comment on topics not on the agenda**
XII.	1:00 PM	**Adjournment**

Agenda
Value-based Benefits Subcommittee (VbBS)
January 18, 2024

8:00 am–1:00pm

Online & Clackamas Community College (Limited seating)

Wilsonville Training Center, Room 111-112

29373 SW Town Center Loop E

Wilsonville, Oregon 97070

All agenda items are subject to change and times listed are approximate.

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

	Time	Topic
I.	8:00 AM	**Call to Order, Roll Call, Approval of Minutes**
II.	8:05 AM	**Staff report** A. 2026 biennial review topics
III	8:15 AM	**New Discussion Topic** A. **Vulvodynia** (Pain in a woman's genitals)
IV.	9:00 AM	**Straightforward/Consent Agenda** Consent table Straightforward guideline note changes
V.	9:15 AM	**Previous Discussion Topics** A. **PANDAS/PANS guideline updates** (Mental health symptoms developed after infection in children) B. **Guideline for acute nasal fractures** (Treatments for broken nose) C. **Lipoprotein testing** (A type of cholesterol test) D. **Coronary lithotripsy** (A procedure to help open blocked blood vessels to the heart)
VI.	10:30 AM	**New Discussion Topics** A. **PSA for prostate cancer screening** (A test to check for prostate cancer) B. **Peristeen anal irrigation** (A system to help manage bowel issues by using irrigation through the anus)

	Time	Topic
		C. **Hepatic metastases** (Liver tumors that started out in some other part of the body) D. **Rectal sensation testing** (A test to check how strong and flexible the muscles in the rectum are, and how well the walls of the rectum can stretch and contract) E. **Esophageal balloon dilation distention testing** (A test to check if the esophagus is causing chest pain that isn't related to the heart) F. **Intraocular steroids for uveitis** (Using steroids inside the eye to treat eye inflammation) G. **Reflectance confocal microscopy** (Examining the skin using a specialized tool that takes close-up image) H. **Pulmonary artery pressure monitoring re-review (CardioMEMS)** (Tracking pressure in the blood vessel that carries blood from the heart to the lungs (pulmonary artery) for people with heart failure) I. **Facet joint injection 2024 review** (A shot to the joints of the spine) J. **Vertigo/benign paroxysmal positional vertigo** (Feeling dizzy or like the world is spinning)
VII.	12:55 PM	**Public comment on topics not on the agenda**
VIII.	1:00 PM	**Adjournment**

Value-based Benefits Subcommittee (VbBS) Summary

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

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

Recommended Code Movement (Changes to the 1/1/2024 Prioritized List unless otherwise noted):

- Place the new dental billing codes on various lines
- Add group psychotherapy as a treatment option for autism spectrum disorder
- Add a new procedure code for coordinated care for the first episode of psychosis on 5 funded lines
- Add two diagnosis codes for unspecified and specified problems related to psychosocial circumstances to a funded line
- Add new genetic testing of cancer-related billing codes to the diagnostic file
- Add the procedure code for computer assisted navigational bronchoscopy as a diagnostic test
- Add the 2024 CPT, PLA and HCPCS codes to various lines
- Add the procedure code for low level laser therapy to lines with chemotherapy and radiation therapy for prevention of severe mouth inflammation
- Add the procedure code for breast reduction as well as the diagnosis code for large breasts to several funded lines
- Make multiple codes changes to facilitate coverage for the treatment of acute nasal fractures
- Add several codes for foot and nail care to a funded line
- Delete the diagnosis and treatment codes for central auditory processing disorder from coverage due to lack of clear criteria for this condition
- Add the procedure code for instrument-based eye testing for children to a funded line
- Add multiple diagnosis codes for severe exfoliating skin conditions to a funded line
- Add a code representing the federal refugee screening process to a funded line
- Make various straightforward coding changes

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Item Considered but No Recommendations for Changes Made:

The PLA code for the OncoExTra code was initially proposed for coverage, but was not added to coverage at the 11/9/23 HERC meeting

Recommended Guideline Changes (Changes to the 1/1/24 Prioritized List unless otherwise noted):

- Edit the non-prenatal genetic testing guideline to add additional testing for certain patients on the autism spectrum or with intellectual or developmental disabilities; also edit to clarify coverage of testing for cystic fibrosis, and adding a new code for cytochrome P450 testing; update the references to the current ACMG standards
- Edit the PET scan guideline to include prostate cancer
- Edit the hereditary cancer genetic testing guideline to clarify that many types of familial cancer testing are covered and allow coverage of these tests when ordered by professionals without board certification in genetics if they are suitably trained and experienced.
- Edit the severe inflammatory skin disease guideline to include criteria for coverage of severe exfoliative dermatitis
- Edit the frenulectomy guideline to specify that coverage is limited to patients under age 21
- Edit the guideline for testing for liver fibrosis to specify that the enhanced liver fibrosis test is covered in certain clinical circumstances
- Edit the smoking and spinal fusion guideline to require cessation from all tobacco products for only 6 weeks prior to surgery and require only one objective test of cessation
- Edit the transcranial magnetic stimulation guideline to only require a trial and failure of 2 medications (no trial of psychotherapy), and allow 6 taper treatments.
- Edit the lung volume reduction surgery guideline to clarify the smoking cessation requirements
- Edit the gender affirming treatment guideline to specify that WPATH 8 is the standard of care to guide coverage
- Edit the guideline for implantable cardiac defibrillators to remove references to cardiac resynchronization therapy and add a new guideline for cardiac resynchronization therapy
- Extensively edit the guideline regarding breast reduction surgery to allow coverage in the funded region under certain conditions
- Add a new guideline specifying when a patient qualifies for foot and nail care
- Add new guidelines regarding computer assisted navigational bronchoscopy, phrenic nerve stimulation, suprachoroidal injections, and low-level laser therapy
- Make various straightforward guideline note corrections

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Minutes
Value-based Benefits Subcommittee (VbBS)

Online meeting
November 9, 2023

Members Present: Holly Jo Hodges, MD, MBA, Chair; Kevin Olson, MD; Cris Pinzon, MPH, RN; Kathryn Schabel, MD; Mike Collins; Adriane Irwin, PharmD; David Saenger, MD; Sara Love, ND.

Members Absent: Brian Duty, MD, Vice-Chair.

Staff Present: Ariel Smits, MD, MPH; Jason Gingerich; Liz Walker, PhD, MPH; Daphne Peck.

Also Attending: Amy Penkin; Shalini Mehta MD; Rebecca Gale; Stephanie Asher; Connie Warner; Lawrence Lyon, MD; Ashley Spivey; Daron Webb; Laura Briggs; Kim Lee; Tim Barr; Jennifer Say; Natasha Harrison; Susan Reehill; Nathalie Huguet; Seth Johnstone; Everett Redente; Steffani Bailey.

Call to Order, Minutes Approval, Staff Report

The meeting was called to order at 8:00 am and roll was called. A quorum of members was present at the meeting. Minutes from the September 28, 2023 VbBS meeting were reviewed and approved with the modification of noting that Dr. Sara Love was present at that meeting.

Jason Gingerich gave the staff report. He reviewed the purpose of advisory panels, and their role in the HERC process. These panels advise staff, have no chairs, have no votes, and all input will be brought to a public meeting such as VbBS in the future.

Gingerich discussed upcoming HERC membership changes and announced that there is a new OHA director, Dr. Sejal Hathi.

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Straightforward/Consent Agenda

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

Recommended Actions:

1) Add 82306 (Vitamin D; 25 hydroxy, includes fraction(s), if performed) to line 59 END STAGE RENAL DISEASE
2) Add 26426 (Repair of extensor tendon, central slip, secondary (eg, boutonniere deformity); using local tissue(s), including lateral band(s), each finger) and 26428 (Repair of extensor tendon, central slip, secondary (eg, boutonniere deformity); with free graft (includes obtaining graft), each finger) to line 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
3) Add 46922 (Simple removal of growth of anus) to line 166 ANAL, RECTAL AND COLONIC POLYPS
4) Add M53.3 (Sacrococcygeal disorders, not elsewhere classified) to line 395 SEVERE SACROILIITIS
5) Remove the following HCPCS codes from ANCILLARY PROCEDURES file and add to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    a. A4238 Supply allowance for adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories necessary for use of the device (i.e., sensors, transmitter); 1 month supply = 1 unit of service
    b. E2102 Adjunctive, non-implanted continuous glucose monitor or receiver; May be covered once every 3 years

Note: this change was not implemented after staff identified that it would have the unintended effect of excluding coverage for adjunctive continuous glucose monitors covered for persons with type 1 diabetes who need them for use in conjunction with insulin pumps.

6) Modify Guideline Note 3 as shown in Appendix A
7) Modify Guideline Note 106 as shown in Appendix A

MOTION: To approve the recommendations as presented in the consent agenda. CARRIES 8-0.

Oral Health Advisory Panel report

Discussion: Smits presented the meeting materials. The recommended placements for the 2024 CDT codes were approved with minimal discussion.

HERC staff information on listening session discussion and ombuds office concerns regarding dental crowns, dentures and dental implants were reviewed. VBBS members did not have further input or concerns.

The recommended changes to guideline note 48 were approved with minimal discussion.

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Recommended Actions:

1) Place the 2024 CDT codes as shown in Appendix C
2) Advise HSD to place CDT D0470 (Diagnostic casts) to the Diagnostic Procedure File and remove from the Excluded file
3) Delete CDT D0801-D0802 (3d dental surface scan) from line 256 DEFORMITIES OF HEAD AND HANDICAPPING MALOCCLUSION and advise HSD to place on the Diagnostic Procedures File
4) Place the following HCPCS codes to line 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
    a. K1027 (Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment)
    b. E0486 (Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment)
5) Modify Guideline Note 48 as shown in Appendix A

MOTION: To approve the recommendations as presented. CARRIES 8-0.

Behavioral Health Advisory Panel report

Discussion: There was no discussion of the straightforward BHAP code change. There was also minimal discussion regarding the 2024 HCPCS codes related to behavioral health. VBBS members discussed that in addition to adding ICD-10-CM Z65.9 to line 445 that ICD-10-CM code Z65.8 (Other specified problems related to psychosocial circumstances) should also be added to this line.

Smits reviewed the summary document regarding recommended changes to the transcranial magnetic stimulation (TMS) guideline. The group discussed that they did not support continuing to include a requirement for psychotherapy. The studies on TMS did not require a trial of psychotherapy prior to TMS, no other payer requires this, and there were concerns about access to psychotherapy, particularly at the required intensity (once a week for 6 weeks). VBBS members changed the guideline recommendations to require only trial and lack of response to two separate psychoactive medication trials.

Recommended Actions:

1) Add CPT 90853 Group psychotherapy (other than of a multiple-family group) to line 193 AUTISM SPECTRUM DISORDERS
2) Add HCPCS H2040 (Coordinated specialty care, team-based, for first episode psychosis, per month) and H2041 (Coordinated specialty care, team-based, for first episode psychosis, per encounter) to the following lines:
    a. 7 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE

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b. 22 SCHIZOPHRENIC DISORDERS
c. 26 BIPOLAR DISORDERS
d. 277 OTHER PSYCHOTIC DISORDERS
e. 411 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED

3) Add ICD-10-CM Z65.8 (Other specified problems related to psychosocial circumstances) and Z65.9 (Problem related to unspecified psychosocial circumstances) to line 445 ADJUSTMENT DISORDERS
4) Modify Guideline Note 102 as shown in Appendix A

MOTION: To approve the recommendations as modified. CARRIES 7-0 (Schabel absent).

Genetic Advisory Panel report

Discussion: Smits reviewed the meeting materials. The friendly staff amendment to the Diagnostic Guideline D25 note (grammar-related) was approved with no discussion.

There was discussion regarding the topic of genetic testing for developmental disabilities and intellectual disabilities. VBBS members felt that the changes to the non-prenatal genetic guideline that GAP did not recommend were actually very helpful changes for CCO reviewers. The changes presented to GAP were therefore approved by VBBS. The continued non-coverage of fragile X panel testing was approved without discussion.

Regarding the 2024 CPT codes related to genetic testing, there was discussion about how next generation sequencing was an umbrella topic. The individual tests represented by CPT or PLA codes were not reviewed, unlike the usual HERC standard for code approval. Individualized code review is not within the ability of current HERC staff, and this field is rapidly advancing.

Recommended Actions:

1) Modify Diagnostic Guideline D25 as shown in Appendix A
2) Modify Diagnostic Guideline D1 as shown in Appendix A
3) Modify Guideline Note 173 regarding fragile X panel testing as shown in Appendix A
4) Place the following CPT codes on the Diagnostic Procedures File subject to the new next generation sequencing of cancer guideline
    a. 81547 Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability
    b. 81548 Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants and microsatellite instability
    c. 81549 Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy

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number variants, microsatellite instability, tumor mutation burden, and rearrangements
    d. 81462 Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements
    e. 81463 Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis, copy number variants, and microsatellite instability
    f. 81464 Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and re
5) Place the following PLA codes on the Diagnostic Procedures File—NOTE: this recommendation was NOT approved by HERC at their 11/9/23 meeting
    a. 0379U Solid Tumor Expanded Panel, Quest Diagnostics®
    b. 0388U InVisionFirst®-Lung Liquid Biopsy
    c. 0391U Strata SelectTM
    d. 0409U LiquidHALLMARK®
    e. 0413U DH Optical Genome Mapping/Digital Karyotyping Assay
6) Modify the new guideline regarding next generation sequencing of malignancies as shown in Appendix B
7) There was minimal discussion of the American College of Medical Genetics (ACMG) guideline reference update topic.

MOTION: To approve the recommendations as modified. CARRIES 8-0.

OncoExTra

Discussion: Smits reviewed the summary document. The recommendation was to place PLA 0392U on the Diagnostic File with modifications to the next generation sequencing of cancer tissue guideline.

Recommended Actions:
NOTE: these changes were not approved at the 11/9/23 HERC meeting

1) Place PLA 0329U (Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations) on the Diagnostic Procedures File
2) Modify the new guideline on cancer genetic sequencing panels as shown in Appendix B

MOTION: To approve the recommendations as presented. CARRIES 8-0.

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Computer Assisted Navigational Bronchoscopy

Discussion: Smits presented the meeting summary. There was minimal discussion.

Recommended Actions:

1) Remove CPT 31627 from line 662 and modify GN173 as shown in Appendix A
    a. Advise HSD to add CPT 31627 (Computer assisted bronchoscopy) to the Diagnostic Procedure File
2) Add a new diagnostic guideline as shown in Appendix B

MOTION: To approve the recommendations as presented. CARRIES 8-0

2024 CPT/PLA/HCPCS code review

Discussion: Smits reviewed the summary documents. There was no significant discussion on any staff-recommended code placements other than the following:

1) 33276-33287 (phrenic nerve stimulation): VBBS added a definition for high spinal cord injury (C3 or above) to the proposed new guideline note. They also removed "alveolar" from the central alveolar hypoventilation disorder entry in that guideline as not the correct name of the condition.
2) 92972 (coronary artery lithotripsy): David Saenger recommended coverage of this technology. He said it is not used frequently, but can be useful in patients with severe artery stenosis. As this technology is used for patients with high risk coronary arteries, it is not surprising that the outcomes of the procedure are not as good for ordinary coronary artery stenting. Dr. Saenger noted that some private insurers are covering. This technology has minimal risk of being abused as it makes the procedure significantly longer. As part of this discussion, it was noted that some interventions currently on the coronary artery disease line, like brachytherapy, as no longer used. HERC staff was directed to look at coronary artery lithotripsy more closely, as well as do a broader review of current coverage of interventional cardiology procedures. HERC staff were also directed to look for the current coding of this procedure (possibly a temporary CPT code) and query for utilization. The placement of this code was tabled until a future meeting.
3) 81517 (enhanced liver fibrosis test): option 1 was recommended. HERC staff were directed to look up the previous code for this test and query utilization.
4) 96547-96548 (HIPEC): VBBS determined that there was no need for a new guideline regarding this treatment as it was highly unlikely to be overused.
5) 97037 (low level laser therapy): VBBS requested that an additional code for this type of treatment (0552T) be added to all lines with chemotherapy/radiation therapy and to the new guideline adopted for low level laser therapy
6) 99459 (Pelvic examination): VBBS members were unclear about how this code would be used as it only related to practice expenses, unlike any other CPT code. The group

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decided to recommend this code for the Excluded File until further clarification on utilization was obtained from CMS.

7) 0377U (lipoprotein profile): David Saenger felt that certain of the lipoprotein tests were evidence based and in common use and asked staff to review this and several related tests at a future meeting..
8) The January 2024 HCPCS code placement review was a handout. There was no discussion. Please see Appendix E.

Recommended Actions:

1) The 2024 CPT codes were placed as shown in Appendix D
2) Guideline Note 173 was modified as shown in Appendix A
3) Add a new guideline for phrenic nerve stimulation as shown in Appendix B
4) Add the following HCPCS codes to line 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
    1. C1778 Lead, neurostimulator (implantable)
    2. C1816 Receiver and/or transmitter, neurostimulator (implantable)
    3. L8680 Implantable neurostimulator electrode, each
    4. L8682 Implantable neurostimulator radiofrequency receiver
    5. L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
5) A new guideline was added for suprachoroidal injections
6) Modify Guideline Note 76 as shown in Appendix A
7) Remove HCPCS S8948 (Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes) and CPT 0552T (Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional) from line 662 and place on all lines with chemotherapy, radiation therapy or stem cell transplant
8) Adopt a new guideline regarding low level laser therapy as shown in Appendix B
9) Modify DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE as shown in Appendix A
10) Place CPT 0243U (Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia) on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
11) Place 0173U, 0175U, and 0345U on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

MOTION: To approve the recommendations as modified. CARRIES 8-0.

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Breast Reduction for Macromastia

Discussion: There was minimal discussion on this topic.

Recommended Actions:

1) Add ICD-10-CM N62 (Hypertrophy of breast) and CPT 19318 (Breast reduction) to the following lines:
    a. 402 CONDITIONS OF THE BACK AND SPINE
    b. 417 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6
    c. 426 SEVERE INFLAMMATORY SKIN DISEASE
2) Modify Guideline Note 166 as shown in Appendix A
3) Add ICD-10-CM L30.4 (Erythema intertrigo) to line 426 SEVERE INFLAMMATORY SKIN

MOTION: To approve the recommendations as presented. CARRIES 8-0.

Standard of Care for Gender Dysphoria Guideline

Discussion: There was minimal discussion on this topic.

Recommended Actions:

1) Modify Guideline Note 127 as shown in Appendix A

MOTION: To approve the recommendations as presented. CARRIES 8-0.

Tobacco Cessation Guidelines

Discussion: Smits reviewed the summary document. The VBBS members generally agreed with the staff recommendations. There was discussion regarding the importance of remaining free from nicotine use for 6 months after spinal fusion surgery. Staff were directed to add wording to this effect to the new Statement of Intent regarding smoking and elective surgery and bring this back to a future meeting.

Recommended Actions:

1) Modify Guideline Note 100 as shown in Appendix A
2) Modify Guideline Note 112 as shown in Appendix A
3) Delete Guideline Note 159 as shown in Appendix A

MOTION: To approve the recommendations as presented. CARRIES 8-0.

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PSMA PET for Prostate Cancer

Discussion: There was minimal discussion on this topic.

Recommended Actions:

1) Modify Diagnostic Guideline D22 as shown in Appendix A
2) Advise HSD to add HCPCS C9156 (Flotufolastat f 18, diagnostic, 1 millicurie) to the Ancillary file

MOTION: To approve the recommendations as presented. CARRIES 8-0.

Cardiac Resynchronization Therapy

Discussion: Smits reviewed the staff summary. David Saenger said that cardiac resynchronization (CRT) can be done together with or separately from implantable defibrillator therapy (ICD). ICD is to prevent sudden death, while resynchronization treats the heart failure. After discussion, the group decided that these services should have separate guidelines. For the ICD guideline, the changes in the meeting materials related to ICDs were retained. The portion of the guideline about CRT alone was approved as well with modifications so that CRT pacemakers would be covered whenever CRT itself is covered.

Recommended Actions:

1) Modify Guideline Note 95 as shown in Appendix A
2) Adopt a new guideline for cardiac resynchronization therapy as shown in Appendix B

MOTION: To approve the recommendations as modified. CARRIES 8-0.

Nasal Fracture Repair

Discussion: There was minimal discussion at VBBS. Note: HERC approved the staff recommendation but requested that staff bring back a proposal for a new guideline that would limit acute treatment of nasal fractures to the first 14 days after injury.

Recommended Actions:

1) Add the following ICD-10-CM codes to line 228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES and remove from line 577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
    a. S02.2XXA Fracture of nasal bones, initial encounter for closed fracture

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   b. S02.2XXD Fracture of nasal bones, subsequent encounter for fracture with routine healing
   c. S02.2XXG Fracture of nasal bones, subsequent encounter for fracture with delayed healing
2) Add the following ICD-10-CM codes to line 228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES and remove from line 443 MALUNION AND NONUNION OF FRACTURE
   a. S02.2XXK Fracture of nasal bones, subsequent encounter for fracture with nonunion
3) Remove the following CPT codes from line 577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
   a. 21325 Open treatment of nasal fracture; uncomplicated
   b. 21330 Open treatment of nasal fracture; complicated, with internal and/or external skeletal fixation
   c. 21335 Open treatment of nasal fracture; with concomitant open treatment of fractured septum
4) Remove the following CPT codes from line 228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
   a. 30420 Rhinoplasty, primary; including major septal repair
   b. 30450 Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
5) Modify Guideline Note 118 as shown in Appendix A
   a. Add line 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
6) Modify Guideline Note 216 as shown in Appendix A
   a. Remove line 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER and line 246 LIFE-THREATENING EPISTAXIS from this guideline as it does not apply to diagnoses on these lines
   b. Add line 577 to the guideline

MOTION: To approve the recommendations as presented. CARRIES 8-0.

Hepatic Metastases

Discussion: Tabled until January 2024

Foot and Nail Care

Discussion: There was minimal discussion on this topic.

Recommended Actions:

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1) Add ICD-10-CM B35. 1 (Tinea unguium), L60.2 (Onychogryphosis), and L60.3 (Nail dystrophy) to line 165 PREVENTIVE FOOT CARE IN HIGH-RISK PATIENTS
2) Add CPT 11755 (Biopsy of nail unit (eg, plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)) to line 165
3) Add HCPCS G0127 (Trimming of dystrophic nails, any number) to line 165
4) Adopt a new guideline regarding testing and treatment of tinea unguium and dystrophic nails as shown in Appendix B

MOTION: To approve the recommendations as presented. CARRIES 8-0.

Central Auditory Processing Disorder

Discussion: There was minimal discussion on this topic.

Recommended Actions:

1) Delete ICD-10-CM H93.25 (Central auditory processing disorder) from line 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS and add to line 655 NEUROLOGIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
2) Modify Guideline Note 173 as shown in Appendix A

MOTION: To approve the recommendations as presented. CARRIES 8-0.

Instrument Based Ocular Screening

Discussion: Smits reviewed the summary and staff recommendations. Cris Pinzon said that that instrument based screening should be covered. She notes that this technology is heavily used by school nurses and community organizations such as the Elks for mass screening. Children really need visual screening, and this is a good population level screening technology. Option 2 in the staff recommendations was unanimously approved.

Recommended Actions:

1) Add photoscreening CPT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS and remove from line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
    i. CPT 99174 Instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral; with remote analysis and report
    ii. CPT 99177 (Instrument based ocular screening (eg, photoscreening, automated-fractions),bilateral; with onsite analysis)
2) Remove the entry for photoscreening from GN172 as shown in Appendix A

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MOTION: To approve the recommendations as presented. CARRIES 8-0.

Severe Exfoliating Skin Conditions

Discussion: There was minimal discussion on this topic.

Recommended Actions:

1) Add the following ICD-10-CM codes to line 426 SEVERE INFLAMMATORY SKIN DISEASE and keep on line 504 ERYTHEMATOUS CONDITIONS

ICD-10 Code	Code Description
L26	Exfoliative dermatitis
L49.7	Exfoliation due to erythematous condition involving 70-79 percent of body surface
L49.8	80-89 percent of BSA
L49.9	90 percent or more of BSA
L53.8	Other specified erythematous conditions
L53.9	Erythematous condition, unspecified
L54	Erythema in diseases classified elsewhere

2) Modify GN21 as shown in Appendix A

MOTION: To approve the recommendations as presented. CARRIES 8-0.

Refugee Screening

Discussion: There was minimal discussion on this topic.

Recommended Actions:

1) Add ICD-10-CM Z65.5 (Exposure to disaster, war and other hostilities) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
   a) Advise HSD to remove ICD-10-CM Z65.5 from the INFORMATIONAL DIAGNOSES file

MOTION: To approve the recommendations as presented. CARRIES 8-0.

Public Comment

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No additional public comment was received.

Issues for next meeting

- Hepatic metastases
- Lipoprotein testing
- Coronary artery lithotripsy
- Guideline for acute nasal fracture treatment
- Modifications for the smoking and elective surgery statement of intent recommending smoking cessation after surgery

Next meeting

January 18, 2024, Online and at Clackamas Community College Training Center, Wilsonville, OR

Adjournment

The meeting adjourned at 1:00 PM.

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Appendix A
Revised Guideline Notes

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

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

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

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

D) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
   1) CPT 81228, 81229 and 81349, Cytogenomic constitutional microarray analysis: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
   2) CPT 81243, 81244, 81171,81172 Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
   3) Additional testing that might be appropriate based on physical exam findings include Rett syndrome testing (CPT 81302-81304) and PTEN testing (CPT 81321-81323). Whole exome sequencing (81415-81416) may be considered when all of the testing above is non-diagnostic and after a genetic counseling/geneticist consultation.
   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 preconception testing/carrier screening:
   1) The following tests are covered for a pregnant patient or patient contemplating pregnancy as well as the male

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reproductive partner:

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

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

F) Related to other tests with specific CPT codes:
1) Certain genetic tests have not been found to have proven clinical benefit. These tests are listed in Guideline Note 173 INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS.
2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
   a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
   b) Diagnostic testing for cystic fibrosis (CF)
      i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220-81224~~, 81221, 81222, 81223~~: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics~~*~~[2] (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~~.

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

d) CPT 81225-81227, 81230-81231, 81418, 0380U (cytochrome P450). Covered only for determining eligibility for medication therapy if required or recommended in the FDA labelling for that medication. These tests have unproven clinical utility for decisions regarding medications when not required in the FDA labeling (e.g. psychiatric, anticoagulant, opioids).

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

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

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

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

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

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

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l) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test
m) CPT 81430-81431, Hearing loss (e.g., nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.
n) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.
o) CPT 81425-81427, whole genome sequencing: testing is only covered when
    i) The testing is for a critically ill infant up to one year of age admitted to an inpatient intensive care unit (NICU/PICU) with a complex illness of unknown etiology; AND
    ii) Whole genome sequencing is recommended by a medical geneticist or other physician sub-specialist, including but not limited to a neonatologist or pediatric intensivist with expertise in the conditions and/or genetic disorder for which testing is being considered.

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

[1] Screening for autosomal recessive and X-linked conditions during pregnancy and preconception: a practice resource of the American College of Medical Genetics and Genomics (ACMG) 2021, found at https://www.gimjournal.org/action/showPdf?pii=S1098-3600%2821%2905152-2

[2] American College of Medical Genetics Statement: updated recommendations for CFTR carrier screening 2023, found at https://www.gimjournal.org/action/showPdf?pii=S1098-3600%2823%2900880-8

DIAGNOSTIC GUIDELINE D22, PET SCANS

Diagnosis:
PET Scans are covered for diagnosis only when:
A) The PET scan is for evaluation of either:
    1) Solitary pulmonary nodules, small cell lung cancer and non-small cell lung cancer, OR
    2) Evaluation of cervical lymph node metastases when CT or MRI do not demonstrate an obvious primary tumor, AND
B) The PET scan will
    1) Avoid an invasive diagnostic procedure, OR
    2) Assist in determining the optimal anatomic location to perform an invasive diagnostic procedure.

Initial staging:
PET scans are covered for the initial staging when:
A) The staging is for one of the following cancers/situations:
    1) Cervical cancer only when initial MRI or CT is negative for extra-pelvic metastasis

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2) Head and neck cancer when initial MRI or CT is equivocal
3) Colon cancer
4) Esophageal cancer
5) Solitary pulmonary nodule
6) Non-small cell lung cancer
7) Lymphoma
8) Melanoma
9) Breast cancer ONLY when metastatic disease is suspected AND standard imaging results are equivocal or suspicious
10) Small cell lung cancer
11) Neuroendocrine tumors
12) Multiple myeloma
13) Thyroid cancers
14) PSMA PET for unfavorable intermediate, high-risk, or very-high-risk prostate cancer

AND

B) Clinical management of the patient will differ depending on the stage of the cancer identified and either:
1) the stage of the cancer remains in doubt after standard diagnostic work up, OR
2) PET replaces one or more conventional imaging studies when they are insufficient for clinical management of the patient.

Monitoring:
For monitoring tumor response during active therapy for purposes of treatment planning, PET is covered for
A) classic Hodgkin's lymphoma treatment
B) metastatic breast cancer ONLY when a change in therapy is contemplated AND PET scan was the imaging modality
initially used to find the neoplasm being monitored.

Restaging:
Restaging is covered only when:
A) the cancer has staging covered above, AND
B) initial therapy has been completed, AND
C) the PET scan is conducted for
1) detecting residual disease, or
2) detecting suspected recurrence, or
3) determining the extent of a known recurrence

Other indications:
PET scans are covered for preoperative evaluation of the brain in patients who have intractable seizures and are candidates for focal surgery. PET scans are covered for patients being considered for treatment with aducanumab or similar FDA approved medications for treatment of Alzheimer's disease.

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Appendix A
Revised Guideline Notes

Non-covered conditions/situations:

A) PET scans are NOT covered to monitor tumor response during the planned course of therapy for any cancer other than classic Hodgkin's lymphoma or the limited indication described above for metastatic breast cancer.
B) PET scans are NOT covered for routine follow up of cancer treatment or routine surveillance in asymptomatic patients.
C) PET scans are NOT covered for cardiac evaluation.

DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING

Related to genetic testing for patients with cancers suspected to be hereditary ~~breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary~~, or patients at increased risk to due to family history (for example, CPT 81162-81167, 81201-81203, 81212, 81215-81217, 81288, 81292-81300, 81317-81319, 81321-81323, 81435, 81436), services are provided according to the Comprehensive Cancer Network Guidelines: Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V2.2024 (9/27/23) www.nccn.org), including the table "Summary of Genes and/or Syndromes Included/Mentioned in Other NCCN Guidelines," or the Genetic/Familial High-Risk Assessment: Colorectal V1.2023 (5/30/2023) www.nccn.org).

~~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 compr Clinical Practice Guidelines in Oncology (Genetic/Familial High-Risk Assessment: Colorectal V1.2022 (6/8/22) www.nccn.org).~~
~~B) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217) for patients without a personal history of breast, ovarian and other associated cancers should be provided to high-risk 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, Ovarian and Pancreatic V1.2023 (9/7/22) www.nccn.org).~~
~~C) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217)) for women with a personal history of breast, ovarian, or other associated cancers and for men with breast or other associated cancers should be provided according to the NCCN Clinical Practice Guidelines in Oncology (Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V1.2023 (9/7/22) 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: Ovarian and Pancreatic. V1.2023 (9/7/22) or Genetic/Familial High-Risk Assessment: Colorectal V1.2022 (6/8/22) www.nccn.org).~~

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.

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~~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.~~

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~~ health care professional with experience in cancer genetics should be covered.
   1) Post-test genetic counseling should be performed as soon as is practical.

~~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 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).~~

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

~~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 guidelines.~~

GUIDELINE NOTE 3, PROPHYLACTIC TREATMENT FOR PREVENTION OF BREAST CANCER IN HIGH-RISK WOMEN

Line 191

Bilateral prophylactic breast removal and/or salpingo-oophorectomy are included on Line 191 for women without a personal history of invasive breast cancer who meet the criteria in the NCCN Clinical Practice Guidelines in Oncology (Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V2.2024 (9/27/23) ~~V1.2023 (9/7/22)~~ www.nccn.org). Prior to surgery, women without a personal history of breast cancer must have a genetics consultation as defined in section B of the DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE.

Contralateral prophylactic mastectomy is included on Line 191 for women with a personal history of breast cancer.

Hysterectomy is only included on Line 191 for women with a BRCA1 pathogenic/likely pathogenic variant who undergo the procedure at the time of risk reducing salpingo-oophorectomy.

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 426,482,504,533,542,555,656

Inflammatory skin conditions included in this guideline are:

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Appendix A
Revised Guideline Notes

A) Psoriasis
B) Atopic dermatitis
C) Lichen planus
D) Darier disease
E) Pityriasis rubra pilaris
F) Discoid lupus
G) Vitiligo
H) Prurigo nodularis

The conditions above are included on Line 426 if severe, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following:

A) At least 10% of body surface area involved
B) Hand, foot, face, or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 482, 504, 533, 542, 555 and 656.

For severe psoriasis, treatments included on this line are topical agents, phototherapy, targeted immune modulator medications and other systemic medications.

For severe atopic dermatitis/eczema, treatments included on this line are topical moderate- to high-potency corticosteroids, topical calcineurin inhibitors (for example, tacrolimus), narrowband UVB, and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, or oral corticosteroids). Targeted immune modulators (for example, dupilumab) are included on this line when:

A) Prescribed in consultation with a dermatologist or allergist or immunologist, AND
B) The patient has failed (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk) a 4 week trial of a combination of topical moderate to high potency topical steroids and a topical non-steroidal agent OR an oral immunomodulator.

JAK inhibitor (for example, upadacitinib or abrocitinib) therapy is included on this line when other immunomodulatory therapy has failed to adequately control disease (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk).

ICD-10-CM Q82.8 (Other specified congenital malformations of skin) is included on Line 426 only for Darier disease.

ICD-10-CM L26 (Exfoliative dermatitis), L49.7-L49.9 (Exfoliation due to erythematous condition involving 70% to >90% of body surface), L53.8 (Other specified erythematous conditions), L53.9 (Erythematous condition, unspecified), and L54 (Erythema in diseases classified elsewhere) are included on line 426 only when representing erythroderma or when the exfoliation extends over 75% of body surface area. Otherwise, these diagnoses are included on line 504.

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Appendix A
Revised Guideline Notes

GUIDELINE NOTE 48, FRENULECTOMY/FRENULOTOMY

Lines 344,661

Labial frenulectomy/frenulotomy (D7961) is included on this line for patients under age 21 in the following situations:

A) When deemed to cause gingival recession
B) When deemed to cause movement of the gingival margin when frenum is placed under tension.
C) Maxillary labial frenulectomy not covered until age 12 and above.

Otherwise, D7961 is included on Line 661.

GUIDELINE NOTE 76, DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE MANAGEMENT IN CHRONIC LIVER DISEASE

Line 198

The following tests are included on this line because of their ability to effectively distinguish F4 from lower levels of fibrosis:

Non-proprietary blood tests:
- Platelet count
- Hyaluronic acid
- Age-platelet index
- AST-platelet ratio
- FIB-4
- FibroIndex
- Forns index
- GUCI
- Lok index

- Proprietary blood test:
  - Enhanced Liver Fibrosis (ELF™), for patients with indeterminate or high FIB-4 score when liver elastography is not available.

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

The following tests are not included on this line (or any other line):
- Real time tissue elastography
- Proprietary blood tests such as:
  - ~~Enhanced Liver Fibrosis (ELF™)~~
  - Fibrometer™
  - FibroTest®

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- Hepascore®
- FIBROSpect® II

Noninvasive tests for liver fibrosis are only indicated for the initial assessment or when monitoring progression from F3 to F4, no more than annually.

Magnetic resonance elastography is included on this line for patients when ALL of the following apply:

- In whom at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminant results, a second one is similarly indeterminant, contraindicated or unavailable
- The patient is suspected to have aggressive disease/advanced fibrosis (e.g. in NAFLD based on older age, diabetes, obesity, high FIB-4, or APRI)
- Cirrhosis is not identified on routine imaging (ultrasound, CT)
- A liver biopsy would otherwise be indicated, but MRE would be an appropriate alternative.

Repeat MR Elastography is not indicated.

GUIDELINE NOTE 95, IMPLANTABLE CARDIAC DEFIBRILLATORS

Lines 97,98,110,281,285

Implantable cardiac defibrillators are included on these lines for patients with one or more of the following:

A) Patients with a personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation. Patients must have demonstrated one of the following:
   1) Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause
   2) Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction

B) Patients with a prior myocardial infarction and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:
   1) New York Heart Association (NYHC) classification IV heart failure; or
   2) Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or
   3) Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary intervention (PCI) with angioplasty and/or stenting, within past 3 months; or
   4) Had a myocardial infarction in the past 40 days; or
   5) Clinical symptoms or findings that would make them a candidate for coronary revascularization

C) Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%. Additionally, patients must not have:

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1) Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
2) Had a myocardial infarction within the past 40 days; or
3) Clinical symptoms and findings that would make them a candidate for coronary revascularization.

D) Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%, been on optimal medical therapy (OMT) for at least 3 months. Additionally, patients must not have:
   1) Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
   2) Had a myocardial infarction within the past 40 days; or
   3) Clinical symptoms and findings that would make them a candidate for coronary revascularization.

E) Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained ventricular tachycardia or ventricular fibrillation), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.

F) Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI) or device/lead malfunction.

For these patients identified in A-E, a formal shared decision making encounter must occur between the patient and a physician or qualified non-physician practitioner using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

All indications above in A-F must meet the following criteria:

A) Patients must be clinically stable (e.g., not in shock, from any etiology);

B) Left ventricular ejection fraction (LVEF) must be measured by echocardiography, radionuclide (nuclear medicine) imaging, or catheter angiography;

C) Patients must not have significant contraindications~~:~~
   ~~1) Significant, irreversible brain damage; or~~
   ~~2) Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or~~
   ~~3) Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.~~

Exceptions to waiting periods for patients that have had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months, or had a myocardial infarction within the past 40 days:

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Appendix A
Revised Guideline Notes

A) Cardiac Pacemakers: Patients who meet all CMS coverage requirements for cardiac pacemakers and who meet the criteria in this guideline ~~national coverage determination~~ for an ICD may receive the combined device in one procedure at the time the pacemaker is clinically indicated;
B) Replacement of ICDs: Patients with an existing ICD may receive a ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI) or device/lead malfunction.

Other Indications:
For patients who are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, ~~coverage of~~ ICDs~~, as with cardiac resynchronization therapy~~, are only included on these lines ~~as~~ a bridge to transplant to prolong survival until a donor becomes available.

GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION

Lines 47,150,200,254,346,361,401,478,530,559

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking and abstinent from all nicotine products for 6 ~~months~~ weeks prior to the planned procedure, as shown by a negative cotinine urine or serum test ~~levels at least 6 months apart, with the second test within 1 month of the surgery date~~. Patients should be given access to appropriate smoking cessation therapy. Non-emergent spinal arthrodesis is defined as surgery for a patient with a lack of myelopathy or rapidly declining neurological exam.

[note additional changes approved at the 11/9/23 HERC meeting shown in purple]
GUIDELINE NOTE 102, ~~REPETITIVE~~ TRANSCRANIAL MAGNETIC STIMULATION

Line 7

~~Repetitive~~ ~~t~~Transcranial magnetic stimulation (CPT 90867-90869) is included on this line only when ALL of the following criteria are met:

A) The patient has a confirmed diagnosis of severe major depressive disorder based on standardized rating scales, AND
B) The patient has treatment resistant depression as evidenced by ~~BOTH of the following:~~ ~~O~~ongoing symptoms despite treatment with ~~one~~ two psychopharmacologic regimens ~~each used for 8 weeks~~ administered at both an adequate dose and adequate duration that are consistent with the FDA label and with a duration that would elicit a favorable response unless not tolerated or contraindicated, AND
C) The patient does not have psychosis, acute suicidal risk, catatonia, significantly impaired essential function, or other condition for which electroconvulsive therapy (ECT) would be clinically superior to TMS; AND

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D) The patient has no contraindications to ~~r~~TMS such as implanted devices in or around the head, increased risk of seizure, etc; AND
E) The therapy is administered by an FDA approved device in accordance to labeled indications; AND
F) The patient is 18 years of age or older.

~~Repetitive t~~Transcranial magnetic stimulation is covered for a maximum of 30 sessions (once a day, up to 5 times per week for 6 weeks) for initial treatment, followed by up to 6 taper treatments. Repeat treatment may be covered if the patient responded to the initial treatment (defined as at least 50 percent reduction in depression score on standardized rating scale) and at least 3 months have elapsed since the initial treatment.

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

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2023 ~~2022~~.
   1) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations/
      a) Treatment of falls prevention with exercise interventions is included on Line 292.
   2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.
B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
   1) http://brightfutures.aap.org. Periodicity schedule available at https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf
      a) Bright Futures is the periodicity schedule for screening for EPSDT for the Oregon Health Plan.
   2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.
C) Health Resources and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines (revised December 2022 ~~January 2022~~). Available at https://www.hrsa.gov/womens-guidelines as of ~~July 28, 2022~~ October 30, 2023.
D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf

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Appendix A
Revised Guideline Notes

1) COVID-19 vaccines are intended to be included on this line even if the specific administration code(s) do not yet appear on the line when the vaccine has both 1) FDA approval or FDA emergency use authorization (EUA) and 2) ACIP recommendation.
2) Other ACIP recommended vaccines not on the routine vaccine schedule are included on Line 3 when administered according to recommendations specified in the Morbidity and Mortality Weekly Review (MMWR) as required by federal law: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html (retrieved 8/8/2023).

Colorectal cancer screening is included on Line 3 for average-risk adults aged 45 to 75, using one of the following screening programs:

A) Colonoscopy every 10 years
B) Flexible sigmoidoscopy every 5 years
C) Fecal immunochemical test (FIT) every year
D) Guaiac-based fecal occult blood test (gFOBT) every year

CT colonography (CPT 74263), FIT-DNA (CPT 81528) and mSEPT9 (HCPCS G0327) are included on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS.

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered after informed decision making between patients and clinicians which includes consideration of the patient's overall health, prior screening history, and preferences.

Supervised evidence-based exercise programs for fall prevention for persons aged 65 or older OR younger patients who are at increased risk of falls are included on Line 3 using CPT 98961 or 98962 or HCPCS S9451. HCPCS S9451 is only included on Line 3 for the provision of supervised exercise therapy for fall prevention. Programs should be culturally tailored/culturally appropriate when feasible.

Note: CPT 96110 (Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument) can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.

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

GUIDELINE NOTE 112, LUNG VOLUME REDUCTION SURGERY

Line 283

Lung volume reduction surgery (LVRS, CPT 32491, 32672) is included on Line 283 only for treatment of patients with radiological evidence of severe bilateral upper lobe predominant emphysema (ICD-10-CM J43.9) and all of the following:

A) BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
B) Stable with ≤20 mg prednisone (or equivalent) dose a day

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C) Pulmonary function testing showing
   1) Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
   2) Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
   3) Residual volume (RV) ≥ 150% predicted post-bronchodilator

D) PCO_2, ≤ 60 mm Hg (PCO 2, ≤ 55 mm Hg if 1-mile above sea level)

E) PO_2, ≥ 45 mm Hg on room air (PO 2, ≥ 30 mm Hg if 1-mile above sea level)

F) Post-rehabilitation 6-min walk of ≥ 140 m

~~G) Non-smoking and abstinence from all nicotine products for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.~~

H) Non-smoking for 4 months prior to initial surgical evaluation and throughout the pre-surgical process
   1) This must be demonstrated by a negative serum or urine cotinine level (if not using nicotine replacement products), or an arterial carboxyhemoglobin ≤ 2.5% if using nicotine replacement) prior to surgical authorization

The procedure must be performed at an approved facility (1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program or (2) approved as Medicare lung or heart-lung transplantation hospitals. The patient must have approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation. The patient must have approval for surgery by cardiologist if any of the following are present: unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF <45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (>5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest).

GUIDELINE NOTE 118, SEPTOPLASTY

Lines 42,119,202,246,287,312,466,506,525,577

Septoplasty is included on line 312 for gender affirming treatment.

Septoplasty is included on lines 42, 119, 202, 246, 287,466, 506, 525 and 577 when

A) The septoplasty is done to address symptomatic septal deviation or deformity which
   1) Fails to respond to a minimum 6 week trial of conservative management (e.g. nasal corticosteroids, decongestants, antibiotics); AND
   2) Results in one or more of the following:
      a. Persistent or recurrent epistaxis, OR
      b. Documented recurrent sinusitis felt to be due to a deviated septum and the patient meets criteria for sinus surgery in Guideline Note 35, SINUS SURGERY; OR
      c. Nasal obstruction with documented absence of other causes of obstruction likely to be responsible for the symptoms (for example, nasal polyps, tumor, etc.) [note: this indication is included only on Line 577; OR

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

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

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Appendix A
Revised Guideline Notes

Septoplasty is not covered for obstructive sleep apnea.

GUIDELINE NOTE 127 GENDER AFFIRMING TREATMENT

Line 312

Gender-affirming treatments are included on this line according to the provisions of House Bill 2002 (2023), when provided according to Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, published by the World Professional Association of Transgender Health (WPATH), whether or not the code for the service appears on the line. These services are included for gender affirming treatment or for any condition represented on this line. To simplify administration, the line includes a variety of procedures that may be considered medically necessary and prescribed in accordance with the WPATH 8.0 standards of care.

Gender affirming treatments billed using CPT or HCPCS codes not on this line must also be covered in accordance with the provisions of the bill.

In addition, the bill prohibits denial or limitation of services determined to be medically necessary by the provider who prescribed the treatment, ~~criteria for medical necessity,~~ prohibits denying or limiting services considered by plans to be 'cosmetic' and requires that any denial or limit be reviewed and upheld by a provider with experience prescribing or delivering gender affirming treatment.

~~**GUIDELINE NOTE 159, SMOKING AND SURGICAL TREATMENT OF ERECTILE DYSFUNCTION**~~

~~*Line 523*~~

~~Surgical treatment of erectile dysfunction is only included on this line when patients are non-smoking and abstinent from all nicotine products for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date~~

GUIDELINE NOTE 166, BREAST REDUCTION SURGERY FOR SYMPTOMATIC MACROMASTIA

Lines 402,417,426,561

~~Breast reduction surgery for macromastia is not covered as a treatment for neck or back pain resulting from the macromastia due to lack of high quality evidence of effectiveness.~~

Breast reduction surgery is included on these lines 402, 417 or 426 only when ALL of the following conditions are met:

1) The patient is aged 15 or older; AND
2) The patient has a diagnosis of macromastia (size D or higher); AND

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3) At least one of the following criteria (a or b) have been met:
    a. Back, neck or shoulder pain
        i. Must be documented to have adverse effects on activities of daily living
        ii. Must be unresponsive to conservative treatments for three months within a year prior. Conservative treatment must include at least three months of
            1. a documented trial of analgesics, AND
            2. physical therapy or chiropractic/osteopathic manipulation treatment or acupuncture, AND
            3. use of support wear for the breast; OR
    b. Persistent severe intertrigo in the inframammary fold unresponsive to documented prescribed medication for at least three months within a year prior; AND
4) The treating surgeon must document that breast reduction has a high likelihood of improving the symptoms that limit activities of daily living caused by the macromastia; AND
5) The expected bilateral reduction volume must be greater than 300 grams (1 cup size) per breast; AND
6) Women aged 40 and older are required to have a negative screening mammogram within two years of the planned reduction mammoplasty; AND
7) Member should be a non-smoker or should not have smoked within the 6 weeks prior to surgery as documented by the surgeon.

Additional criteria for patients aged 15-17 years:

1) The patient must have completed puberty (Tanner stage V)
2) The patient must have a one year history of growth stabilization evidenced by a minimum of four visits with documented heights or puberty completion as shown on wrist radiograph read by a radiologist

Otherwise, breast reduction surgery is included on line 561.

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

Line 502

The following interventions are prioritized on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

Procedure Code	Intervention Description	Rationale	Last Review
~~99174, 99177~~	~~Photoscreening~~	~~More costly than equally effective methods of screening~~	~~May 2019~~

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Appendix A
Revised Guideline Notes

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
A4238 E2102	Non-therapeutic continuous glucose monitors	Insufficient evidence of effectiveness	November 2023
~~S8948~~	~~Low level laser therapy and all similar therapies~~	~~Insufficient evidence of effectiveness~~	~~August 2020~~
22836-22838	Anterior thoracic vertebral body tethering	Insufficient evidence of effectiveness	November 2023
31242, 31243	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation or cryoablation, posterior nasal nerve	Insufficient evidence of effectiveness	November 2023
~~31627~~	~~Computer assisted bronchoscopy~~	~~Insufficient evidence of effectiveness~~	~~March 2021~~
52284	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis	Insufficient evidence of effectiveness	November 2023
~~0404T~~ 58580	~~Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency~~ Transcervical ablation of uterine fibroid(s)	Insufficient evidence of effectiveness	~~August 2021~~ November 2023
76376-76377 93319, C7557, C9793	3D rendering of imaging studies	No additional proven benefit beyond the standard study, therefore not reimbursed separately	November 2021
81470, 81471	X-linked intellectual disability (XLID) genomic sequence panels	Insufficient evidence of effectiveness	~~November, 2014~~ November 2023

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Appendix A
Revised Guideline Notes

Procedure Code	Intervention Description	Rationale	Last Review
83700-83704, 0377U	Lipoprotein, blood	Insufficient evidence of effectiveness	October 2006
92620-92621	Evaluation of central auditory function	Insufficient evidence of effectiveness	~~January 2005~~ November 2023
97037	Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non-ablative) for post-operative pain reduction	Insufficient evidence of effectiveness	November 2023
0173U, 0175U, 0345U, 0392U, 0411U, 0419U	Pharmacogenetics testing for management of psychiatric medications	Insufficient evidence of effectiveness	November 2023
0390U, 0243U	Maternal serum biomarker tests with or without additional algorithmic analysis for prediction of preeclampsia	Insufficient evidence of effectiveness	November 2023

GUIDELINE NOTE 216, RHINOPLASTY

Lines 42,119,~~202~~,~~246,~~287,312,466,506,525,577

Rhinoplasty is included on line 312 for gender affirming treatment.

Rhinoplasty is included on lines ~~42, 119, 202, 246, 287, 466, 506 and 525~~ 42 and 119, when A) it is performed to correct a nasal deformity secondary to congenital cleft lip and/or palate or other severe congenital craniofacial anomaly. ~~; OR~~

B) Rhinoplasty is included on lines 228, 287, 506, 525 and 577 when It is performed as part of reconstruction after accidental or surgical trauma or disease (~~e.g.,~~ for example Wegener's granulomatosis, ~~choanal atresia,~~ nasal malignancy, abscess, septal infection with saddle deformity~~, or congenital deformity~~) AND

1) There is prolonged, persistent obstructed nasal breathing unresponsive to a six week trial of conservative management (e.g. nasal corticosteroids, decongestants, antibiotics); AND
2) Airway obstruction will not respond to septoplasty and turbinectomy alone; AND
3) Photographs demonstrate an external nasal deformity; AND

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4) There is significant obstruction of one or both nares, documented by nasal endoscopy, computed tomography (CT) scan or other appropriate imaging modality. ~~; OR~~

C) Rhinoplasty is included on line 466 when t~~T~~here is nasal airway obstruction causing chronic rhinosinusitis when all of the following are met:

1) The criteria for sinus surgery are met in Guideline Note 35, SINUS SURGERY; AND
2) Airway obstruction will not respond to septoplasty and turbinectomy alone; AND
3) Photographs demonstrate an external nasal deformity; AND
4) There is significant obstruction of one or both nares), documented by nasal endoscopy, computed tomography (CT) scan or other appropriate imaging modality

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Appendix B
NEW GUIDELINE NOTES

Note: wording shown in purple below was not approved by HERC at their 11/9/23 meeting

DIAGNOSTIC GUIDELINE DX, NEXT GENERATION SEQUENCING OF MALIGNANCIES

Next Generation Sequencing (NGS, for example CPT 81479, 81455, 0037U) is covered when all of the following requirements are met:

1) The patient has
    a. ~~Either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer a~~ tissue diagnosis confirming cancer and has been evaluated by an oncologist or oncologic surgeon; AND
    b. Has not been previously tested using the same NGS test for the same primary diagnosis of cancer, unless the criteria in 4) below are met; AND
    c. Decided to seek further cancer treatment (for example, therapeutic chemotherapy) and has adequate performance status (ECOG 0-2) to undergo such treatment; AND
2) The diagnostic laboratory test using NGS must have:
    a. Clinical Laboratory Improvement Amendments (CLIA)-certification; AND
    b. The test is being used as a companion diagnostic test in accordance with Food & Drug Administration (FDA)-approved therapeutic labeling; AND
    c. Results provided to the treating physician for management of the patient using a report template to specify treatment options; AND
3) A single CPT or HCPCS code is covered for each multigene panel performed on tumor tissue. Additional codes for individual genes and for molecular pathology procedures CPT 81400-81408 are excluded from coverage when the multigene panel is covered under the appropriate CPT or HCPCS code.
4) Repeat NGS testing may be required in the setting of patients who have clinically progressed per standardized professional guidelines after therapy. Coverage in this situation is limited to 3 times per primary malignancy unless there is indication for additional testing after individualized review of medical necessity.
5) Whole exome sequencing of cancer tissue (for example, 0329U or 0211U) is covered ONLY when all of the following criteria are met:
    a. The patient has advanced or metastatic cancer; AND
    b. The test is used to assess tumor mutation burden and identify candidates for checkpoint inhibition immunotherapy; AND
    c. The patient has progressed following prior treatment; AND
    d. There are no satisfactory alternative treatment options.

DIAGNOSTIC GUIDELINE DX COMPUTER ASSISTED NAVIGATIONAL BRONCHOSCOPY

Computer assisted navigational bronchoscopy (CPT 31627) is covered for EITHER

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Appendix B
NEW GUIDELINE NOTES

1) Patients for whom nonsurgical biopsy is indicated when both transthoracic needle biopsy and conventional bronchoscopy are considered inadequate to accomplish the diagnostic or interventional objective; OR
2) The pre-treatment placement of fiduciary markers within lung tumor(s).

GUIDLEINE NOTE XXX PHRENIC NERVE STIMULATION

Line 71

Phrenic nerve stimulation is included on this line when all of the following criteria are met

1) The patient has severe, chronic respiratory failure requiring mechanical ventilation due to EITHER
    a. A stable high spinal cord injury defined as C3 or above; OR
    b. Central hypoventilation disorder; AND
2) The patient has intact and sufficient function in the phrenic nerve, lungs, and diaphragm; AND
3) Stimulation of the diaphragm either directly or through the phrenic nerve results in sufficient muscle activity to accommodate independent breathing without the support of a ventilator for at least 4 continuous hours and day.

GUIDELINE NOTE XXX SUPRACHOROIDAL INJECTION

Line 360

Suprachoroidal space injection (CPT 67516) is only included on this line for treatment of macular edema associated with uveitis with triamcinolone acetonide.

GUIDELINE NOTE XXX LOW LEVEL LASER THERAPY

All lines with chemotherapy/radiation therapy/stem cell transplant

Low level laser therapy (HCPCS S8948, CPT 0552T) is included on these lines only for prevention of oral mucositis for members undergoing cancer treatment associated with increased risk of oral mucositis, including chemotherapy, radiotherapy, and/or hematopoietic stem cell transplantation.

GUIDELINE NOTE XXX CARDIAC RESYNCHRONIZATION THERAPY

Lines 97,98,110,281,285

Cardiac resynchronization therapy (CRT) is only covered for patients with NYHA Class II-III and ambulatory IV heart failure with an ejection fraction ≤ 35% as well as one of the following:

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1) left bundle branch block (LBBB) and a QRS complex over 120 msec; OR
2) QRS complex ≥ 150ms

CRT-pacemaker is covered for the patients for whom CRT is covered.

GUIDELINE NOTE XXX HIGH RISK FOOT CARE

Lines 165, 489

Foot care by a medical professional, including pairing and cutting of corns and calluses, debridement of nails, avulsion of nail plates, trimming of dystrophic nails, and biopsy of nails, is included on line 165 only when:

1) The patient is at high risk for complications from nail and foot problems due to a systemic condition that has resulted in severe circulatory insufficiency and/or areas of desensitization in the lower extremities; OR
2) The patient resides in a skilled nursing facility, rehabilitation facility, group home or similar institutional setting.

Evaluation for and treatment of tinea unguium (ICD-10-CM B35.1) including biopsy of nails, nail paring, and treatment with topical or oral antifungal medications is included on line 165 only when:

1) The patient is in one of the two high risk groups identified above; AND
2) There is clinical evidence of mycosis of the toenail; AND
3) The patient has documented marked limitation of ambulation, pain, and/or secondary bacterial infection resulting from the thickening and dystrophy of the infected toenail plate.

Otherwise, evaluation and treatment of tinea unguium is included on line 489.

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CDT code	Descriptor	Recommended Placement
D0396	3D printing of a 3D dental surface scan to obtain a physical model.	Diagnostic Procedures File
D1301	A review of a patient's vaccine and medical history, and discussion of the vaccine benefits, risks, and consequences of not obtaining the vaccine. Counseling also includes a discussion of questions and concerns the patient, family, or caregiver may have and suggestions on where the patient can obtain the vaccine.	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
D2976	A band, typically cemented around a molar tooth after a multi-surface restoration is placed, to add support and resistance to fracture until a patient is ready for the full cuspal coverage restoration.	343 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment BASIC RESTORATIVE
D2989		343 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment BASIC RESTORATIVE
D2991	Preparation of tooth surfaces and topical application of a scaffold to guide hydroxyapatite regeneration.	646 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment ELECTIVE DENTAL SERVICES
D6089		619 DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment IMPLANTS
D7284		Diagnostic Procedures File
D7939	A guide is stabilized to the teeth and/or the bone to allow for virtual guidance of osteotomy.	619 DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment IMPLANTS
D9938		645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS Treatment COSMETIC DENTAL SERVICES
D9939		645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS Treatment COSMETIC DENTAL SERVICES

CDT code	Descriptor	Recommended Placement
D9954	Device for use immediately after removing a mandibular advancement device to aid in relieving muscle/jaw pain and occlusal changes.	202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
D9955	Post-delivery visit for titration of a mandibular advancement device and to subsequently evaluate the patient's response to treatment, integrity of the device, and management of side effects.	202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
D9956	Sleep apnea test, for patients who are at risk for sleep related breathing disorders and appropriate candidates, as allowed by applicable laws. Also, to help the dentist in defining the optimal position of the mandible.	Excluded File
D9957	Screening activities, performed alone or in conjunction with another evaluation, to identify signs and symptoms of sleep-related breathing disorders.	Excluded File

Code	Description	Code Placement Recommendation
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device	183 FRACTURE OF PELVIS, OPEN AND CLOSED 398 SEVERE SACROILIITIS 530 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
33277	Insertion of phrenic nerve stimulator transvenous sensing lead (List separately in addition to code for primary procedure)	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES

Code	Description	Code Placement Recommendation
33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
33279	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
33280	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
33288	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
52284	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
58580	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Code	Description	Code Placement Recommendation
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 249 PARKINSON'S DISEASE
61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 249 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
61892	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 249 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 457 URINARY INCONTINENCE 529 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 457 URINARY INCONTINENCE 529 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT

Code	Description	Code Placement Recommendation
67516	Suprachoroidal space injection of pharmacologic agent (separate procedure)	360 CHORIORETINAL INFLAMMATION
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care profes	Diagnostic Procedures File
76984	Ultrasound, intraoperative thoracic aorta (eg, epiaortic), diagnostic	Diagnostic Procedures File
76987	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report	Diagnostic Procedures File
76988	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only	Diagnostic Procedures File
76989	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; interpretation and report only	Diagnostic Procedures File
81457	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability	Diagnostic Procedures File
81458	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants and microsatellite instability	Diagnostic Procedures File
81459	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements	Diagnostic Procedures File

Code	Description	Code Placement Recommendation
81462	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements	Diagnostic Procedures File
81463	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis, copy number variants, and microsatellite instability	Diagnostic Procedures File
81464	Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and re	Diagnostic Procedures File
81517	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk	198 CHRONIC HEPATITIS; VIRAL HEPATITIS
82166	Anti-mullerian hormone (AMH)	Diagnostic Procedures File
86041	Acetylcholine receptor (AChR); binding antibody	Diagnostic Procedures File
86042	Acetylcholine receptor (AChR); blocking antibody	Diagnostic Procedures File
86043	Acetylcholine receptor (AChR); modulating antibody	Diagnostic Procedures File
86366	Muscle-specific kinase (MuSK) antibody	Diagnostic Procedures File
87523	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis D (delta), quantification, including reverse transcription, when performed	Diagnostic Procedures File
87593	Infectious agent detection by nucleic acid (DNA or RNA); Orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each	Diagnostic Procedures File
90380	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use	Added to line 3 at the September 2023 HERC meeting
90381	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use	Added to line 3 at the September 2023 HERC meeting

Code	Description	Code Placement Recommendation
90589	Chikungunya virus vaccine, live attenuated, for intramuscular use	Excluded File
90611	Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous use	Added to line 3 in August 2022
90622	Vaccinia (smallpox) virus vaccine, live, lyophilized, 0.3 mL dosage, for percutaneous use	Added to line 3 in August 2022
90623	Meningococcal pentavalent vaccine, conjugated Men A, C, W, Y-tetanus toxoid carrier, and Men B-FHbp, for intramuscular use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
90679	Respiratory syncytial virus vaccine, preF, recombinant, subunit, adjuvanted, for intramuscular use	Added to line 3 at the September 2023 HERC meeting
90683	Respiratory syncytial virus vaccine, mRNA lipid nanoparticles, for intramuscular use	Added to line 3 at the September 2023 HERC meeting
92622	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes	311 HEARING LOSS - AGE 5 OR UNDER 446 HEARING LOSS - OVER AGE OF FIVE
92623	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (List separately in addition to code for primary procedure)	311 HEARING LOSS - AGE 5 OR UNDER 446 HEARING LOSS - OVER AGE OF FIVE
92972	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)	PENDING
93150	Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
93151	Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES

Code	Description	Code Placement Recommendation
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
93153	Interrogation without programming of implanted phrenic nerve stimulator system	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES

Code	Description	Code Placement Recommendation
93584	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart	45 CORONARY ARTERY ANOMALY 67 VENTRICULAR SEPTAL DEFECT 70 CONGENITAL PULMONARY VALVE ANOMALIES 76 PATENT DUCTUS ARTERIOSUS; AORTIC PULMONARY 84 ENDOCARDIAL CUSHION DEFECTS 85 CONGENITAL PULMONARY VALVE ATRESIA 88 DISCORDANT CARDIOVASCULAR CONNECTIONS 89 CONGENITAL MITRAL VALVE STENOSIS/INSUFFICIENCY 104 ETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 105 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 110 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 118 ATRIAL SEPTAL DEFECT, SECUNDUM 128 COMMON TRUNCUS 130 TOTAL ANOMALOUS PULMONARY VENOUS CONNECTION 134 INTERRUPTED AORTIC ARCH 138 EBSTEIN'S ANOMALY 176 COMMON VENTRICLE 188 CONGENITAL TRICUSPID ATRESIA AND STENOSIS 232 HYPOPLASTIC LEFT HEART SYNDROME 264 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE 653CARDIOVASCULAR CONDITIONS WITH NO OR
93585	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemiazygos venous system (List separately in addition to code for primary procedure)	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653

Code	Description	Code Placement Recommendation
93586	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus (List separately in addition to code for primary procedure)	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
93587	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or above the heart (eg, from innominate vein) (List separately in addition to code for primary	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
93588	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (eg, from the inferior vena cava) (List separately in addition to code for primary	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
96547	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes (List separately in addition to code for primary procedure)	157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 238 CANCER OF OVARY 261 CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY
96548	Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; each additional 30 minutes (List separately in addition to code for primary procedure)	157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS 238 CANCER OF OVARY 261 CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY
97037	Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non-ablative) for post-operative pain reduction	All lines with chemotherapy, radiation therapy or stem cell transplant
97550	Caregiver training in strategies and techniques to facilitate the patientΓÇÖs functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, probl	any line with CPT codes for PT, OT or speech therapy services

Code	Description	Code Placement Recommendation
97551	Caregiver training in strategies and techniques to facilitate the patientΓÇÖs functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, probl	any line with CPT codes for PT, OT or speech therapy services
97552	Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (eg, activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, p	any line with CPT codes for PT, OT or speech therapy services
99459	Pelvic examination (List separately in addition to code for primary procedure)	Excluded File
0355U	APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
0377U	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables))	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
0380U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype	DIAGNOSTIC PROCEDURES
0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Code	Description	Code Placement Recommendation
0392U	Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
0411U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
0419U	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
0396U	Pre-implantation genetic testing	Excluded
0408U	Omnia COVID test	DIAGNOSTIC PROCEDURES

Appendix E
HCPCS Codes

HCPC	LONG DESCRIPTION	Recommended Placement
C7556	Bronchoscopy, rigid or flexible, with bronchial alveolar lavage and transendoscopic endobronchial ultrasound (ebus) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s), including fluoroscopic guidance, when performed	DIAGNOSTIC PROCEDURES
C7557	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed and intraprocedural coronary fractional flow reserve (ffr) with 3d functional mapping of color-coded ffr values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C7558	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography with pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed	DIAGNOSTIC PROCEDURES

HCPC	LONG DESCRIPTION	Recommended Placement
C7560	Endoscopic retrograde cholangiopancreatography (ercp) with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s) and endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s)	55 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS 190 NEOPLASMS OF ISLETS OF LANGERHANS 195 ACUTE PANCREATITIS 250 CHRONIC PANCREATITIS 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 293 ANOMALIES OF GALLBLADDER, BILE DUCTS, AND LIVER 315 CANCER OF LIVER 316 CANCER OF PANCREAS 363 CYST AND PSEUDOCYST OF PANCREAS 435 CANCER OF GALLBLADDER AND OTHER BILIARY 641 GALLSTONES WITHOUT CHOLECYSTITIS

HCPC	LONG DESCRIPTION	Recommended Placement
C7561	Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less with manual preparation and insertion of drug-delivery device(s), deep (e.g., subfascial)	131 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME 160 TRAUMATIC AMPUTATION OF ARM(S), HAND(S), THUMB(S), AND FINGER(S) (COMPLETE)(PARTIAL) WITH AND WITHOUT COMPLICATION 205 SUPERFICIAL ABSCESSES AND CELLULITIS 207 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT 235 LIMB THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR COMPLICATIONS 254 CHRONIC OSTEOMYELITIS 276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 379 CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
C7903	Group psychotherapy service for diagnosis, evaluation, or treatment of a mental health or substance use disorder provided remotely by hospital staff who are licensed to provide mental health services under applicable state law(s), when the patient is in their home, and there is no associated professional service	All lines with psychotherapy
C9793	3d predictive model generation for pre-planning of a cardiac procedure, using data from cardiac computed tomographic angiography with report	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9794	Therapeutic radiology simulation-aided field setting; complex, including acquisition of pet and ct imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling)	All lines with radiation therapy

HCPC	LONG DESCRIPTION	Recommended Placement
C9795	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	262 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS
G0011	Individual counseling for pre-exposure prophylaxis (prep) by physician or qualified health care professional (qhp)to prevent human immunodeficiency virus (hiv), includes hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence, 15-30 minutes	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
G0012	Injection of pre-exposure prophylaxis (prep) drug for hiv prevention, under skin or into muscle	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
G0013	Individual counseling for pre-exposure prophylaxis (prep) by clinical staff to prevent human immunodeficiency virus (hiv), includes: hiv risk assessment (initial or continued assessment of risk), hiv risk reduction and medication adherence	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
G0017	Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); first 60 minutes	All lines with psychotherapy
G0018	Psychotherapy for crisis furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting); each additional 30 minutes (list separately in addition to code for primary service)	All lines with psychotherapy

HCPC	LONG DESCRIPTION	Recommended Placement
G0019	Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (sdoh) need(s) that are significantly limiting the ability to diagnose or treat problem(s) addressed in an initiating visit: person-centered assessment, performed to better understand the individualized context of the intersection between the sdoh need(s) and the problem(s) addressed in the initiating visit. ++ conducting a person-centered assessment to understand patient's life story, strengths, needs, goals, preferences and desired outcomes, including understanding cultural and linguistic factors and including unmet sdoh needs (that are not separately billed). ++ facilitating patient-driven goal-setting and establishing an action plan. ++ providing tailored support to the patient as needed to accomplish the practitioner's treatment plan. practitioner, home-, and community-based care coordination. ++ coordinating receipt of needed services from healthcare practitioners, providers, and facilities; and from home- and community-based service providers, social service providers, and caregiver (if applicable). ++ communication with practitioners, home- and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors. ++ coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. ++ facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) to address the sdoh need(s). health education-helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, and preferences, in the context of the sdoh need(s), and educating the patient on how to best participate in medical decision-making. building patient self-advocacy skills, so that the patient can interact with members of the health care team and related	All lines with E&M codes
G0022	Community health integration services, each additional 30 minutes per calendar month (list separately in addition to g0019)	All lines with E&M codes

HCPC	LONG DESCRIPTION	Recommended Placement
G0023	Principal illness navigation services by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator; 60 minutes per calendar month, in the following activities: person-centered assessment, performed to better understand the individual context of the serious, high-risk condition. ++ conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors and including unmet sdoh needs (that are not separately billed). ++ facilitating patient-driven goal setting and establishing an action plan. ++ providing tailored support as needed to accomplish the practitioner's treatment plan. identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services. practitioner, home, and community-based care coordination. ++ coordinating receipt of needed services from healthcare practitioners, providers, and facilities; home- and community-based service providers; and caregiver (if applicable). ++ communication with practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors. ++ coordination of care transitions between and among health care practitioners and settings, including transitions involving referral to other clinicians; follow-up after an emergency department visit; or follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities. ++ facilitating access to community-based social services (e.g., housing, utilities, transportation, likely to promote personalized and effective treatment of their condition. health care access / health system navigation. ++ helping the patient access healthcare, including identifying appropriate practitioners or providers for clinical care, and helping secure appointments with them. ++ providing the patient with information/resources to consider participation in clinical trials or clinical research as applicable. facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals. facilitating and providing social and emotional support to help the patient cope	All lines with E&M codes
G0024	Principal illness navigation services, additional 30 minutes per calendar month (list separately in addition to g0023)	All lines with E&M codes
G0136	Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5-15 minutes	DIAGNOSTIC PROCEDURES

HCPC	LONG DESCRIPTION	Recommended Placement
G0137	Intensive outpatient services; weekly bundle, minimum of 9 services over a 7 contiguous day period, which can include individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under state law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; and such other items and services (excluding meals and transportation) that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services in accordance with a physician certification and plan of treatment (provision of the services by a medicare-enrolled opioid treatment program); list separately in addition to code for primary procedure	4 SUBSTANCE USE DISORDER

HCPC	LONG DESCRIPTION	Recommended Placement
G0140	Principal illness navigation - peer support by certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist; 60 minutes per calendar month, in the following activities: person-centered interview, performed to better understand the individual context of the serious, high-risk condition. ++ conducting a person-centered interview to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors, and including unmet sdoh needs (that are not billed separately). ++ facilitating patient-driven goal setting and establishing an action plan. ++ providing tailored support as needed to accomplish the person-centered goals in the practitioner's treatment plan. identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services. practitioner, home, and community-based care communication. ++ assist the patient in communicating with their practitioners, home-, and community-based service providers, hospitals, and skilled nursing facilities (or other health care facilities) regarding the patient's psychosocial strengths and needs, goals, preferences, and desired outcomes, including cultural and linguistic factors. ++ facilitating access to community-based social services (e.g., housing, utilities, transportation, food assistance) as needed to address sdoh need(s). health education. helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and sdoh need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making. building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition. developing and proposing strategies to help meet person-centered treatment goals and supporting the patient in using chosen strategies to reach person-centered treatment goals. facilitating and providing social and emotional support to help the patient cope with the condition, sdoh need(s), and adjust daily routines to better meet person-centered diagnosis and treatment goals. leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to	All lines with E&M codes
G0146	Principal illness navigation - peer support, additional 30 minutes per calendar month (list separately in addition to g0140)	All lines with E&M codes

Section 2.0

Staff Report

HERC Staff Listening Session Report

12/12/23

Topic 1: Alopecia areata

Speaker: Sabra Leitenberger, OHSU pediatric dermatology

Dr. Leitenberger requested a reconsideration of non-coverage for alopecia areata, a rare autoimmune disease causing chronic inflammation resulting in hair loss. This loss can be patchy, involve the entire scalp, or involve the entire body. This condition can result in a negative impact on psychosocial functioning and quality of life similar to psoriasis and vitiligo, which as currently covered conditions.

Currently, alopecia areata is on a non-covered line on the Prioritized List. At the time of prioritization, there were no effective treatments for this condition. New treatments now exist, such as baricitinib and ritlecitinib, which are FDA approved for treatment of alopecia. Wigs are also not covered for alopecia, based on a guideline restricting wig coverage to hair loss from cancer treatments.

Dr. Leitenbergers' request was to move alopecia areata to a covered line for severe cases, with a guideline that would define severe. This would allow coverage for FDA approved medications. Wig coverage should also be considered.

HERC staff next steps: HERC staff are in discussions with OHA leadership regarding this topic. CMS historically has not allowed Medicaid programs to cover medications for hair loss, without clarification regarding whether this hair loss is due to normal aging or to autoimmune disease. A Medicaid State Plan Amendment would be required before the medications could be covered. The Pharmacy and Therapeutics Committee has planned a drug class review on these medications. Based on the results of the review staff may bring a proposal to HERC for reprioritization of this condition.

Topic 2: Coverage for hemorrhoids

Speaker: Paul DenOuden, Portland physician

Dr. DenOuden requested consideration for coverage of various treatments for hemorrhoids. In his practice, hemorrhoids are common. Over the counter medications are sufficient for treatment of minor hemorrhoids. However, many of his patients have pain and/or bleeding from their hemorrhoids which does not respond to over the counter treatments. He refers patients to a proctologist in these cases, but the proposed treatments, such as banding or sclerotherapy, are not covered by OHP. His non-OHP patients, however, can receive all of these treatments. He has seen patients with recurrent bleeding from hemorrhoids, who seek care in urgent care or the ED or in his office. The cost of these multiple visits is much more than the cost of the recommended treatment. It is also a waste of OHP resources to have a proctology consultation but not have any ability to act on the consult recommendations. Dr. DenOuden is requesting coverage of prescription strength hydrocortisone foam, creams and/or suppositories. He is also requesting consideration of coverage for banding, sclerotherapy and surgery for refractory hemorrhoids particularly when very painful or recurrently bleeding.

HERC staff next steps: HERC staff have consulted with P&T staff and determined that prescription strength hydrocortisone is covered without PA, and therefore should be available for treatment of hemorrhoids. HERC staff will reach out to proctologists or rectal surgeons for input on which patients require procedures, and which procedures have the best evidence of effectiveness. HERC staff will then prepare a proposal for consideration by HERC.

Topic 3: Continuous glucose monitors for patients with very high A1c values

Speaker: Alec Vera, nurse at Outside In

Ms. Vera spoke about the need for expanding coverage of continuous glucose monitors (CGMs) beyond recent changes by the HERC. She noted that diabetes is more common in women, older persons, Blacks, Latinos, and Native Americans. Good control of diabetes requires dietary changes, exercise, medication compliance, finger pricks, and multiple office visits. In her experience, many patients cannot adequately manage their diabetes with traditional finger stick glucose measurements. For example, people who work at jobs without access to hand washing facilities or regular breaks, parents with small children, and people who find finger pricks very painful. In her experience, CGMs are empowering. They help patients see how food, exercise, and lifestyle changes affect their blood sugars. This is particularly important for people with a1c values greater than 9. These patients are at high risk for expensive complications and high downstream costs. This is an equity issue, as wealthier people can pay for CGMs out of pocket.

When asked about the standard of care to start patients with an a1c>9 on insulin, which would allow CGM coverage, Ms. Vera replied that 60% of her patients with a1cs > 9 refuse to start insulin. She acknowledged that some CGMs require a smart phone for use, which is another barrier for many patients.

Danielle Shannon, a clinical pharmacist who works in diabetes management, also spoke. She noted that insulin causes weight gain, which is a problem in diabetes. CGMs are a significant tool in diabetes care. They are also cost effective when compared to GLP1 agonist medications.

HERC staff next steps: These issues were considered in the recent coverage guidance. The Commission can take them up again if it so chooses.

Section 3.0

Errata January 2024

Errata
January 2024

1) On January 8, 2024, staff deleted the entry for CPT 77061-77063 (Digital breast tomosynthesis) from Guideline Note 173 as per a decision made at the August 17, 2023, HERC meeting. (The Commission recommended that HCPCS G0279 (Diagnostic digital breast tomosynthesis, unilateral or bilateral) be placed on the Diagnostic Procedures file.)

2) After the January 1, 2024 Prioritized List was published, staff received revisions to the HCPCS codeset from CMS. HCPCS C7561 (Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less with manual preparation and insertion of drug-delivery device(s), deep (e.g., subfascial)) was deleted, and removed from the following lines on the Prioritized List:
   a) 131 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME
   b) 160 TRAUMATIC AMPUTATION OF ARM(S), HAND(S), THUMB(S), AND FINGER(S) (COMPLETE)(PARTIAL) WITH AND WITHOUT COMPLICATION
   c) 204 SUPERFICIAL ABSCESSES AND CELLULITIS
   d) 206 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
   e) 234 LIMB THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR COMPLICATIONS
   f) 252 CHRONIC OSTEOMYELITIS
   g) 274 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA

3) At the November 9, 2023 meeting, the HERC voted to approve staff's recommendation to move two codes (HCPCS A4238 and E2102) related to non-therapeutic continuous glucose monitoring from the Ancillary Procedures File to Line 654/Guideline 173 as part of the coverage guidance decision to only approve therapeutic continuous glucose monitors for type 2 diabetes management. Shortly after the meeting, staff were made aware that non-therapeutic monitors were used for insulin pump management for type 1 diabetes. Since HERC's intent was not to remove this coverage for the type 1 population, these two codes were not moved to Line 654/Guideline 173 but instead left on the Ancillary Procedures File:
   a) A4238 Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
   b) E2102 Adjunctive, non-implanted continuous glucose monitor or receiver

Section 4.0

Plain Language Summaries

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
January 18, 2024

This plain language summary provides a short and non-technical explanation of the topics that will be discussed at the meeting, along with the staff recommendations. Decisions are not final unless approved by the Health Evidence Review Commission (which usually meets later on the same day). The Commission may approve, modify, or not approve staff recommendations.

Vulvectomy and Other Treatments for Vulvodynia

Plain Language Summary:

Coverage question: Should OHP cover a surgery that removes a portion of a woman's genitals (vulva) for a condition (vulvodynia) that causes burning, pain and discomfort even when there is no sign of injury of infection?

Should OHP cover this treatment?
Option 1: No. The research on the medical treatment is not very strong and the risks of harms of greater than the benefits.
Option 2: Yes. Surgical treatment and physical therapy can benefit this condition.

PANDA/PANS Guideline Edits January 2024

Plain Language Summary:

Coverage question: PANDAS and PANS are complicated conditions where certain infections may cause mental health symptoms to develop in children. In 2022, the Commission approved guidelines to help treat some patients. At a Listening Session with staff members, patient representatives said the guideline needs to clarify when specialist visits should happen and when other treatments should be tried.

Should OHP amend the guideline note to address the barriers? Yes, it makes sense to specify timeframes. The subcommittee should discuss what timeframes seem most appropriate.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
January 18, 2024

Acute Nasal Fracture Guideline

Plain Language Summary:

Coverage question: Should OHP cover treatments for a recently broken nose?

Should OHP cover this treatment? Yes, when the treatment for the broken nose happens within 14-days of the original injury.

Lipoprotein Testing

Plain Language Summary:

Coverage question: Should OHP cover a type of cholesterol test (lipoprotein a)?

Should OHP cover this treatment?
Option 1: Yes, based on expert opinion.
Option 2: No. There is no evidence showing the benefit of testing for this type of cholesterol.

2023 CPT Code Review: Coronary Lithotripsy

Plain Language Summary:

Coverage question: Should OHP cover a medical procedure to help open blocked blood vessels to the heart?

Should OHP cover this treatment? No. It has not been compared to more common treatments and no studies found evidence of it working well.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
January 18, 2024

PSA for Prostate Cancer Screening

Plain Language Summary:

Coverage question: Should OHP cover a test to check for prostate cancer (prostate specific antigen PSA)?

Should OHP cover this treatment? Yes. There are two options to consider:
Option 1: Add the test with no special limits
Option 2: Add the test with a guideline to include the test only for men aged 55-69 years.

Peristeen Transanal Irrigation System

Plain Language Summary:

Coverage question: Should OHP cover a system to assist with bowel problems by using anal irrigation?

Should OHP cover this treatment? Yes, medical studies show this systems helps certain patients.

Treatment of Liver Metastases

Plain Language Summary:

Coverage question: Liver metastases are tumors that started out in some other part of the body and have spread to the liver. Should OHP cover treatments for this condition?

Should OHP cover these treatments? Yes, certain types of treatments should be covered in limited cases.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
January 18, 2024

Rectal Sensation, Tone, and Compliance Test

Plain Language Summary:

Coverage question: Should OHP cover a test to check how strong and flexible the muscles in the rectum are?

Should OHP cover this treatment? Yes, this routine test checks bowel movement issues.

Esophageal Balloon Distention Provocation Study

Plain Language Summary:

Coverage question: Should OHP cover a test with balloon dilation to check if the esophagus is causing chest pain that isn't related to the heart?

Should OHP cover this treatment? No, testing the esophagus with balloon dilation doesn't seem very reliable, it's not commonly recommended and there's no evidence that it can predict how well a treatment will work.

Intraocular Steroids for Uveitis 2023

Plain Language Summary:

Coverage question: Should OHP remove the part of a guideline about treatments for eye inflammation that says members have to try of oral steroid medication first?

Should OHP cover this treatment? Yes, and remove the whole guideline as it is out of date.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
January 18, 2024

Reflectance Confocal Microscopy

Plain Language Summary:

Coverage question: Should OHP cover the use of a specialized tool that takes close-up images of the skin?

Should OHP cover this treatment? No, this is relatively new technology and hasn't been thoroughly researched yet.

CardioMEMS Implantable Wireless Pulmonary Artery Pressure Monitor for Heart Failure

Plain Language Summary:

Coverage question: Should OHP cover a device that gets implanted to keep track of heart rate and pressure in the pulmonary artery (the blood vessel connected to the heart) for some people with heart failure?

Should OHP cover this treatment? No, expert guidelines in this field do not recommend using this device.

Facet Joint Injections 2024 Review

Plain Language Summary:

Coverage question: Should OHP cover shots in the spine joints (facet joints) with numbing or steroids medicine for back pain?

Should OHP cover this treatment? No. Studies showed that these shots didn't work better than shots with no active ingredients. The research found that these shots didn't really help reduce pain or improve how well people could move.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
January 18, 2024

Benign Paroxysmal Positional Vertigo

Plain Language Summary:

Coverage question: Should OHP cover a condition causing dizziness or a feeling that the world is spinning?

Should OHP cover this treatment? Yes, treatment of benign paroxysmal positioning vertigo (BVVP), a condition that causes dizziness and unsteady feelings when changing head positions, should be covered for some patients. Studies show physical therapy treatment is effective.

Section 5.0

Consent Agenda-

Straightforward Items

Consent Agenda Issues—January 2024

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
59409 59414	Vaginal delivery only (with or without episiotomy and/or forceps) Delivery of placenta (separate procedure)	35 TERMINATION OF PREGNANCY	Multiple denials were found on the most recent HSD denials summary for pairing of these codes. Oregon abortion providers confirmed that this is a correct pairing for pregnancy terminations after 20 weeks EGA. Per ACOG coding guidelines, CPT 59414 may also be billed in certain late term pregnancy terminations	Add 59409 and 59414 to line 35
92134	Imaging of retina	8 TYPE 1 DIABETES MELLITUS 27 TYPE 2 DIABETES MELLITUS	Imaging of the retina is a common procedure for ophthalmology exams to evaluate for diabetic retinopathy. There were multiple denied claims for this.	Add 92134 to lines 8 and 27
Z00.110	Health examination for newborn under 8 days old	2 BIRTH OF INFANT	Multiple denials found for this pairing. Z00.110 is on line 3, but newborn hospital codes are on line 2	Add Z00.110 to line 2
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral	Diagnostic Procedures File	Breast tomosynthesis was added for coverage in 2023; however, the HCPCS code for the professional portion of that test was not added to coverage. HERC staff have requested HSD open this code as diagnostic ASAP.	Add G0279 to the Diagnostic Procedures File

Straightforward Guideline Note Changes

January 2024

Smoking and spinal fusion

At the November, 2023 VBBS meeting, members requested that staff add wording to the statement of intent regarding smoking cessation and elective surgery to reflect the HERC intent that patients who undergo spinal fusion should remain abstinent for 6 months from all nicotine products, based on evidence of harm.

a. HERC staff recommendation:
    i. Modify SOI8 as shown below

STATEMENT OF INTENT 8: SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES

Tobacco smoking has been shown to increase the risk of surgical complications. It is the intent of the Commission that current tobacco smokers should be given access to appropriate smoking cessation therapy prior to elective surgical procedures. Pharmacotherapy (including varenicline, bupropion and all five FDA-approved.

It is the intent of the Commission that patients undergoing spinal fusion procedures be strongly encouraged to abstain from all tobacco products for 6 months after surgery due to evidence of harms.

Formatting change to spinal fusion criteria

There is confusion about Guideline Note 37 with a section labeled “Note” this is really a definition of a term above and not a separate section. This is confusing reviewers.

b. HERC staff recommendation:
    i. Modify GN37 as shown below

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

Lines 346,530

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

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

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

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

Note: for foraminal stenosis, there must be MRI evidence of moderate or severe foraminal stenosis of the nerve root that correlates with the objective findings above in section A.

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

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

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

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

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

Non-adjunctive continuous glucose monitors for Type 1 diabetes with insulin pumps

Adjunctive continuous glucose monitors where added to line 615/GN173 at the September 2023 VBBS/HERC meeting. These types of CMGs are actually used with insulin pumps and were added back to line 8 TYPE 1 DIABETES as an errata and removed from line 615. The CMG guideline needs to be updated to reflect this change.

c. HERC staff recommendation:
    i. Modify GN108 as shown below

GUIDELINE NOTE 108, CONTINUOUS GLUCOSE MONITORING

Lines 1,8,27,60

Real-time (personal) continuous glucose monitoring (CGM) is included on Line 8 for:

A) Adults with type 1 diabetes mellitus not on insulin pump management:
    1) Who have received or will receive diabetes education specific to the use of CGM AND
    2) Who have used the device for at least 50% of the time at their first follow-up visit AND
    3) Who have baseline HbA1c levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM).
B) Adults with type 1 diabetes on insulin pump management (including the CGM-enabled insulin pump):
    1) Who have received or will receive diabetes education specific to the use of CGM AND
    2) Who have used the device for at least 50% of the time at their first follow-up visit.
C) Women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels.
D) Children and adolescents under age 21 with type 1 diabetes:
    1) Who have received or will receive diabetes education specific to the use of CGM AND
    2) Who have used the device for at least 50% of the time at their first follow-up visit

Therapeutic continuous glucose monitors (HCPCS A4239 and E2103) are included on Lines 1 and 27 for individuals with type 2 diabetes or gestational diabetes who use multiple daily insulin injections when ALL of the following criteria are met:

A. Have received or will receive diabetes education specific to the use of CGM, *AND*
B. Have used the device for at least 50% of the time by their first follow-up visit, *AND*
C. Have one of the following at the time of CGM therapy initiation:
    1. Baseline HbA1c levels greater than or equal to 8.0%, *OR*
    2. Frequent or severe hypoglycemia, *OR*
    3. Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM), *OR*
    4. Diabetes-related complications (for instance, peripheral neuropathy, end-organ damage)

Every 6 months following the initial prescription for CGM, the prescriber must conduct an in-person or telehealth visit with the member to document adherence to their CGM regimen to ensure that CGM is used for diabetes treatment planning.

Two trials per year of CGM are allowed to meet adherence for continuation of coverage.

CPT 95250 and 95251 (Ambulatory continuous glucose monitoring) are included on these lines for services related to real-time continuous glucose monitoring but not retrospective (professional) continuous glucose monitoring. Adjunctive/non-therapeutic continuous glucose monitors (HCPCS A4238 and E2102) are only included on Line 8 for people with type 1 diabetes who use an insulin pump.

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.

Examples of genetic testing codes for hereditary cancer

At the November VBBS/HERC meeting, the Hereditary Cancer Genetic Testing guideline was modified. One modification was to add additional example code. Myriad Genetics has reached out to request 3 additional codes be added to the example section to clarify the intent [81432 Test for detecting genes associated with inherited breast cancer-related disorders, 81433 Gene analysis (breast and related cancers), duplication or deletion variants, and 81479 Molecular pathology procedure]. These codes were mentioned in older versions of D25.

a) HERC staff recommendation
    i) Modify Diagnostic Guidelines D25 as shown below

DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING

Related to genetic testing for patients with cancers suspected to be hereditary, or patients at increased risk due to family history (for example, CPT 81162-81167, 81201-81203, 81212, 81215-81217, 81288, 81292-81300, 81317-81319, 81321-81323, 41432-81435, 81436, 81479), services are provided according to the Comprehensive Cancer Network Guidelines: Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V2.2024 (9/27/23) www.nccn.org), including the table "Summary of Genes and/or Syndromes Included/Mentioned in Other NCCN Guidelines," or the Genetic/Familial High-Risk Assessment: Colorectal V1.2023 (5/30/2023) www.nccn.org).

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 health professional with expertise and experience in cancer genetics. Genetic counseling is recommended for cancer survivors when test results would affect cancer screening.
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 health care professional with experience in cancer genetics should be covered.
    1) Post-test genetic counseling should be performed as soon as is practical.

Hidradenitis suppuritiva guideline change

The hidradenitis suppurativa guideline calls out adalimumab. There are other targeted immune modulators now approved for this condition. P&T staff recommend that the guideline be made more generic to reflect the additional medication approvals. These newer approved medications also have initial trials that are different from 12 weeks. For example, secukinumab initial trial is 16 weeks.

b) HERC staff recommendation
   i) Modify Guideline Note 198 as shown below

GUIDELINE NOTE 198, HIDRADENITIS SUPPURATIVA

Lines 415,507

Hidradenitis suppurativa is included on Line 415 only for moderate to severe disease (e.g. Hurley Stage II or Hurley Stage III); otherwise this condition is included on Line 507.

Initial treatment with ~~adalimumab~~ targeted immune modulators is limited to adults whose disease has not responded to at least a 90-day trial of conventional therapy (e.g., oral antibiotics), unless such a trial is not tolerated or contraindicated. Treatment with ~~adalimumab~~ targeted immune modulators after ~~12 weeks~~ the initial trial is only included on Line 415 for patients with a clear evidence of response, defined as:

A) a reduction of 25% or more in the total abscess and inflammatory nodule count, AND
B) no increase in abscesses and draining fistulas.

Section 6.0

New Discussion Items

Vulvectomy and Other Treatments for Vulvodynia

Plain Language Summary:

Coverage question: Should OHP cover a surgery that removes a portion of a woman's genitals (vulva) for a condition (vulvodynia) that causes burning, pain and discomfort even when there is no sign of injury of infection?

Should OHP cover this treatment?
Option 1: No. The research on the medical treatment is not very strong and the risks of harms of greater than the benefits.
Option 2: Yes. Surgical treatment and physical therapy can benefit this condition.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should vulvectomy be added as a treatment for vulvodynia?

Question source: Medical Management Committee of OHA

Background: Vulvodynia is persistent pain in the vulvar area (the area around the vaginal opening). When no specific cause is found for the vulvar pain, it is referred to as vulvodynia. It is diagnosed by ruling out conditions that can cause vulvar pain, such as yeast infections, bacteria vaginosis, lichen sclerosis, etc. Treatments include topical anesthetics, pudendal nerve blocks, botulinum toxin injections, tricyclic antidepressants, anticonvulsants, biofeedback, pelvic floor physical therapy, TENS, and in severe cases vulvectomy (removal of the vulva).

The Health Systems Division's Medical Management Committee (MMC) has seen several cases in the past year of women with severe vulvodynia who do not respond to conservative therapy and their providers are requesting vulvectomy. Currently, vulvectomy is not paired with vulvodynia.

Previous HSC/HERC reviews:
No previous review found for vulvodynia or vulvectomy in HOSC/HSC or VBBS/HERC minutes.

Current Prioritized List/Coverage status:
ICD-10-CM N94.810 (Vulvar vestibulitis), N94.818 (Other vulvodynia) and N94.819 (Vulvodynia, unspecified) are on line 525 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA

Line 532 does not contain CPT codes for physical therapy, acupuncture, botulinum toxin injections or vulvectomy.

Vulvectomy and Other Treatments for Vulvodynia

CPT 56620 (Vulvectomy simple; partial) is on lines 284 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS, 309 GENDER DYSPHORIA/TRANSEXUALISM, and 433 PRECANCEROUS VULVAR CONDITIONS
CPT 56625 (Vulvectomy simple; complete) is on lines 284, 309
CPT 56630 (Vulvectomy, radical, partial) is on lines 284

Evidence:

1) **Schlaeger 2023,** systematic review of treatments for vulvodynia
    a. one large multicenter parallel group randomized trial, one randomized controlled trial (RCT), and one uncontrolled study showed that lidocaine applied to the vulvar vestibule reduced vulvar pain and dyspareunia either alone or with oral desipramine (a TCA)
    b. Amitriptyline cream alone and amitriptyline cream with baclofen cream, an antispasmotic, showed a reduction in dyspareunia in unspecified vulvodynia and in PV. These studies had no control group
    c. In a small-sample double-blind RCT of 20 women with PV, equine conjugated estrogen showed no reduction in dyspareunia compared with the placebo cream control group
    d. There were 2 small-sample double-blind RCTs of vaginal diazepam for hypertonic pelvic floor dysfunction that showed no reduction in vulvar pain. A third double-blinded RCT of diazepam with intravaginal transcutaneous electrical nerve stimulation (TENS) versus placebo with TENS for PV also showed no reduction in vulvar pain. All 3 studies were underpowered
    e. Oral TCAs, serotonin norepinephrine reuptake inhibitors (SNRIs), and selective serotonin reuptake inhibitors (SSRIs) ability to reduce pain in women with vulvodynia has been inconsistent
    f. A double-blind placebo RCT compared intravaginal TENS with a TENS sham. TENS significantly reduced pain and dyspareunia
    g. Acupuncture in an RCT significantly reduced vulvar pain and dyspareunia in vulvodynia compared with a waitlist control.
    h. Botulinum injection was studies in 2 RCTs that showed no difference in vulvar pain
    i. CBT was studied in 2 non-controlled studies that found inconsistent results
    j. Two studies on vestibulectomy found significant reduction in vulvar pain and dyspareunia, one of which was compared with group CBT and EMG biofeedback that continued 2.5 years postoperatively. Twenty-seven percent of women declined to participate after they had been randomized to the vestibulectomy group, suggesting that not all women may view vestibulectomy as an acceptable treatment option. Vestibulectomy is not widely used because of limited patient acceptability. Because of its invasive nature, vestibulectomy should be considered a treatment of last resort
        i. Bergerone et al 2001/2008, N=78. Compared vestibulectomy to CBT and biofeedback. 27% of women randomized to the vestibulectomy group declined participation. All three groups had significant reduction in vulvar pain (unknown pain scale). Vestibulectomy reduced pain by 46.8%, CBT by 27.7%, and biofeedback by 22.8%
        ii. Tommola et al 2011, N=57, prospective cohort study. 19 (35.2%) of participants reported they were cured by vulvectomy (complete response); 30 (55.6%) had partial response, and 5 (9.3%) had no response
2) **Andrews 2011,** systematic review of vulvodynia interventions
    a. N=55 articles

   i. 28 interventions
   ii. Most of the studies had several methodological weaknesses, including lack of: control or placebo group, double-blind evaluation, pretreatment pain and functional status evaluation, validated outcome measures of pain and sexual functioning, and long-term outcomes
   iii. The majority of the published studies were case series, and almost all reported an effect, when comparing the pretreatment data to the post-treatment data (before and after data). There were 11 randomized trials; of these, 6 were not placebo-controlled. There were 3 nonblinded randomized trials of surgical interventions, compared with other surgical interventions or compared with cognitive behavioral therapy or electromyographic biofeedback. Two nonblinded randomized trials of medical interventions demonstrated no absolute effect. The 5 placebo-controlled randomized trials of medical interventions all showed no effect of the target intervention, when compared to placebo.
   iv. The placebo intervention effect, described as a greater than 50% decline in the pain score(s) ranged from 40% to 50% of subjects

b. There was fair evidence of a lack of efficacy for botulinum toxin injections. The body of evidence for other injections was poor; there was insufficient evidence regarding: steroid and “caine”-drug mixed injections, multilevel nerve blocks, intramuscular interferon, and intralesional interferon
c. There was fair evidence of a lack of efficacy for 5% xylocaine topical application, for topical cromolyn, and for topical nifedipine. The body of evidence for other topical applications was poor; there was insufficient evidence regarding: capsaicin, montelukast, steroid, gabapentin, and ketoconazole
d. There was fair evidence of a lack of efficacy for oral desipramine, and for oral fluconazole. There was insufficient evidence regarding oral calcium citrate.
e. There was insufficient evidence regarding cognitive behavioral therapy
f. There was insufficient evidence for use of dilators and for pelvic floor physiotherapy
g. There was insufficient evidence for electronic stimulation, and for acupuncture
h. There was fair evidence of effect of vestibulectomy surgery
   i. Case series of 1138 patients and randomized trials of 118 patients reported an effect of 31% to 100%, with a median of 79% for patients who reported at least some improvement to complete relief. For 12 studies reporting complete relief as an outcome, the median effect size was 67%
   ii. The absolute effect was estimated to be 30% from 1 randomized controlled trial (RCT)
   iii. The effect size from this single RCT could be consistent with the effect size seen with case series, on the basis that surgery has been reported to have a placebo effect of 35%, and the placebo effect seen with vestibulodynia in RCTs of nonsurgical interventions was 40% to 50%
   iv. There is insufficient evidence to support that any specific vestibulectomy surgical technique is superior to another vestibulectomy surgical technique
i. Conclusions: There is insufficient evidence to support that any of the nonsurgical therapies confers a net benefit for patients with vestibulodynia. There is fair evidence that vestibulectomy surgery provides a benefit for patients with vestibulodynia, but the size of this effect cannot be determined with confidence, and the number-needed-to-treat is not known.

Vulvectomy and Other Treatments for Vulvodynia

Submitted literature:

1) Andrews 2011: already included above
2) Arnold 2006:
    a. In a small mailed survey study, vulvodynia was found to have a negative impact on quality of life
3) Bergeron 2008: included in Andrews 2011 review
4) Bornstein 2019: paper on the diagnostic criteria for vulvodynia
5) Brown 2018: included in the Sclaeger 2023
6) Foster 2010: included in the Andrews 2011 and Sclaeger 2023 reviews
7) Goetsch 2007: included in the Andrews 2011 review
8) Goetsch 2010: included in the Andrews 2011 review
9) Haefner 2005: older review than the two included above
10) Leclair 2011: basic science study
11) Payne 2005: small (N=34) case control study
12) Stockdale 2014: clinical guideline older that the ACOG 2020 guideline included in the materials
13) Sutton 2009: demographic study
14) Tommola 2010: included in Sclaeger 2023 above
15) 25 additional articles submitted that were >20 years old and therefore were not reviewed

Expert guidelines:

1) **ACOG 2016 (reaffirmed 2020)**, committee opinion persistent vulvar pain
    a. Most evidence for treating vulvodynia is based on clinical experience, descriptive and observational studies. Few RCTs of vulvodynia treatment exist
    b. Medications sued to treat vulvar pain include topical, oral and intralesional medicinal substances, as well as pudendal nerve blocks and botulinum toxin. Tricyclic antidepressants and anticonvulsants also can be used for vulvodynia pain control.
    c. Biofeedback and physical therapy, including pelvic floor physical therapy, can be used to treat localized and generalized vulvar pain
    d. An emerging treatment is transcutaneous electrical nerve stimulation (TENS)
    e. When other nonsurgical management options have been tried and failed, and the pain is localized to the vestibule, vestibulectomy may be an effective treatment. The lack of randomized studies and unsufficient information on complication rates preclude recommendation for vestibulectomy as the initial treatment for localized pain. The success rate for vestibulectomy ranges between 60% and 90% compared with 40% to 80% for nonsurgical interventions. However, there is no consensus method for evaluation of outcomes between studies or a standardized definition of successful treatment
2) **2021 European guidelines** for the management of vulval conditions
    a. Topical therapy
        i. Topical lidocaine, botulinum injection, amitriptyline cream, capsaicin cream have no demonstrated benefit compared to placebo
    b. Oral medications

   i. Tricyclic antidepressants, amitriptyline, desipramine, and gabapentin had no demonstrated benefit over placebo. There is little evidence for the use of pregabalin
   ii. Milnacipran reduced coital pain in one study
c. TENS had no evidence of efficacy, and an FDA safety warning
d. Acupuncture has shown effectiveness in small clinical trails for pain and sexual functioning
e. There are conflicting recommendations on hormonal treatment
f. Physical therapy is considered first line therapy (Grade 1B)
g. CBT was shown to improve pain during intercourse as much as vestibulectomy and was superior to topical corticosteroids and supportive psychotherapy in terms of reduction of pain and improvement of sexual functioning
h. Surgery is usually not recommended for chronic pain related to a dysfunction in pain processing (such as vulvodynia). However, despite a low level of evidence, vestibulectomy (posterior or total, with or without vaginal advancement) is currently considered as a 'last resort' intervention for provoked vestibulodynia, after failure of all the available therapeutical options. According to the published data, vestibulectomy durably reduces introital dyspareunia and patients are satisfied with the results. Short and long term complications may occur such as bleeding, wound dehiscence, Bartholin's cyst and unsatisfying cosmetic appearance

Other payer policies:

1) Aetna 2022
   a. Covers physical therapy and vestibulectomy for members with vulvodynia/vulvar vestibulitis
   b. Considers botulinum toxin therapy, acupuncture, laser therapy, biofeedback, and multiple topical medications to be experimental

Expert input:

OHSU Vulvar Health Program: please see letter in packet

Vulvectomy and Other Treatments for Vulvodynia

HERC staff summary: The evidence supporting topical or oral medications, TENS, botulinum injection and CBT for treatment of vulvodynia is very weak and in controlled studies show little to no effect. Acupuncture showed some effectiveness in small clinical trials. CBT studies have found inconsistent results. Pelvic floor physical therapy is considered first line therapy, but there is insufficient evidence supporting its use. Vulvectomy appears to be more effective than other therapies for vulvodynia, but this is based on case series and a single RCT with a high refusal rate in the surgical arm. The complications of vulvectomy have not been well studied.

Ten public comments were received on this topic from patients and providers. All recommended coverage of vulvodynia, and of pelvic PT and vulvectomy in particular. ACOG also recommends pelvic PT, vulvectomy, topical medications, and biofeedback for treatment of vulvodynia.

HERC staff recommend making no changes to the current procedures paired with vulvodynia due to the lack of evidence of effectiveness of most therapies, and the unclear benefit/harm ratio of surgical interventions. Based on public comments, HERC staff has added an option for discussion that adds coverage of vulvodynia, with specific pairing with pelvic PT and with vulvectomy.

HERC staff recommendations:

1) **Option 1** [HERC staff preferred]
    a. Make no changes to line 532 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA
2) **Option 2** [Expert preferred]
    a. Add ICD-10-CM N94.810 (Vulvar vestibulitis), N94.818 (Other vulvodynia) and N94.819 (Vulvodynia, unspecified) to line 324 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION and remove from line 532 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA
        i. Delete these codes from line 525 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA
    b. Add CPT 56620 (Vulvectomy simple; partial) and CPT 56625 (Vulvectomy simple; complete) to line 324
        i. Physical therapy CPT codes are already on line 324
        ii. Will not pair with botulinum injections, acupuncture, biofeedback or CBT codes

Vulvodynia

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Discussion Table

IDs/#s	Summary of Issue	HERC Staff Response
All	All commenters supported adding coverage of treatments for vulvodynia, particularly vulvectomy.	VBBS/HERC should discuss adding coverage for this condition. HERC staff propose two options: one for continued non-coverage and one which adds coverage for pelvic PT and vulvectomy for vulvodynia.

Commenters

Identification	Stakeholder
A	Lisa Bayer MD MPH – Oregon Legislative Committee, ACOG *[Submitted December 12, 2023]*
B	Amy Stetson, MD – OHSU Gynecology *[Submitted December 8, 2023]*
C	Ellie Schmidt, MD – OHP provider *[Submitted December 8, 2023]*
D	Erin Foster MD PhD – OHP provider *[Submitted December 8, 2023]*
E	Sam Melville, MD – OHP provider *[Submitted December 11, 2023]*
F	Abby Furukawa – OHP provider *[Submitted December 11, 2023]*
G	MJ (Mary Jane) Strauhal, PT – OHP provider *[Submitted December 12, 2023]*
H	Carter Scott, MD – OHSU physician *[Submitted December 15,2023]*
I	Karen Hampton – OHP member *[Submitted December 18,2023]*

Vulvodynia

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J	Gina Allison, MD – OHP provider *[Submitted December 16, 2023]*

Public Comments

ID/#	Comment	Disposition
A	The American College of Obstetricians and Gynecologists (ACOG) represents more than 60,000 physicians and partners dedicated to advancing women's health and the health of individuals seeking obstetric and gynecologic care, including more than 712 practicing obstetrician-gynecologists in Oregon. ACOG supports OHP expanded coverage for vulvodynia and vulvar vestibulitis using vestibulectomy and physical therapy. Vestibulectomy is a minor procedure involving the surgical excision of the painful portion of the vestibule. This procedure can be life changing for patients with vulvodynia who have failed nonsurgical treatment. In addition to surgery, physical therapy is another tool to help these patients. Both surgery and physical therapy can allow patients to stop systemic medications, including use of pain medications. ACOG supports use of vestibulectomy as well as pelvic floor physical therapy in such select patients the Committee Opinion on Persistent Vulvar Pain (reaffirmed 2020): • When other nonsurgical management options have been tried and failed, and the pain is localized to the vestibule, vestibulectomy may be an effective treatment. • This procedure should be done only after failure of other treatments. • The success rate for vestibulectomy ranges between 60% and 90% compared with 40% and 80% for nonsurgical interventions.	*Thank you for your comments.* The 2020 ACOG guideline is included in the meeting materials.

Disposition of Public Comments

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	• Patients should be evaluated for vaginismus and, if present, treated before a vestibulectomy is considered or performed. • There may, however, be subsets of patients more likely to experience a benefit from vestibulectomy surgery. Patients with secondary dyspareunia have greater odds of improvement compared with patients with primary dyspareunia; those with constant pain in addition to dyspareunia are less likely to achieve pain reduction after surgery. • There may, however, be subsets of patients more likely to experience a benefit from vestibulectomy surgery. Patients with secondary dyspareunia have greater odds of improvement than patients with primary dyspareunia; those with constant pain in addition to dyspareunia are less likely to achieve pain reduction after surgery ACOG Recommendations and Conclusions • Biofeedback and physical therapy, including pelvic floor physical therapy, can be used to treat localized and generalized vulvar pain. • When other nonsurgical management options have been tried and failed, and the pain is localized to the vestibule, vestibulectomy may be an effective treatment	
B	My 10 years of clinical experience in providing simple partial vulvectomies with vaginal flap advancement for patients with vestibulodynia (localized vulvodynia or vestibulitis) have affirmed the data that suggest an 85% improvement in sexual pain and quality of life when coupled with physical therapy and counseling. In my expert clinical opinion, this is really the only option that leads to significant improvement and/or cure for these patients. None of the topical or systemic therapies result in meaningful improvement. My clinical experience very much reflects the literature that is included in the	*Thank you for your comments. Your clinical perspective is valuable for the HERC as it deliberates this topic.*

Disposition of Public Comments

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	supporting documents for this session. It is really important to provide this service for our patients with Oregon Health Plan insurance and ensure that they can access equitable care compared to patients with other types of insurance.	
C	This is essential healthcare, and this surgery is effective to improve quality of life for patients struggling with this medical condition	*Thank you for your comment.*
D	I would like to support coverage by OHP of vulvectomies for vestibular and vulvar pain. Patients suffering from pain should not be denied an effective and efficient manner of restoring normal healthy sensation to their vulvas.	*Thank you for your comment*
E	OHP should cover vestibulectomy and pelvic floor physical therapy for the diagnosis of PVD and pelvic floor myalgia (vaginismus) I wish to express my support for Dr. LeClair, Stenson, Leaverton and Bonham's position for OHP to cover Vulvectomy as a treatment for Vulvodynia. As a resident physician in obstetrics and gynecology, I have already seen firsthand the debilitating and lifelong struggle that is vulvodynia. Pelvic floor physical therapy is one of the most effective treatments I frequently prescribe in clinic, and helps to save thousands in additional future treatments for my patients alone. In addition, these providers are asking for insurance coverage for a last resort treatment well-established in the literature (vestibulectomy). They should be granted their reasonable request. Furthermore, providing coverage for treating this condition would help to resolve a historic injustice. OHP provides coverage for all first line treatments and last resort treatment for	*Thank you for your comments. Your clinical perspective is valuable for the HERC.* *Thank you for submitting the literature references. HERC staff reviewed the 14 articles that were published in the past 20 years. These articles were either included in the systematic reviews in the meeting materials, or were older reviews that the reviews in the meeting materials.*

Disposition of Public Comments

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	male genital pain and dysfunction. It is imperative that this commission provide equal coverage for both male and female patients when it comes to personal and painful conditions. Granting coverage for these treatments will right a historic wrong	
F	As a gynecologist of nearly 15 years, I know the benefits that vestibulectomy has for helping women control painful intercourse. This should be a covered service for OHP!	*Thank you for your comments.*
G	According to a consensus document by the International Society for the Study of Vulvovaginal Disease, the International Society for the Study of Women Sexual Health, and the International Pelvic Pain Society, the definition of vulvodynia is vulvar pain of at least three months' duration without a clear identifiable cause.1 It is a diagnosis of exclusion and is considered an idiopathic pain disorder. Vulvodynia can cause pain that is severe, debilitating, and devastating to the patients suffering from it. The cause of vulvodynia is not known. Possible contributing causes include injury or irritation to the nerves that transmit pain from the vulva to the spinal cord, an increase in the number and sensitivity of nerve fibers in the vulva, elevated levels of inflammatory substances including cytokines in the vulva, abnormal response to environmental factors, genetic susceptibility, and pelvic floor muscle weakness, spasm, or instability. Other diagnoses must be ruled out, such as infections, inflammation, neoplastic diseases, neurologic disorders, vulva trauma, iatrogenic, and hormonal deficiencies. Descriptors that are occasionally used include the terms localized (e.g., vestibulodynia, clitorodynia) or generalized or mixed (localized and generalized), provoked (e.g., insertional, contact) or spontaneous or mixed (provoked and spontaneous), onset (primary or secondary), temporal pattern (intermittent, persistent, constant, immediate, delayed). In the literature, there is much	*Thank you for your comments. Thank you for the information.*

Disposition of Public Comments

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	confusion regarding the terms used to indicate vulvodynia. The term vulvar vestibulitis is an outdated term and has been replaced by the tern local, provoked vestibulodynia. Most providers use the generic term “pelvic pain” when referring to physical therapy. A vestibulectomy is a surgery that is used to remove all or only portions of the vaginal vestibule that are painful after pain mapping has indicated the exact areas involved. This is NOT a removal of “the outside of a woman’s genitals. Vestibulectomies are not first line treatment but have good data to support their use. Physical therapy is an excellent first line treatment for vulvodynia when the nerves or pelvic floor muscles are involved and should also be a covered treatment.	
H	Vulvodynia and vestibulodynia are conditions that can be life-altering. Sexual functioning is a key component to health for most adults, and disruptions can be significantly detrimental to quality of life, sense of self-worth, and interpersonal relationships. Vestibulectomy, when performed by experienced providers, can be a life-altering procedure that improves patients' daily quality of life. I have seen firsthand the improvement in symptoms and quality of life this straightforward procedure can provide. I strongly encourage OHP coverage of this procedure.	*Thank you for your comments. Your clinical perspective is valuable for the HERC as it deliberates this topic*
I	In 2007 I received surgery to treat vulvar vestibulitis (aka vestibulodynia). Basically that means I felt pain on contact which presented challenges in my everyday life and long term relationship. The discomfort was distracting and time consuming and expensive to treat prior to surgery. The surgery was a vestibulectomy, and it worked - I have not experienced that type of pain again since. As a result I have had more time and energy to focus on advancing my career, my relationship with my partner, and my social life. But, the surgery was not fully covered by my insurance and my family had to pay out of pocket. This was a big hit to our savings and set us back for years after. Had I not been able to pay for this I would have spent even more money long term flailing	*Thank you for your comments. Your perspective as a patient is important to the HERC.*

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	with other, less effective treatments. Please help my friends in Oregon who face a similar dilemma.	
J	I am writing to express my strong support for vestibulectomy as a covered treatment option for patients with vulvodynia. I concur with the data and studies shared by Drs. Leclair and Stenson. I am a community gynecologist in Tualatin, Oregon. I trained at OHSU in the Vulvar Health Center (the only center of its kind on the West Coast) and have made caring for patients with vulvovaginal disorders a focus in my practice. Patients find me by referral from their primary provider and also via self-referral. One of the most common issues I see patients for is vestibulodynia. This disorder causes sexual pain and, in some cases, makes sexual intercourse impossible (both for pleasure and reproduction). Vestibulectomy is one of the most, if not the most effective treatment for this type of vulvodynia. It is unreasonable to categorize sexual intercourse as an elective activity for a person. It feels inhumane to have a treatment option that is straightforward, and relatively inexpensive, be withheld from patients who are suffering. Sexual activity is a most basic human function and experience. Being unable to participate in sexual activity due to vulvodynia causes tremendous physical and psychological pain for patients as well as their partners. Please consider vestibulectomy among the first line treatment options for vestibulodynia	*Thank you for your comments. Your clinical perspective is valuable for the HERC as it deliberates this topic*

Disposition of Public Comments

References Provided by Commenters

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A	ACOG Committee Opinion: Persistent Vulvar Pain. Number 673, reaffirmed 2020
B	None provided
C	None provided
D	None provided
E	1. Harlow BL, Stewart EG. A population-based assessment of chronic unexplained vulvar pain: have we underestimated the prevalence of vulvodynia? J Am Med Womens Assoc 2003;58(2):82-8. 2. Goetsch MF. Vulvar vestibulitis: prevalence and historic features in a general gynecologic practice population. Am J Obstet Gynecol 1991;164(6 Pt 1):1609-14; discussion 1614-6. 3. Haefner HK, Collins ME, Davis GD, Edwards L, Foster DC, Hartmann EH, Kaufman RH, Lynch PJ, Margesson LJ, Moyal-Barracco M, Piper CK, Reed BD, Stewart EG; Wilkinson EJ. The vulvodynia guideline. J Low Genit Tract Dis 2005; 9(1):40-51. 4. Stockdale C, Lawson H. 2013 Vulvodynia Guideline Update. J Low Genit Tract Dis 2014; 18 (2): 93-100. 5. Meana M, Binik YM, Khalifé S. Dyspareunia: sexual dysfunction or pain syndrome? J Nerv Ment Dis 1997; 185(9):561-9. 6. Van Lankveld JJ, Weijenborg PT, ter Kuile MM. Psychologic profiles of and sexual function in women with vulvar vestibulitis and their partners. Obstet Gynecol 1996; 88(1):65-70. 7. Gates EA, Galask RP. Psychological and sexual functioning in women with vulvar vestibulitis. J Psychosom Obstet Gynaecol 2001; 22(4):221-8. 8. Payne KA, Binik YM, Amsel R, Khalifé S. When sex hurts, anxiety and fear orient attention towards pain. Eur J Pain, 2005; 9(4):427-36. 9. Aikens JE, Reed BD, Gorenflo DW, Haefner, HK. Depressive symptoms among women with vulvar dysesthesia. Am J Obstet Gynecol 2003; 189(2):462-6. 10.Arnold LD, Bachmann GA, Rosen R, Kelly S, Rhoades GG. Vulvodynia: characteristics and associations with comorbidities and quality of life. Obstet Gynecol 2006; 107(3):617-24. 11.Schmidt S, Bauer A, Greif C, Merker A, Elsner P, Strauss B. Vulvar pain. Psychological profiles and treatment responses. J Reprod Med 2001; 46(4):377- 84.

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F	None provided
G	Bornstein, J., Preti, M., Simon, J. A., As-Sanie, S., Stockdale, C. K., Stein, A., ... & Goldstein, A. (2019). Descriptors of vulvodynia: a multisocietal definition consensus (international society for the study of vulvovaginal disease, the international society for the study of women sexual health, and the international pelvic pain society). Journal of lower genital tract disease, 23(2), 161-163.
H	None provided
I	None provided
J	None provided

December 1, 2023

RE: Covered treatments for provoked localized vulvodynia (PVD)

Audience: Ariel Smits, MD, MPH, Medical Director
Health Evidence Review Commission

Intent: What is the current evidence supporting treatments for provoked localized vulvodynia (aka vulvar vestibulitis syndrome or vestibulodynia)? Currently the Oregon Health Plan only covers certain topical and oral medications, most of which are not supported by the evidence. Pelvic floor physical therapy and vulvar surgery for the treatment of localized vulvodynia is not currently covered by OHP. What is the current evidence and support?

Background: Provoked Localized Vulvodynia (PVD) is a complex sexual pain condition affecting 8-15% of women and is the most common cause of dyspareunia[1-4]. PVD represents the most common type of vulvodynia and typically presents as painful penetration. With history and physical exam, PVD should be distinguished from generalized unprovoked vulvodynia, pudendal neuralgia and clitorodynia since these conditions are treated DIFFERENTLY than PVD.

PVD is a devastating condition since it leads to deterioration in quality of life, sexual function, and psychological wellness and women with PVD report higher rates of sexual dysfunction and mental health problems.[5-12] The cause is unknown. However, histologic studies show evidence of **neruo-proliferative and inflammatory changes in the vulva vestibule compared to controls**[13-16], a small ring of skin surrounding the vaginal opening. Whether these changes cause, or are a result of, prolonged pain remains unclear. As such, clinicians struggle to find the best way to treat this devastating disorder often focusing on ways to control inflammation or nerve changes.

Importantly, women with painful penetration due to PVD often develop a secondary vaginismus response (pelvic floor myalgia). Repeated attempts at penetration lead to involuntary guarding, pelvic floor dysfunction and emotional trauma. Coupled treatment for the painful vestibule skin and for the dysfunctional muscles provide the most hope at returning women to normal sexual function.

Over the last 3 decades, researchers have studied a variety of non-surgical and surgical treatments [3-4]. Results for non-surgical treatment, including oral medicines, topical medicines, local injections with interferon or botox, topical anesthetics (lidocaine), pelvic floor physical therapy and sex therapy, are disappointing in success (clinical improvement in pain) ranging from 37-65%[4,17-18]. For example, two recent RCTs provide level A evidence that two most commonly used oral medicines (desipramine [tricyclic antidepressant] and gabapentin) are not effective in treating PVD[19-20]. *In contrast, surgical studies, particularly combined with pelvic floor physical therapy, provide better evidence of success*.

Research show that **surgical removal of the painful vestibule is the most effective way to manage PVD[18, 21-30]**. To date, more than 30 studies have reported on the success of vestibulectomy to manage vestibular pain with reported success between 60-90%. In a review, Tommola[21] identified and reviewed 33 studies evaluating surgical treatment. Overall, 64% of women reporting a *complete cure* of painful intercourse and 80% of women reporting *significant pain relief*.

Surgery & Complications: Vestibulectomy is an operation performed in the Day Surgery Unit in approximately 45 minutes using MAC (modified anesthesia care/deep sedation) for anesthesia. It includes removing approximately 2 inches of skin at the inner vulva (vestibule) and advancing vaginal tissue to cover the defect. Women are discharged from the Day Surgery unit the same day with < 10 tabs of opiate and strict instructions for the next 72 hours. After that, activity is liberalized. Most women are away from primary work duties for < 7 days. Complications of bleeding and infection are < 1 %, wound separation < 3% and Bartholin gland occlusion < 5%. The estimated blood loss from the procedure is approximately 30mL. Women are seen back in the office at 2 and 6 weeks postoperative.

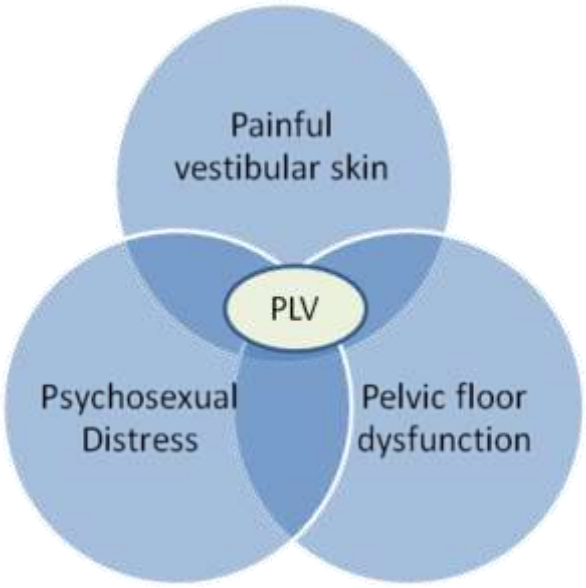
Pelvic Floor Physical Therapy: Although the prevalence of pelvic-floor myalgia (vaginismus) with PVD has not been formally reported, studies from the OHSU Program in Vulvar Health suggest that at least 50% of women with vulvar pain have concomitant pelvic-floor myalgia[32]. Spano and Lamont[33] suggested that chronic dyspareunia results in anticipatory anxiety due to the distress from repeated painful sexual encounters, which leads to poor arousal and tense pelvic-floor muscles. This, in turn, promotes painful intercourse, resulting in a vicious cycle of pain. The efficacy of PFPT (pelvic floor physical therapy) as a treatment for PVD is likely tied not only to the reduction of musculoskeletal pain but to the acquisition of coping techniques that decrease anticipatory anxiety.

In one study investigating pelvic floor muscle hypertonicity, researchers found that women with PVD showed significant muscle tension compared to controls[34]. These findings suggest that women with PVD have significant pelvic-floor myalgia that likely contributes to dyspareunia. Data from a study by Har-Toov, et al. found that 50% of women with PVD treated with PFPT resumed intercourse and required no further treatment[35]. Bergeron, et al. reported 51% of women treated with PFPT had significant resolution of pain with intercourse[34]. In 2 studies evaluating the contribution of pelvic-floor myalgia to residual pain **after vestibulectomy**, Abramov, et al. and Goetsch found that women treated with PFPT reported **greater improvement than women treated only with surgery[36-37], suggesting that treating pelvic-floor muscles is as important as excising the painful vestibular skin**. In an RCT comparing separate treatments of surgery, PPFT, and psychosexual counseling, the PFPT group showed >35% reduction in pain, a result similar to the group-CBT (cognitive behavior therapy) group[38] with the **surgical arm showing the most improvement**. Both RCTs support PFPT as an effective treatment for PLV, with improvement, on average, hovering around 50%. **This is lower than surgery alone**. A number of questions regarding the role of PFPT in treating PVD remain unanswered, including whether PFPT is the best,

initial treatment alone or in combination with surgery. Regardless, the effectiveness of this as a PRIMARY TREATMENT for PVD should be considered and thus covered as a benefit for member of OHP.

In support of Vestibulectomy & PFPT: In Goetsch's review[37] of 111 surgical patients treated with a vestibulectomy, 69% had tight pelvic-floor muscles, and 49% had consulted a physical therapist before or after surgery for this problem. Following pelvic-floor treatment, women reported 90% improvement in pain when combined with surgery. Goetsch concluded that treatment for pelvic-floor dysfunction affects timing of intercourse, especially following surgery. Finally, a review of vestibulectomy concluded that its benefit was not maintained unless other treatments (e.g. PT, vaginal dilators, behavioral therapy) were also used[21]

Although the literature suggests that removing the painful vestibular skin appears to be a critical step in alleviating pain, a number of studies indicate that most women require additional treatment to the pelvic-floor muscles and/or psychosexual state in order to treat all pain. We believe that adequate preparation of the surgical candidate with PVD, with pelvic-floor treatment and psychosexual counseling in a multi-modality approach, may provide the necessary support to lead to better outcomes. This is the current model we use in the Program in Vulvar Health. We believe in treating the WHOLE person---the painful skin, the dysfunctional muscles and the psychosexual distress---in a shared decision model where the patient has autonomy of her body, her choices for treatment and her health.



Sentiment of the Public and Medical Community: In the past, when PVD was less understood and treatment trials were scarce, caution was expressed around the appropriateness of vestibulectomy for the treatment of PVD. Research over the last 3 decades has brought the field forward and now level A evidence exists refuting the effectiveness of past treatments, namely topical lidocaine, oral tricyclic antidepressant (i.e. amitriptyline or desipramine) and oral gabapentin. In fact, our own college, American College of Obstetricians and Gynecologists, still considers surgery as a "last resort" for women who have failed medical treatments[31]. We agree that discussion of treatments options exemplifies shared decision making with the affected patient. Additionally, supporting recommendations with evidence-based-medicine is vital to provide the patient with the opportunity to judge her options. So why withhold surgery as a covered benefit when it may be the most effective way to treat the condition? Women with PVD see, on average, at least 3 health care providers before receiving a diagnosis/treatment and although millions of women have vulvar pain, only 70% see medical care[1,3]. Loss of productivity, loss of health care dollars (spent on wasted appointment and treatments) and loss of personal health are all in jeopardy when appropriate treatments are withheld.

We implore you to consider covering vestibulectomy and pelvic floor physical therapy for the diagnosis of PVD and pelvic floor myalgia (vaginismus). These women deserve a chance to have effective and evidence-based treatment to improve this challenging and life-changing condition

Sincerely,
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Review

Continuing Education

Evaluation and Treatment of Vulvodynia: State of the Science

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Vulvodynia affects 7% of American women, yet clinicians often lack awareness of its presentation. It is underdiagnosed and often misdiagnosed as vaginitis. The etiology of vulvodynia remains unknown, making it difficult to identify or develop effective treatment methods. The purpose of this article is to (1) review the presentation and evaluation of vulvodynia, (2) review the research on vulvodynia treatments, and (3) aid the clinician in the selection of vulvodynia treatment methods. The level of evidence to support vulvodynia treatment varies from case series to randomized controlled trials (RCTs). Oral desipramine with 5% lidocaine cream, intravaginal diazepam tablets with intravaginal transcutaneous electric nerve stimulation (TENS), botulinum toxin type A 50 units, enoxaparin sodium subcutaneous injections, intravaginal TENS (as a single therapy), multimodal physical therapy, overnight 5% lidocaine ointment, and acupuncture had the highest level of evidence with at least one RCT or comparative effectiveness trial. Pre to posttest reduction in vulvar pain and/or dyspareunia in non-RCT studies included studies of gabapentin cream, amitriptyline cream, amitriptyline with baclofen cream, up to 6 weeks' oral itraconazole therapy, multimodal physical therapy, vaginal dilators, electromyography biofeedback, hypnotherapy, cognitive behavioral therapy, cold knife vestibulectomy, and laser therapy. There is a lack of rigorous RCTs with large sample sizes for the treatment of vulvodynia, rendering it difficult to determine efficacy of most treatment methods. Clinicians will be guided in the selection of best treatments for vulvodynia that have the highest level of evidence and are least invasive.
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Keywords: pain management, pharmacology, patient education

INTRODUCTION

Vulvodynia is chronic vulvar pain of unknown etiology lasting at least 3 months in duration and may be accompanied by other potentially associated factors.[1] Vulvodynia can severely impact the lives of women and of individuals assigned female sex at birth. Vulvodynia often affects the ability to have sexual intercourse, devastating intimate relationships.[2,3] Even with adjuvant drugs and opioids, women with vulvodynia reported an average pain intensity score of 6.7 out of 10; 60% of women drank alcohol and 43% used analgesics (including opioids) and alcohol together to reduce their pain.[4] Vulvodynia can cause severe chronic pain resulting in physical disability[5] and can lead to suicidal ideation.[6]

Vulvodynia pain can be localized to one area, generalized to multiple areas, or mixed (localized and generalized). Pain can be either provoked (by vaginal penetration or contact to the vulva), spontaneous, or mixed (provoked and spontaneous). The onset of pain is either primary (with first intercourse or tampon insertion) or secondary (occurring later). The pain pattern can be either continuous or constant, rhythmic or intermittent, and transient or brief.[7] The 2 most common types of vulvodynia are provoked vestibulodynia (PV) and generalized vulvodynia. PV is localized pain confined to the vulvar vestibule and vaginal introitus that is provoked or triggered by touch.[7,8] Generalized vulvodynia is unprovoked or spontaneous diffuse pain of the vulva and may extend into the inner thighs and perineum.[7,8] Terms used for PV are not standardized and include *localized provoked vestibulodynia*, *vestibulodynia*, *provoked vestibulodynia*, *vulvar vestibulitis*, *provoked vulvodynia*, and *localized vulvodynia*. Some published studies do not differentiate between vulvodynia types (provoked and generalized vulvodynia) and report findings on unspecified vulvodynia. The purpose of this article was to (1) review the presentation and evaluation of vulvodynia, (2) review the research on vulvodynia treatments, and (3) aid the clinician in the selection of vulvodynia treatment methods.

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Table 8. Surgical Treatments for Vulvodynia

Treatment	Author/ Year/ Sample Size	Level of Evidence	Study Design/Treatment Groups/Dosages	Results
Cold knife vestibulectomy vs GCBT vs EMG biofeedback	Bergeron et al[56,57] 2001 and 2008 N = 78 Vulvar vestibulitis	2b	2001: Prospective uncontrolled randomized trial 3 arms: (1) Cold knife vestibulectomy with a 6-wk postoperative visit (2) GCBT, 8 sessions over 12 wk (3) Surface EMG biofeedback 8 sessions over 12 wk with twice daily practice sessions All treatment methods had a posttreatment and 6-mo follow-up 2008: 2.5-y follow-up study conducted in 2008	2001: 7 of 26 (27%) of women randomized to the vestibulectomy group declined participation ($P < .01$). All 3 treatment groups had significant reduction in cotton swab test vulvar pain (average of 2 test scores, scale not provided) at posttreatment, 6 mo, and 2.5 y ($P < .01$). Vestibulectomy reduced vulvar pain by 70%, GCBT by 28.6%, and biofeedback by 23.7%. Vestibulectomy reduced vulvar pain significantly from baseline to posttreatment, and through 6-mo follow-up compared with GCBT and to EMG biofeedback ($P < .01$). All 3 groups had significant improvement in pain intensity during intercourse (NRS 0-10) ($P < .01$). Vestibulectomy reduced intercourse pain by 52.5%, GCBT by 37.5%, and biofeedback by 35%. Vestibulectomy significantly improved pain intensity during intercourse from baseline to 6-mo follow-up compared with GCBT and EMG biofeedback ($P <0.01$). Pain (MPQ PRI 0-78) significantly reduced in all treatment groups ($P < .01$). Vestibulectomy reduced pain by 46.8%, GCBT by 27.7%, and biofeedback by 22.8%. Between-group comparison was not reported. 2008: 68% of women participated at 2.5-y follow-up. All groups had a significant reduction in pain at 2.5 y ($P < .01$). Vestibulectomy group had significantly lower cotton swab test vulvar pain from 6 mo to 2.5 y as compared with biofeedback $F(62,75) = 8.96$ ($P < .01$), and GCBT $F(2,75) = 10.38$ ($P < .01$). Vestibulectomy group had significantly lower pain during intercourse than the biofeedback group $F(2,75) = 3.50$ ($P < .05$) but was not compared with the GCBT group. Vestibulectomy group pain (MPQ PRI) was significantly lower than biofeedback ($P < .05$) and GCBT groups ($P < .05$).

(*Continued*)

Table 8. (Continued)

Treatment	Author/ Year/ Sample Size	Level of Evidence	Study Design/Treatment Groups/Dosages	Results
Cold knife posterior vulvectomy	Tommola et al[78,93] 2011 N = 57 Vulvar vestibulitis	2c	Prospective descriptive cohort study Cold knife posterior vulvectomies performed from 1995 to 2007 Long-term follow-up performed for a median of 36 mo (range 5 to 158 mo) No set time points for data collection	19 (35.2%) of participants reported they were cured by vulvectomy (complete response); 30 (55.6%) had partial response, and 5 (9.3%) had no response. Dyspareunia (VAS 0-10) reduced from 9 to 3 (66.7% decrease; $P < .001$). 7 (13%) women reported dyspareunia that required topical anesthetic postoperatively. Posterior vestibular tenderness measured with the cotton swab test (0-10) was absent in 34 (64.2%) participants, 14 (25.9%) reported some degree of constant vulvar pain, and 21% had complications (bleeding, hematoma, infection, Bartholin's cyst, vulvar fissure). Duration of wound pain was 14 d (range = 0-90 d). Duration of sick leave for postoperative recovery was 10.5 d (range 3-24 d).
Yag laser Multidisciplinary Treatment	Trutnovsky et al[79] 2021 N = 67 Vulvodynia	1c	Case study 2 arms: (1) Yag laser up to 3 sessions with 1 session per mo along with a multidisciplinary treatment program (n = 35) (2) Interprofessional treatment program that did not include Yag laser (n = 32)	Yag laser significantly reduced mean (SD) pain during a vulvar cotton swab test (NRS 0-10) from 6.1 (2.6) to 3.1 (2.6) 1-mo posttreatment ($P < .001$). At 9-12 mo Yag laser group participants reported 26% were a lot better, 17% better, 23% a little better and 34% unchanged. Multidisciplinary group reported 13% a lot better, 41% better, 28% a little better, and 19% unchanged. At 9-12 mo there was 73% overall improvement with no significant difference between groups ($P = .6$).
Fractional CO_2 laser	Murina et al[80] 2016 N = 70 Vestibulodynia, n = 37 Genitourinary syndrome of menopause, n = 33	4	Case series Women underwent 3 fractional CO_2 laser treatments Data collected at baseline, 4, 8, 12 wk, and 4 mo	Using analysis of covariance, there was a statistically significant difference in vulvar pain scores (VAS 0-10) in both groups ($P < .05$) through 4-mo follow-up. No statistical results reported, only discussion of results. 13 (35.2%) of the vestibulodynia group reported dyspareunia (Marinoff dyspareunia scale 0-3) symptoms were very improved, 12 (32.4%) reported symptoms improved, and 12 (32.4%) reported no change in dyspareunia.

(*Continued*)

Table 8. (Continued)

Treatment	Author/ Year/ Sample Size	Level of Evidence	Study Design/Treatment Groups/Dosages	Results
Arthroscopic surgery	Coady et al[13] 2015 N = 26 Femoral acetabular impingement syndrome and generalized vulvodynia or clitorodynia	4	Case series Uncontrolled observational Arthroscopic surgery to remove impingement between acetabular rim and femoral head	Vulvar pain (NRS 0-10) was reduced from 6.7 to 3 postoperatively in the improvement group. Pain was reduced from 6.7 to 4.8 postoperatively in the non-improvement group. There was a significant reduction in pain between groups ($P = .03$). Only 6 (23%) had significant reduction in pain after arthroscopy, and they were all under 30 y old. 1 woman had worse pain.

Abbreviations: EMG, electromyography; GCBT, group cognitive behavioral therapy; MPQ PRI, McGill Pain Questionnaire Pain Rating Index; NRS, numeric ratings scale; VAS, visual analog scale

Table 9. Cannabis for the Treatment of Vulvodynia

Treatment	Author/ Year/ Sample Size	Level of Evidence	Study Design/Treatment Groups/Dosages	Results
Cannabis	Barach et al[85] 2020 N = 38 Vulvodynia	2c	Online survey Pain relief of vulvodynia symptoms from cannabis use. Average use 17.3 d/mo Route of consumption not stated	Using cannabis significantly improved sharp/stabbing, dyspareunia, soreness, burning, stinging, throbbing, rawness, itching, and pain with sitting, exercise, and tight pants (Likert −2 to 2) ($P = .002$) as well as tampon insertion pain ($P < .001$) using two-tailed t-test.

multiple treatment groups with one another. These design flaws limit validity, rigor, reproducibility, and generalizability, which makes it difficult for clinicians to prescribe therapies for vulvodynia that are evidence-based. Also, measures of pain and dyspareunia are not standardized between studies, making it difficult to compare study results.[86] There is little evidence supporting the efficacy of treatments for vulvodynia, singularly or together. Most vulvodynia studies were performed in a clinical setting with women expecting treatment and not expecting to be randomized to a non-treatment or placebo control group.[2] It is unknown what the effect of a control group would have had on study treatment outcomes for vulvar pain and dyspareunia. For example, several RCTs[21,46,47] found no reduction in dyspareunia compared with placebo controls. Placebo treatments can have a therapeutic effect of up to 58%.[87] Without a control group it cannot be determined if findings are due to the treatment or other influencing factors. Placebo groups allow for the true treatment effect to be determined. Also, in studies testing multiple treatments, the benefit of using multiple modalities compared with individual treatments has not been tested.[2]

Recommended Treatments for Vulvodynia

There is uncertainty as to how to afford relief to women who suffer from the debilitating pain of vulvodynia. Clinicians tend to prescribe empirically, based on treatments that have worked for women or recommendations from colleagues. The authors recommend that once women are diagnosed with vulvodynia, clinicians teach women to evaluate their vulvar pain and dyspareunia on a 0 to 10 NRS, keeping a log of their pain ratings and treatments attempted. Tracking this information will enable the clinician and woman to develop a personalized treatment plan.

Once diagnosed, women can be referred to the National Vulvodynia Association (nva.org), which has resources and listings for local support groups, as well as a quarterly newsletter summarizing the latest research. The National Vulvodynia Association also has clinician resources. There are also support groups on social media, including Facebook and Reddit.

Changes in sexual position, vaginal lubricants, and good hygiene will not reduce the pain of vulvodynia. Suggestions that women need "to just relax" during intercourse or get more

Table 10. Treatment Recommendations for Vulvodynia Based on Level of Evidence	
Line	**Treatment Recommendation**
First line: RCT or comparative effectiveness	
Non-pharmacologic	Multimodal physical therapy[22]
	Acupuncture[64]
	Intravaginal TENS as a single therapy[60]
Pharmacologic	Overnight 5% lidocaine cream applied with gauze to vulvar vestibule[22]
	Oral desipramine with 5% lidocaine cream[21]
	Intravaginal diazepam tablets with intravaginal TENS[48]
Invasive pharmacologic	Botulin toxin type A 50 units[67]
	Enoxaparin sodium (low-molecular-weight heparin) subcutaneous injections[70]
Second line: Non-pharmacologic; pre to posttest or group comparison without a control group	Vaginal dilators as a single therapy[55]
	EMG biofeedback[56–58]
	Hypnotherapy[76]
	Cognitive behavioral therapy[26,56,57,72–75]
Third line: Topical pharmacologic; pre to posttest without a control group	Gabapentin cream[28]
	Amitriptyline cream[30]
	Amitriptyline with baclofen cream[29]
	Ketamine-amitriptyline cream[31]
	Conjugated equine estrogen cream[33]
	Estradiol/testosterone cream[32]
Fourth line: Case studies or prospective descriptive studies or invasive	Milnacipran[50]
	Laser therapy[79,80]
	Cold knife vestibulectomy[56,57,78]

Abbreviations: EMG, electromyography; RCT, randomized controlled trial; TENS, transcutaneous electrical nerve stimulation

"turned on" in response to reports of dyspareunia are patronizing, dismissive, and not therapeutic. It is the authors' opinion that these comments may be offered by the clinician because women may not respond to treatments and clinicians may feel helpless.

There are 8 treatments that have the highest level of evidence for reduction of pain and/or dyspareunia based on either RCTs or a comparative effectiveness trial. The authors recommend clinicians first prescribe these 8 treatments. Therapies that are non-pharmacologic and least or minimally invasive can be attempted first with additional treatments as needed: (1) multimodal physical therapy (education, pelvic floor muscle exercises with biofeedback, manual therapy, and vaginal dilators),[22] (2) acupuncture,[64] (3) intravaginal TENS (as a single therapy),[60] (4) overnight 5% lidocaine ointment soaked in a gauze and applied to the vulvar vestibule,[22] (5) oral desipramine with 5% lidocaine cream,[21] (6) intravaginal diazepam tablets with intravaginal TENS,[48] (7) botulinum toxin type A 50 units,[67] and (8) enoxaparin sodium (low-molecular-weight heparin) subcutaneous injection.[70]

The following non-pharmacologic treatments have shown reduction in pain and/or dyspareunia in pre to posttest studies or group comparisons without a control group. This group includes vaginal dilators (as a single therapy),[55] EMG biofeedback,[56–58] hypnotherapy,[76] and CBT.[26,56,57,72–75]

If further treatment is warranted, there is low-quality evidence for the following topical treatments that were shown to reduce pain in pre to posttest studies (without a control group): gabapentin cream,[28] amitriptyline cream,[30] amitriptyline with baclofen cream,[29] ketamine-amitriptyline cream,[31] conjugated equine estrogen cream,[33] and estradiol/testosterone cream.[32]

There is also low-quality evidence for the use of oral milnacipran (reduced pain pre to posttest studies without a control group)[50] and laser therapy (reduced pain in a case series).[79,80] Because of the invasive nature of cold knife vestibulectomy,[56,57,78] it should be used after other treatment options have been exhausted. See Table 10 for a quick guide to treatment recommendations.

Treatments That Have No Support for Use in Vulvodynia

Cromolyn sodium, a mast cell stabilizer, reduces chronic urticaria, inflammation, and hypersensitivity reactions. A small-sample double-blind study in women with PV showed that cromolyn sodium cream did not reduce vulvar pain compared with placebo.[34] There is no evidence to support prescribing cromolyn sodium for vulvodynia. Nifedipine, a calcium channel blocker, relaxes smooth muscles, decreases inflammatory infiltrates, and reduces hypertonicity of the

Table 11. Level of Evidence for Appraising Research	
Level	**Description**
1a	Systematic review of randomized controlled trials
1b	Randomized controlled trials
1c	Case series
2a	Systematic review of cohort studies
2b	Cohort study or subpar randomized controlled trials
2c	Ecological or outcomes research
3a	Systematic review of case control studies
3b	Case control study
4	Case series and subpar cohort or case control studies

Adapted from the Oxford Centre for Evidence-Based Medicine: Levels of Evidence (2009).[17]

internal anal sphincter in patients with chronic anal fissures.[88] In a double-blind RCT,[35] nifedipine showed no reduction in dyspareunia in women with PV as compared with placebo. Antiepileptics treat vulvodynia by calming the central nervous system and are used to treat neuropathic pain conditions.[89,90] In a multicenter double-blind crossover RCT, oral gabapentin did not reduce dyspareunia.[90] There is no evidence to support the use of oral gabapentin for vulvodynia.

Future of Vulvodynia Treatments

Because the etiology of vulvodynia remains unknown, it has been virtually impossible to develop effective treatments for the 7% of American women suffering from vulvodynia. Vulvodynia treatments are still based largely on case and anecdotal reports. As of late, vulvodynia specialists are beginning to focus more on uncovering the etiologic factors of vulvodynia and their potential associations that may guide future vulvodynia treatments. This scientific progress is reflected in emerging new diagnostic subcategories of vulvodynia based on etiology.[91] These diagnostic subcategories have not been validated. Most are based on either histological findings from vulvar biopsy or response to expensive or invasive testing such as 3 Tesla magnetic resonance imaging and serial pudendal nerve blocks. Currently, expert clinicians have started to use these diagnostic subcategories to guide their management of women with vulvodynia.[91] These subcategories may be subject to change and are based on specific clinical findings. They are (1) hormonally associated vestibulodynia, (2) inflammatory vestibulodynia, (3) congenital neuroproliferative vestibulodynia, (4) acquired neuroproliferative vestibulodynia, and (5) overactive (hypertonic) pelvic floor muscle dysfunction. Other factors associated with vulvodynia that have been identified include (1) pudendal neuralgia, (2) spinal pathology and vulvar dysesthesia, and (3) persistent genital arousal disorder. There are no plans at this time to issue a new set of definitions and guidelines for the diagnosis and treatment of vulvodynia. An NIH-sponsored study, "Vestibulodynia: Understanding Pathophysiology and Determining Appropriate Treatments (VBD UPDATe)," is currently underway.[92] The investigators have identified 2 distinct subtypes of vestibulodynia that may benefit from 2 distinct types of treatments. The subtypes differ based on patient-reported outcomes, physical and mental health, production of cytokines involved with inflammation, and expression of microRNAs that regulate gene expression. The study is in its third of 5 years.

CONCLUSION

It is remarkable how many treatments, including vestibulectomy, women are willing to undergo to obtain relief from the symptoms of vulvodynia.[18] Because current treatments for vulvodynia only focus on symptom amelioration, there is a need for research that focuses on the etiology and characterization of vulvodynia. This article provides a framework for clinicians to understand, diagnose, and treat women with vulvodynia using evidence-based approaches. The authors encourage clinicians to avail themselves of changes in the state of the science when treating women with vulvodynia. Importantly, there is an urgent need to conduct rigorous controlled trials to identify the most effective treatments for this difficult condition.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

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CME REVIEW ARTICLE 14

CHIEF EDITOR'S NOTE: This article is part of a series of continuing education activities in this Journal through which a total of 36 *AMA/PRA Category 1 Credits™* can be earned in 2011. Instructions for how CME credits can be earned appear on the last page of the Table of Contents.

Vulvodynia Interventions—Systematic Review and Evidence Grading

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Introduction: State of the art guidance exists for management of vulvodynia, but the scientific basis for interventions has not been well described. Although there are many interventional therapies, and their use is increasing, there is also uncertainty or controversy about their efficacy.

Objective: To systematically assess benefits and harms of interventional therapies for vulvodynia and vestibulodynia.

Methods: The following databases were searched, using MeSH terms for studies related to the treatment of vulvodynia or vulva pain/pruritus/dysesthesia/hyperesthesia/hypersensitivity: MEDLINE, PsycINFO, Scopus, Cochrane Library, EBSCO Academic, and Google Scholar. Using Medical Subject Reference sections of relevant original articles, reviews, and evidence-based guidelines were screened manually. Manual searching for indirect evidence supporting interventions was done whenever no direct evidence was found for a treatment described within a review or guideline. Each modality is assessed with a grading system similar to the Grades of Recommendation, Assessment, Development, and Evaluation system. The grading system assesses study quality, effect size, benefits, risks, burdens, and costs.

Results: For improvement of pain and/or function in women with vestibulodynia (provoked localized vulvodynia), there was fair evidence that vestibulectomy was of benefit, but the size of the effect cannot be determined with confidence. There was good evidence of a placebo effect from multiple studies of nonsurgical interventions. There was fair evidence of lack of efficacy for several nonsurgical interventions. There were several interventions for which there were insufficient evidence to reliably evaluate. There was insufficient evidence to judge harms or to judge long-term benefits.

For clinically meaningful improvement of pain in women with generalized unprovoked vulvodynia, there was insufficient evidence for benefit of any intervention. There was fair evidence of a placebo effect in people with neuropathic pain and functional pain syndromes, from multiple studies of interventions. Based on indirect evidences from studies of patients with other pain disorders, interventions may be selected for future research.

Conclusion: There is fair evidence for effectiveness of vestibulectomy for vestibulodynia; however, there is uncertainty about the size of the absolute effect, because of the risk of bias inherent in studies of pain interventions without a placebo control group. Providers and patients looking for evidence-based interventions for generalized unprovoked vulvodynia may need to rely on indirect evidences from studies of neuropathic pain and functional pain syndromes.

Target Audience: Obstetricians & Gynecologists, Family Physicians

Learning Objectives: After completion of this educational activity, the obstetrician/gynecologist should be better able to identify potential causes of vulvar pain to facilitate diagnosis of vulvodynia and vestibulodynia, distinguish between the symptoms of localized, provoked vulvodynia and generalized unprovoked vulvodynia to select the most appropriate therapies, evaluate the efficacy of surgical and nonsurgical interventions for the treatment of generalized unprovoked and localized, provoked vulvodynia. In addition, assess the benefits and risks of interventional therapies for vulvodynia and vestibulodynia to improve patient care.

The author, faculty, and staff in a position to control the content of this CME activity and their spouses/life partners (if any) have disclosed that they have no financial relationships with, or financial interest in, any commercial organizations pertaining to this educational activity.

Dr. Andrews has disclosed that the U.S. Food and Drug Administration has not approved the use of botulinum toxin, Interferon, Cromolyn, Nifedipine, Montelukast, TENS, Nitroglycerin, Photodynamic therapy, and Magnetic field therapy for the treatment of vestibulodynia as discussed in this article. Please consult the product's labeling for approved information.

The author is solely responsible for the content of this article and the decision to submit for publication. No statement in this article should be construed as an official position of the Vanderbilt Evidence Practice Center, the International Society for the Study of Vulvovaginal Disease, nor the GRADE Working Group.

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GUIDELINE

2021 European guideline for the management of vulval conditions

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Conflicts of interest

Dr Boffa is President, Maltese Association of Dermatology & Venereology and Elected member of Malta Medical Council. Dr Lewis has received royalties for contribution to textbooks A Practical Guide to Vulval Disease. Ridley's 'The Vulva' 3rd edition and honoraria for teaching on dermatology. She is a Council member of the European College for the Study of Vulval Disease. Professor Tiplica has received lecture honoraria from Antibiotice SA and Novartis Pharma. He is chair of IUSTI Europe and president of the Romanian Association of Dermato-Venereologists. Dr Sherrard is a Member of the European Sexually Transmitted Infections Guidelines Editorial Board; and she is an officer of the International Union against Sexually Transmitted Infections (membership secretary). She is UK representative to the EBDV at UEMS. The other authors declare no conflict of interest.

Funding source

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Changes to this guideline since the 2015 version:

- Evaluation scale for genital psoriasis lesions
- Use of ixekizumab, secukinumab and ustekinumab in treating genital psoriasis
- Diagnostic criteria for vulval lichen planus
- Changed first line management recommendations for vulvodynia

Search strategy

- Guidelines produced by the British Association for Sexual Health and HIV (www.bashh.org) were reviewed.
- Searched libraries: MEDLINE, MEDLINE process, Embase, Cochrane library.
- Search up to June 2021 with no date limitation. The search strategy comprised the following terms in the title or abstract: Vulval lichen sclerosus, Vulval lichen planus, Vulval eczema, Vulval lichen simplex, Vulval psoriasis, Vulval intraepithelial neoplasia, High-grade SIL of the vulva, vulval HSIL, Vulval pain syndromes/vulvodynia.

Scope

This guideline covers the more common conditions affecting the vulva:

1 Vulval dermatitis (eczema)
2 Psoriasis
3 Lichen simplex chronicus
4 Lichen sclerosus
5 Lichen planus
6 Vulvodynia
7 Vulval intraepithelial neoplasia (VIN)

General advice for delivery of vulval care

Vulval conditions may present to a variety of clinicians including dermatologists, genitourinary medicine physicians, gynaecologists and primary care physicians or general practitioners (GP). Investigations and management span across this spectrum, so women with vulval conditions are best managed by a multidisciplinary approach, which includes clear referral pathways between disciplines or access to a specialist multidisciplinary

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vulval service. There should also be access to clinico- pathological services to allow discussion and review of histology results.

Physical examination of the patient

Informed consent is a pre-requisite for all examinations, investigations and treatments. Consent is particularly important for intimate examinations of the anogenital area. A chaperone should be offered in all cases and this should be documented clearly in the patient records. The proposed examination should be adequately explained to patients before they undress. All attempts should be made to maintain patients' dignity, providing privacy to dress and undress, and keeping them covered as much as possible. Appropriate facilities and equipment for investigations should be available prior to commencing the examination. The room should be well lit, private and soundproofed, with a suitable examination couch of adjustable height.[1]

Dermatoses and STIs may co-exist or a woman with a pre-existing dermatosis may contract an STI. Screening for sexually transmitted infections (STI) should be considered in all patients, depending on symptoms and risk factors. If the patient presents with vulval itch, particularly with increased discharge, vulvovaginal candidiasis should be excluded. If the symptoms are not relieved by anti-candidal treatment, especially if cultures are negative for candida, then a full genital examination including a speculum examination[2] should be undertaken unless done recently, and other causes considered. Possible alternate diagnoses include lichen sclerosus, lichen planus, lichen simplex chronicus, psoriasis or a neoplastic condition (particularly HPV-related vulval intra-epithelial neoplasia in young women). Sexual dysfunction should be considered and assessed if appropriate in all patients, either as the cause of the symptoms or developed secondary to the symptoms.

Conditions where STI testing should be specifically considered, is when genital ulcers are present, even in the presence of a dermatosis that causes ulceration. In these cases, testing for herpes simplex and syphilis is recommended. Additionally, where lesions fail to heal with standard treatment, investigations to exclude concurrent STIs should be undertaken.

Cutaneous disorders may be the initial signs of HIV-related immunosuppression and many associated skin diseases are more severe in this group. With the onset of immunosuppression, nonspecific skin changes occur, such as common disorders with atypical clinical features, including numerous hyperkeratotic warts, treatment-resistant seborrheic dermatitis and new or severe psoriasis. HIV testing should be considered in all patients but especially in these presentations.

General advice for all vulval conditions

- Avoid contact with soap, shampoo and bubble bath. Simple emollients can be used as a soap substitute and general moisturizer
- Avoid tight fitting garments which may irritate the area
- Avoid use of spermicidally lubricated condoms and those containing local anaesthetics
- Patients should be given a detailed explanation of their condition, with particular emphasis on any long-term health implications, which should be reinforced by giving them clear and accurate written information about the condition
- Consent should be sought for the patient's GP to be informed about the diagnosis and management.

Topical treatments

- Ointment bases are preferably used on the anogenital skin, because of the reduced need for preservatives in an ointment base, and hence less risk of a secondary contact allergy. Furthermore, cream bases may sting as they contain more water. Regular application of a barrier emollient to the affected areas may protect against local irritants for example urine and menstrual blood.

Sexual partners

- Partner tracing is not required unless screening detects a sexually transmitted infection.

Vulval dermatitis (Eczema)

Dermatitis (also named 'eczema') is an inflammatory reaction characterized histologically by spongiosis, variable acanthosis and a superficial dermal lymphohistiocytic inflammatory infiltrate. The main symptom is itch. Exogenous and endogenous factors can be involved in aetiology.

There is a danger in labelling any erythematous pruritic condition as dermatitis or eczema. Therefore, it is best practice to use the specific diagnosis instead of using these terms, namely atopic dermatitis or irritant/allergic contact dermatitis.[3]

Aetiology

Atopic dermatitis – there is increasing evidence that this is due to a defect in the barrier function of the skin.[4] In many atopic individuals, the genital area is spared, but vulval lichen simplex chronicus may be a manifestation of atopic dermatitis, either as isolated vulval disease or in association with disease at other sites.[5]

Irritant contact dermatitis – the commonest type of eczema to affect the vulva. The vulval epithelium is less efficient as a barrier than skin elsewhere[6] and is in contact with moisture, such as sweat and urine, and prone to friction. Cleansers, fragrances, lubricants and many other topical preparations can exacerbate the symptoms. Irritant dermatitis is a particular problem in those with urinary incontinence.

Allergic contact dermatitis – a type IV delayed hypersensitivity reaction, where the individual has developed an allergy to a

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Section 7.0

Previously Discussed Items

PANDA/PANS Guideline Edits January 2024

Plain Language Summary:

Coverage question: PANDAS and PANS are complicated conditions where certain infections may cause mental health symptoms to develop in children. In 2022, the Commission approved guidelines to help treat some patients. At a Listening Session with staff members, patient representatives said the guideline needs to clarify when specialist visits should happen and when other treatments should be tried.

Should OHP amend the guideline note to address the barriers? Yes, it makes sense to specify timeframes. The subcommittee should discuss what timeframes seem most appropriate.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: How should the guideline regarding PANDAS/PANS care be modified to clarify timing between consultation and approval of IVIG?

Question source: Northwest PANDAS/PANS Network; Oregon Department of Consumer and Business Affairs

Background: The Oregon Department of Consumer and Business Affairs (DCBS) is requesting clarification on the timing between non-IVIG treatments and between the specialist consult and the approval of IVIG therapy. DCBS is creating rules for private insurance to follow regarding treatment of PANDAS/PANS to comply with SB 628 (2023).

Previously, advocate Sarah Lemley requested the same clarification. Specific advocate questions included:

1) The guideline requires that a patient try and fail two or more less intensive therapies before IVIG treatment, but does not specify the timeframe. Advocates would like clarification of whether these other therapies could have been tried in the past, or whether such care needed to be more current (such as in the past year).
2) The guideline does not specify a timeframe in which the subspecialist consultation must occur prior to approving IVIG. The advocates are requesting that a timeframe for the subspecialist consultation be added to the guideline, and they are suggesting "within the past year."

The PANDAS/PANS guideline was discussed at the September 2023 VBBS/HERC meetings based on these advocates' requests. At that time, HERC staff expressed concerns that these requests at a level of detail not appropriate for HERC to address. Staff reviewed multiple treatment protocols for PANDAS/PANS and did not find any guideline which included specific timeframes for these steps. Staff recommended continuing to have non-specific wording in these areas.

PANDA/PANS Guideline Edits January 2024

Previous HSC/HERC reviews:

There was a 2022 coverage guidance on this topic. Its recommendation is the basis of the current guideline note text.

Current Prioritized List/Coverage status:

ICD-10-CM D89.89 (Other specified disorders involving the immune mechanism, not elsewhere classified) D89.9 (Disorder involving the immune mechanism, unspecified) are on line 313 DISORDERS INVOLVING THE IMMUNE SYSTEM

GUIDELINE NOTE 228, PANDAS, PANS AND AUTOIMMUNE ENCEPHALITIS

Line 313

ICD-10-CM G04.82 (Other encephalitis and encephalomyelitis) is only included on this line for autoimmune encephalitis and related non-PANDAS/PANS conditions and is not included in this guideline. Autoimmune encephalitis must meet established diagnostic criteria (for example, the International Encephalitis Consortium 2013 diagnostic criteria).

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) is included on this line when coded with ICD-10-CM D89.89 (Other specified disorders involving the immune mechanism, not elsewhere classified). Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) is included on this line when coded with ICD-10-CM D89.9 (Disorder involving the immune mechanism, unspecified).

Up to 3 monthly immunomodulatory courses of intravenous immunoglobulin (IVIG) therapy is included on this line to treat PANDAS and PANS when both of the following are met:

A) A clinically appropriate trial of two or more less-intensive treatments (for example, appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, short-course antibiotic therapy) was either not effective, not tolerated, or did not result in sustained improvement in symptoms (as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient's primary symptom complex). These trials may be done concurrently, AND
B) A consultation with and recommendation from a pediatric subspecialist (for example, pediatric neurologist, pediatric psychiatrist, pediatric mental health nurse practitioner, neurodevelopmental pediatrician, pediatric rheumatologist, pediatric allergist/immunologist, as well as the recommendation of the patient's primary care provider (for example, family physician, pediatrician, pediatric or family nurse practitioner, family or pediatric physician assistant, naturopathic physician). The subspecialist consultation may be a teleconsultation. For adolescents, an adult subspecialist consult may replace a pediatric subspecialist consult.

A reevaluation at 3 months by both the primary care provider and pediatric expert is required for continued therapy of IVIG. This evaluation must include clinical testing with a validated instrument, which must be performed pretreatment and posttreatment to demonstrate clinically meaningful improvement.

Long term antibiotic therapy is not included on this line for treatment of PANDAS/PANS.

PANDA/PANS Guideline Edits January 2024

Therapeutic plasma exchange (CPT 36514) does not pair with PANDAS or PANS (ICD-10-CM D89.89 or D89.9).

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

Expert input:

Dr. Martine Sacks, Developmental Pediatrician at Providence

> Dr. Sacks could not find guidelines or other information on the timing that should be required between less-intensive therapies and consideration of IVIG or between expert consultation and treatment with IVIG. She thought that a 2-year timeline might be appropriate if the HERC chose a timeline. She recommended adding PA, FNPs, etc. to the types of providers in the example section.

Staff contacted the appointed experts from the coverage guidance about this issue but has not received responses about this specific issue.

HERC staff summary:

Multiple stakeholders are requesting clarification regarding the timeframe between "two or more less intensive treatments" and approval of IVIG. Similarly, multiple stakeholders are requesting clarification regarding the timeframe between the specialist consultation and approval of IVIG. There is no evidence or standard guidelines that would inform these questions. Advocates have requested that the subspecialist consult occur within the past year; expert input is within the past 2 years. HERC staff recommends considering several options (6 months, 12 months, 18 months, and 24 months). Experts were not able to provide input on the optimal timing between less intensive and more intensive therapies.

HERC staff recommendation:

1) Discuss which timeframe should be considering in Guideline note 228

GUIDELINE NOTE 228, PANDAS, PANS AND AUTOIMMUNE ENCEPHALITIS

Line 313

ICD-10-CM G04.82 (Other encephalitis and encephalomyelitis) is only included on this line for autoimmune encephalitis and related non-PANDAS/PANS conditions and is not included in this guideline. Autoimmune encephalitis must meet established diagnostic criteria (for example, the International Encephalitis Consortium 2013 diagnostic criteria).

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PANDA/PANS Guideline Edits January 2024

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A) A clinically appropriate trial of two or more less-intensive treatments (for example, appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, short-course antibiotic therapy) was either not effective, not tolerated, or did not result in sustained improvement in symptoms (as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient's primary symptom complex). These trials may be done concurrently. Both trials of less intensive treatments must have occurred no more than [6 months, 12 months, 18 months, and 24 months] prior to consideration of IVIG therapy; AND

B) A consultation with and recommendation from a pediatric subspecialist (for example, pediatric neurologist, pediatric psychiatrist, pediatric mental health nurse practitioner, neurodevelopmental pediatrician, pediatric rheumatologist, pediatric allergist/immunologist, as well as the recommendation of the patient's primary care provider (for example, family physician, pediatrician, pediatric or family nurse practitioner, family or pediatric physician assistant, naturopathic physician). The subspecialist consultation may be a teleconsultation. For adolescents, an adult subspecialist consult may replace a pediatric subspecialist consult. Specialist consultation must have occurred no more than [6 months, 12 months, 18 months, and 24 months] prior to consideration of IVIG therapy;

A reevaluation at 3 months by both the primary care provider and pediatric expert is required for continued therapy of IVIG. This evaluation must include clinical testing with a validated instrument, which must be performed pretreatment and posttreatment to demonstrate clinically meaningful improvement.

Long term antibiotic therapy is not included on this line for treatment of PANDAS/PANS.

Therapeutic plasma exchange (CPT 36514) does not pair with PANDAS or PANS (ICD-10-CM D89.89 or D89.9).

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

Acute Nasal Fracture Guideline

Plain Language Summary:

Coverage question: Should OHP cover treatments for a recently broken nose?

Should OHP cover this treatment? Yes, when the treatment for the broken nose happens within 14-days of the original injury.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should a new guideline regarding nasal fractures be added to the Prioritized List?

Question source: HERC

Background: At the November 2023 HERC meeting, the HERC approved various coding changes regarding treatment of acute nasal fractures. The discussion included the intent that treatments for fractures should be covered during the acute phase, within 14 days of the fracture. Acute fracture coverage is generally emergency department care or primary care physician office care, possible splinting or nasal packing. Open nasal fractures were already covered for various ear nose and throat and craniofacial surgeries, depending on the extent of the injury.

Previous HSC/HERC reviews:

At the November 2023 meeting, several ICD-10-CM codes for nasal bone fractures were added to line 227 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES

Current Prioritized List/Coverage status:

Nasal fracture ICD-10 codes appear on line 227 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES

Sequelae of nasal fractures, such as acquired deformity of the nose, appear on line 570 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT

ICD-10-CM Code	Code Description	Current Placement
M95.0	Acquired deformity of nose	570 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT

Acute Nasal Fracture Guideline

S02.2XXA	Fracture of nasal bones, initial encounter for closed fracture	227 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.2XXB	Fracture of nasal bones, initial encounter for open fracture	227
S02.2XXD	Fracture of nasal bones, subsequent encounter for fracture with routine healing	227
S02.2XXG	Fracture of nasal bones, subsequent encounter for fracture with delayed healing	227
S02.2XXK	Fracture of nasal bones, subsequent encounter for fracture with nonunion	227
21315	Closed treatment of nasal bone fracture with manipulation; without stabilization	227
21320	Closed treatment of nasal bone fracture with manipulation; with stabilization	227
21325	Open treatment of nasal fracture; uncomplicated	227
21330	Open treatment of nasal fracture; complicated, with internal and/or external skeletal fixation	227
21335	Open treatment of nasal fracture; with concomitant open treatment of fractured septum	227
21336	Open treatment of nasal septal fracture, with or without stabilization	227
21337	Closed treatment of nasal septal fracture, with or without stabilization	227
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip	309 GENDER AFFIRMING TREATMENT 463 CHRONIC SINUSITIS 499 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES 570
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip	309,463,499,570
30420	Rhinoplasty, primary; including major septal repair	309,463,499,570
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)	309,463,499

Acute Nasal Fracture Guideline

HERC staff summary:

The intent of the HERC is that acute (within 14 days) nasal fractures should be covered on line 228. Subacute or old fractures (more than 14 days) should be included on line 577. Open fractures and fractures associated with other major facial trauma should be covered on line 228.

HERC staff recommendation:

1) Modify GN216 as shown below

GUIDELINE NOTE 216, RHINOPLASTY

Lines 42,119,227,285,309,463,499,518,570

Rhinoplasty is included on Line 309 for gender affirming treatment.

Rhinoplasty is included on Lines 42 and 119 when

A) It is performed to correct a nasal deformity secondary to congenital cleft lip and/or palate, or other severe congenital craniofacial anomaly.

B) Rhinoplasty is included on Lines 227,-285, 499, 518 and 570 when it is performed as part of reconstruction after accidental or surgical trauma or disease (for example, Wegener's granulomatosis, nasal malignancy, abscess, septal infection with saddle deformity) AND
   1) There is prolonged, persistent obstructed nasal breathing unresponsive to a six week trial of conservative management (e.g. nasal corticosteroids, decongestants, antibiotics); AND
   2) Airway obstruction will not respond to septoplasty and turbinectomy alone; AND
   3) Photographs demonstrate an external nasal deformity; AND
   4) There is significant obstruction of one or both nares, documented by nasal endoscopy, computed tomography (CT) scan or other appropriate imaging modality.

C) Rhinoplasty is included on Line 463 when there is nasal airway obstruction causing chronic rhinosinusitis when all of the following are met:
   1) The criteria for sinus surgery are met in Guideline Note 35, SINUS SURGERY; AND
   2) Airway obstruction will not respond to septoplasty and turbinectomy alone; AND
   3) Photographs demonstrate an external nasal deformity; AND
   4) There is significant obstruction of one or both nares), documented by nasal endoscopy, computed tomography (CT) scan or other appropriate imaging modality

Care for acute nasal fractures (up to 14 days from the injury) is included on line 227. Sequalae of nasal fractures, including nasal deformities, are included on line 570.

42 CLEFT PALATE WITH AIRWAY OBSTRUCTION
119 CHOANAL ATRESIA
227 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
285 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX
309 GENDER DYSPHORIA/TRANSEXUALISM
463 CHRONIC SINUSITIS
499 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES
518 BENIGN NEOPLASM OF NASAL CAVITIES, MIDDLE EAR AND ACCESSORY SINUSES
570 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT

Lipoprotein Testing

Plain Language Summary:

Coverage question: Should OHP cover a type of cholesterol test (lipoprotein a)?

Should OHP cover this treatment?
Option 1: Yes, based on expert opinion.
Option 2: No. There is no evidence showing the benefit of testing for this type of cholesterol.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should some or all lipoprotein tests be added to coverage?

Question source: Dr. David Saenger, VBBS member and cardiologist

Background: Currently, many types of lipoprotein testing (CPT 83700-83704) are on line 662/GN173. Lipoproteins are a type of cholesterol. The standard cholesterol test includes some types of lipoproteins, namely HDL (high density lipoproteins) and LDL (low density lipoproteins). There are multiple other types of lipoproteins that can be tested for that have variable evidence that they affect clinical management or outcomes.

At the November 2023 VBBS meeting, a new PLA code for a type of lipoprotein test was added to the lipoprotein entry in GN173. Dr. Saenger noted that there are some types of lipoprotein testing in the current code range in the GN173 entry that actually should be covered. Specifically, Dr. Saenger noted that lipoprotein(a) and apolipoprotein B levels are becoming increasingly important clinically. VBBS requested that HERC staff review this topic more fully.

Lipoprotein tests have not been reviewed in the past 5 years.

Previous HSC/HERC reviews:

Most of the lipoprotein test codes had brief evidence reviews done as part of a new CPT code placements.

Current Prioritized List/Coverage status:

CPT code	Code Description	Current Placement
80061	Lipid panel This panel must include the following: Cholesterol, serum, total (82465) Lipoprotein, direct measurement, high density cholesterol (HDL cholesterol) (83718) Triglycerides (84478)	DIAGNOSTIC PROCEDURES
82172	Apolipoprotein, each	DIAGNOSTIC PROCEDURES

Lipoprotein Testing

	Note: includes apolipoprotein B	
82465	Cholesterol, serum or whole blood, total	DIAGNOSTIC PROCEDURES
83695	Lipoprotein (a)	654 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)	654
83700	Lipoprotein, blood; electrophoretic separation and quantitation	654
83701	Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (eg, electrophoresis, ultracentrifugation)	654
83704	Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed	654
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)	DIAGNOSTIC PROCEDURES
83719	Lipoprotein, direct measurement; VLDL cholesterol	DIAGNOSTIC PROCEDURES
83721	Lipoprotein, direct measurement; LDL cholesterol	DIAGNOSTIC PROCEDURES
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	654
84478	Triglycerides	DIAGNOSTIC PROCEDURES
0377U	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)	654

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

Line 654

The following Interventions are prioritized on Line 654 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**
83695	Lipoprotein (a)	Insufficient evidence of effectiveness	January, 2014
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)	Insufficient evidence of effectiveness	October 2013

Lipoprotein Testing

83700-83704, 0377U	Lipoprotein, blood	Insufficient evidence of effectiveness	October 2006
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	Insufficient evidence of effectiveness	November, 2018

Evidence

1) **Reyes-Soffer 2021**, impact of race and ethnicity on lipoprotein(a) levels and cardiovascular risk
    a. Lp(a) concentrations are elevated in Blacks compared to their White and East Asian counterparts; however, there exists considerable variation in these data, with mean concentrations ranging between 43 mg/dL and 99 mg/dL (71-132 nmol/L), and median concentrations ranging between 27.11 mg/dL and 46 mg/dL (60-79 nmol/L), with wide IQRs. Hispanic participants tend to have relatively low mean (14.9 mg/dL; n = 2073) and median serum Lp(a) levels (14.7-24 nmol/L); it is necessary to acknowledge that data on this group are limited, and few studies examining serum Lp(a) in Hispanics are published. Published literature suggests that East Asian populations tend to have lower mean and median serum Lp(a) concentrations compared to Whites, and especially Black and South Asian counterparts. East Asian median Lp(a) concentrations range between 1.11 mg/dL and 12.9 mg/dL (22-38 nmol/L)

Expert guidelines:

1) **Alebna 2023**, Update on Lipoprotein(a)
    a. Available at **https://www.acc.org/Latest-in-Cardiology/Articles/2023/09/19/10/54/An-Update-on-Lipoprotein-a**
        i. Accessed 11/22/23
    b. Lipoprotein(a) (Lp[a]) is an independent risk factor for atherosclerotic cardiovascular disease (CVD) and calcific valvular aortic stenosis.
    c. There is no generalized consensus on Lp(a) risk thresholds
    d. Statins slightly increase Lp(a) levels, or levels remain stable with therapy. Ezetimibe reduces Lp(a) levels by 7.6% according to the findings of one meta-analysis; however, other studies' findings revealed no change. Bile acid sequestrants and fibrates do not have a significant correlation with Lp(a) levels; some studies' findings show an increase and others' show no effect. Niacin decreases Lp(a) levels by 23%; however, it is not recommended for use because it lacks mortality and morbidity benefit in patients at risk of cardiovascular disease (CVD).
2) **AHA 2021**, Scientific statement on lipoprotein(a) testing
    a. We currently lack definitive proof that specific pharmacological lowering of Lp(a) reduces adverse cardiovascular outcomes.
    b. The most effective clinically available intervention for Lp(a) lowering is lipoprotein apheresis. It is typically done every 2 weeks
    c. Limited clinical trial data suggest that Lp(a) lowering with lipoprotein apheresis may reduce the risk of ASCVD events, but definitive studies are needed.
    d. Standard LDL-C and apoB lowering treatments have minimal Lp(a)-lowering efficacy, with some statins minimally increasing Lp(a) levels.

e. data from trials of monoclonal antibodies directed against PCSK9 demonstrated dramatic LDL-C lowering by an average of 50% to 60%, but also modest Lp(a) lowering of 25% to 30%.
f. In patients with recent acute coronary syndrome on optimized statin therapy and LDL-C <70 mg/dL), alirocumab only lowered major adverse cardiovascular events in patients with mildly elevated (>13.7 mg/dL) Lp(a); there was no such interaction between Lp(a) levels and alirocumab benefit when LDL-C was ≥70 mg/dL
g. Niacin may dose-dependently lower Lp(a) up to 25% to 40%, but the cardiovascular benefit of this intervention is unknown, and the adverse side effect profile of niacin in the setting of statins may be a concern
h. Several experimental therapies targeting the apo(a) moiety of Lp(a) are in development
i. International standards for measurement of Lp(a) need to be established and codified to allow for consistent measurement, using assays expressing results in nanomoles per liter, and a common protocol is needed for monitoring of assay performance to ensure comparable results between laboratories
j. At present, the evidence in favor of screening for Lp(a) is the strongest for those with a family or personal history of ASCVD, with consideration of cascade screening in appropriate individuals

3) **ACC/AHA 2019** guideline on primary prevention of cardiovascular disease
    a. Risk-enhancing factors for clinical-patient risk discussion
        i. If measured:
            1. Elevated Lp(a): A relative indication for its measurement is family history of premature ASCVD. An Lp(a) ≥50 mg/dL or ≥125 nmol/L constitutes a risk-enhancing factor, especially at higher levels of Lp(a)
            2. Elevated apoB (≥130 mg/dL): A relative indication for its measurement would be triglyceride ≥200 mg/dL. A level ≥130 mg/dL corresponds to an LDL-C >160 mg/dL and constitutes a risk-enhancing factor
    b. If ASCVD risk 5-7.5%, then look for risk enhancers
        i. Risk enhancers: family history of premature ASCVD, persistently elevated LDL-C, chronic kidney disease, metabolic syndrome, premature menopause, inflammatory diseases, ethnicity, persistently elevated triglycerides
            1. In selected individuals if measured:
                a. Elevated high-sensitivity C-reactive protein (≥2.0 mg/L)
                b. An Lp(a) ≥50 mg/dL or ≥125 nmol/L
                c. apoB (≥130 mg/dL):
                d. Ankle-brachial index (ABI) <0.9
        ii. If risk enhancers are prevent, discuss moderate intensity statin (Class IIb)
    c. If ASCVD risk 7.5-20%, then risk estimate + risk enhancers as above, state moderate intensity statin (Class I). If risk discussion is uncertain, measure coronary artery calcium score
    d. However, no available RCT evidence supports lipoprotein (a) levels as a target of therapy
4) **Grundy 2018** AHA/ACC/AACVPR/AAPA/ ABC/ACPM/ADA/AGS/APhA/ASPC/ NLA/PCNA Guideline on the Management of Blood Cholesterol
    a. Because apoB is the major apolipoprotein embedded in LDL and VLDL, several investigators identify strength of association between apoB and ASCVD. Others report a high correlation between apoB and non–HDL-C. Under certain circumstances, particularly in patients with hypertriglyceridemia, the measurement of apoB may have advantages. Nevertheless, apoB measurement carries extra expense, and its

measurement in some laboratories may not be reliable. A relative indication for its measurement would be triglyceride ≥200 mg/dL. A level >130 mg/dL corresponds to an LDL-C level ≥160 mg/dL and constitutes a risk-enhancing factor. A persistent elevation of apoB can be considered a risk-enhancing factor.

b. Lp(a) is a modified form of LDL that appears to possess atherogenic potential. Relative indications for its measurement are family history of premature ASCVD or personal history of ASCVD not explained by major risk factors. Lp(a) increases ASCVD risk especially at higher levels. Thus, if a decision is made to measure Lp(a), an Lp(a) ≥50 mg/dL or ≥125 nmol/L, Lp(a) may be considered a risk-enhancing factor. Current evidence shows that it should be considered in women only in the presence of hypercholesterolemia and with the understanding that the improvement in risk prediction in adult women in a large clinical trial was minimal

Other payer policies:

1) CMS LCD 2023, Biomarkers in Cardiovascular Risk Assessment
   a) Covers: CPT 82172, 83695, 83698, 83700, 83701, 83703, 83719, 83721
2) Cigna 2023
   a) Lipoprotein-associated phospholipase A2 (Lp–PLA2) testing (CPT® 83698) is considered medically necessary for ANY of the following individuals who are at intermediate- or high-risk for developing coronary heart disease (CHD):
      i. any age with at least two or more major risk factors (e.g., smoking, hypertension, family history of premature CHD, diabetes mellitus, low levels of HDL cholesterol) •
      ii. age ≥ 65 years with one major risk factor
      iii. cigarette smoking
      iv. fasting blood glucose level of ≥ 100 mg/dl
      v. metabolic syndrome
   b) Apolipoprotein B testing (CPT® 82172) is considered medically necessary when the individual is undergoing management for lipoprotein abnormalities and ANY of the following conditions is met:
      i. established coronary heart disease (CHD), as evidenced by ANY of the following:
         i. previous history of myocardial infarction (MI)
         ii. stable or unstable angina
         iii. revascularization with coronary artery bypass grafting
         iv. percutaneous coronary angioplasty
      ii. diabetes mellitus
      iii. two or more major risk factors (i.e., tobacco smoking, hypertension, family history of premature CHD, low levels of HDL cholesterol, age [men ≥ 45 years, women ≥ 55 years])
   c) Lipoprotein(a) enzyme immunoassay (Lp[a]) testing (CPT® 83695) is considered medically necessary for ANY of the following at-risk groups, when used to assess risk and guide treatment of lipoprotein abnormalities:
      a. family history of premature CHD
      b. genetic predisposition for hypercholesterolemia
      c. established atherosclerotic heart disease with a normal routine lipid profile
      d. hyperlipidemia refractory to therapy
      e. history of recurrent arterial stenosis
   d) Considers the following to be experimental

a. 83700 Lipoprotein, blood; electrophoretic separation and quantitation
b. 83701 Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (eg, electrophoresis, ultracentrifugation)
c. 83704 Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed
d. 83719 Lipoprotein, direct measurement; VLDL cholesterol

3) Aetna 2023
   a) Aetna considers measurement of apolipoprotein B (apoB) medically necessary for use in high-risk persons with hypercholesterolemia to assess whether additional intense interventions are necessary when LDL cholesterol goals are reached (LDL cholesterol less than 70 mg/dL and non-HDL cholesterol less than 100 mg/dL in persons with known cardio-vascular disease (CVD) or diabetes mellitus, or LDL-C less than 100 mg/dL and non-HDL cholesterol less than 130 mg/dL in persons with other risk factors). High-risk persons are those with one or more of the following criteria:
      a. Diabetes mellitus; *or*
      b. Known CVD; *or*
      c. Two or more of the following CVD risk factors:
         1. Current cigarette smoking; *or*
         2. Family history of premature CVD (CHD in male first-degree relative less than 55 years of age; CHD in female first-degree relative less than 65 years of age); *or*
         3. Hypertension (BP of 140 mm Hg or higher, or on anti-hypertensive medication).
   b) Considers the following to be experimental

83695	Lipoprotein (a)
83698	Lipoprotein-hyphenassociated phospholipase A2 (Lp-hyphenPLA2)
83700	Lipoprotein, blood; electorophoretic separation and quantitation
83701	high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (eg, electrophoresis, ultracentrifugation) [VAP cholesterol test]
83704	quantitation of lipoprotein particle numbers and lipoprotein particle subclasses (eg, by nuclear magnetic resonance spectroscopy)
83719	Lipoprotein, direct measurement; VLDL cholesterol
83722	Lipoprotein, direct measurement; small dense LDL cholesterol

Expert input:

David Saenger, OHSU cardiology

Most recent guidelines I find recommend once in a lifetime testing of lipoprotein (a) in all individuals with increased risk of CAD. Canadian Cardiovascular Society Guidelines recommend testing it once in everyone. European guidelines recommend testing it if there is increased risk. I'm including here a summary of this from the ACC website.

Also important to mention that elevated Lp (a) is present in 15-20% of people. It is common. And it is especially common in underrepresented minorities. It is more common in people of African and South Asian descent. Because these individuals can have less access to preventive care, screening takes on even more importance, I think.

And the elevated risk is substantial. I tell my patients that it is probably akin to smoking that can't be quit. Which is worth knowing about.

And it is not just associated with CAD. Studies also show strong linkages to aortic stenosis, renal failure, PVD and CVA.

If a patient has elevated Lp (a), I would have a lower threshold for suspecting CAD and a lower threshold for aggressive prevention.

Also, in these patients I'm going to look for other issues more diligently as well. Aortic stenosis, for example.

And then I will modify those other risk factors as much as possible. I would have a lower threshold to prophylactic aspirin. I will be more aggressive with blood pressure, probably.

Admittedly, there are no randomized clinical trials to support this. Nor will there ever be such a trial. It would be almost impossible to conduct. Editorials in JACC have advocated this strategy. The Canadian Cardiovascular Society advocates universal Lp (a) screening. Other official societies recommend screening for it in any patient at increased risk (however that is defined).

Regarding treatment:

Clinical trials of a specific therapy are underway. And it is true that there is no current therapy for elevated Lp (a). Statins raise it by about 5%. But the point is that if I identify a patient with elevated Lp (a), I focus on lowering Apo B as much as possible and modifying other cardiac risk factors as aggressively as possible. I have even used it to identify patients with early stage aortic stenosis.

There is some evidence that people with elevated Lp (a) benefit more from primary prevention with low dose aspirin... Aspirin for these patients is at least something currently actionable.

Dr. Abigail Khan, OHSU cardiology

I would argue that expanding access to preventative services is an especially high priority for underserved/at risk populations. I am concerned that we are perpetuating an inequity by creating a system whereby higher income individuals with commercial insurance and able to gain access to risk stratification tools and those on Medicaid are not.

HERC staff summary:

Lipoprotein(a) measurement is listed in expert guidelines as a possible test to do to help with risk estimation of CVD. However, expert guidelines also acknowledge there is no current treatment that affects lipoprotein(a) level. There is no consensus on what level of Lp(a) increases cardiac risk, although

Lipoprotein Testing

≥50 mg/dL appears to be the most accepted standard. It is unclear what clinical management changes are recommended if Lp(a) levels are high, or whether such changes affect clinical outcomes. Private insurers vary on coverage of this test. Experts recommend coverage of this test, as it is a one time test without major adverse effects that can help a clinician counsel a patient and can help in clinical decision making regarding CVD risk reduction. Lp(a) levels have been reported to be higher in people who are Black and of South Asian ancestry; however, there is considerable variation in this data.

Apolipoprotein B levels similarly are listed in expert guidelines as possible tests to conduct to evaluation persons at intermediate risk of CVD. This test is already covered under OHP.

Other lipoprotein tests (other than standard tests such as LDL, HLD, total cholesterol, etc.) are not mentioned in national expert guidelines and tend to not be covered by private insurers.

HERC staff recommends making no change in current coverage of most non-standard lipoprotein tests. HERC staff recommends consideration of coverage of lipoprotein(a) testing as it is low cost (<$100) and experts recommend use.

HERC staff recommendation:

Option 1: Continue non-coverage of lipoprotein(a)

a. Update lipoprotein(a) entries in 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 654

The following Interventions are prioritized on Line 654 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
83695	Lipoprotein (a)	Insufficient evidence of effectiveness	~~January, 2014~~ January 2024
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)	Insufficient evidence of effectiveness	~~October 2013~~ January 2024
83700-83704, 0377U	Lipoprotein, blood	Insufficient evidence of effectiveness	~~October 2006~~ January 2024
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	Insufficient evidence of effectiveness	~~November, 2018~~ January 2024

Option 2: Add coverage of lipoprotein(a)

a. Delete the lipoprotein(a) entry from GN173
b. Add CPT 83695 to the Diagnostic Procedures file
c. Update the date of last review other lipoprotein tests in GN173

Lipoprotein Testing

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

Line 654

The following Interventions are prioritized on Line 654 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
~~83695~~	~~Lipoprotein (a)~~	~~Insufficient evidence of effectiveness~~	~~January, 2014~~
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)	Insufficient evidence of effectiveness	~~October 2013~~ January 2024
83700-83704, 0377U	Lipoprotein, blood	Insufficient evidence of effectiveness	~~October 2006~~ January 2024
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	Insufficient evidence of effectiveness	~~November, 2018~~ January 2024

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Arteriosclerosis, Thrombosis, and Vascular Biology

AHA SCIENTIFIC STATEMENT

Lipoprotein(a): A Genetically Determined, Causal, and Prevalent Risk Factor for Atherosclerotic Cardiovascular Disease: A Scientific Statement From the American Heart Association

The International Atherosclerosis Society endorses this statement.

Gissette Reyes-Soffer, MD, FAHA, Chair; Henry N. Ginsberg, MD, FAHA; Lars Berglund MD, PhD; P. Barton Duell, MD, FAHA; Sean P. Heffron, MD, MS, MSc; Pia R. Kamstrup, MD, PhD; Donald M. Lloyd-Jones, MD, ScM, FAHA; Santica M. Marcovina, PhD, ScD, FAHA; Calvin Yeang, MD, PhD; Marlys L. Koschinsky PhD, FAHA, Co-Chair; on behalf of the American Heart Association Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; and Council on Peripheral Vascular Disease

ABSTRACT: High levels of lipoprotein(a) [Lp(a)], an apoB100-containing lipoprotein, are an independent and causal risk factor for atherosclerotic cardiovascular diseases through mechanisms associated with increased atherogenesis, inflammation, and thrombosis. Lp(a) is predominantly a monogenic cardiovascular risk determinant, with ≈70% to ≥90% of interindividual heterogeneity in levels being genetically determined. The 2 major protein components of Lp(a) particles are apoB100 and apolipoprotein(a). Lp(a) remains a risk factor for cardiovascular disease development even in the setting of effective reduction of plasma low-density lipoprotein cholesterol and apoB100. Despite its demonstrated contribution to atherosclerotic cardiovascular disease burden, we presently lack standardization and harmonization of assays, universal guidelines for diagnosing and providing risk assessment, and targeted treatments to lower Lp(a). There is a clinical need to understand the genetic and biological basis for variation in Lp(a) levels and its relationship to disease in different ancestry groups. This scientific statement capitalizes on the expertise of a diverse basic science and clinical workgroup to highlight the history, biology, pathophysiology, and emerging clinical evidence in the Lp(a) field. Herein, we address key knowledge gaps and future directions required to mitigate the atherosclerotic cardiovascular disease risk attributable to elevated Lp(a) levels.

Key Words: AHA Scientific Statements ■ apolipoprotein B100 ■ atherosclerotic cardiovascular disease ■ cholesterol, low-density lipoprotein ■ lipoprotein(a)

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Cardiovascular disease (CVD) is the leading cause of death and disability worldwide.[1] Advances over the past 70 years have led to the identification of common and novel CVD risk factors, and the introduction of many pharmacological interventions for use in primary and secondary prevention, as well. Despite significant progress, there remains substantial residual CVD risk, even among well-treated groups.[2] The role of apolipoprotein B100 (apoB) containing lipoproteins as the central determinants of atherogenesis and risk for CVD is well established.[3] The apoB concentration in plasma is a marker of both cardiovascular risk and disease severity.[4] Lipoprotein(a) [Lp(a)] is an apoB-containing lipoprotein bound to a hydrophilic, highly glycosylated protein called apolipoprotein(a) [apo(a)][5,6] (Figure, see location **a**).

Epidemiological, genome-wide association, and Mendelian randomization data[7–11] provide clear support for a causal role for elevated Lp(a) in the development of atherosclerotic cardiovascular disease (ASCVD).[12] What is defined as high Lp(a) levels can differ, depending on (1) the assay and units of measurement (milligrams per deciliter versus nanomoles per liter) used; (2) the population ancestry; and (3) the underlying disease and clinical characteristics of the cohort. These factors have made it difficult to establish universal thresholds for clinical use.[13,14] Our current ability to lower Lp(a) with approved

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Circulation

ACC/AHA CLINICAL PRACTICE GUIDELINE

2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

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Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, the American Geriatrics Society, the American Society of Preventive Cardiology, and the Preventive Cardiovascular Nurses Association

ACC/AHA Task Force Members, see page e623

Key Words: AHA Scientific Statements ■ guidelines ■ antihypertensive agents ■ aspirin ■ atherosclerosis ■ atherosclerotic cardiovascular disease ■ atrial fibrillation ■ behavior modification ■ behavior therapy ■ blood cholesterol ■ blood pressure ■ body mass index ■ cardiovascular team-based care ■ cardiovascular ■ cardiovascular disease ■ cholesterol ■ chronic kidney disease ■ coronary artery calcium score ■ coronary disease ■ coronary heart disease ■ cost ■ diet ■ dietary patterns ■ dietary fats ■ dietary sodium ■ dyslipidemia ■ e-cigarettes ■ exercise ■ healthcare disparities ■ health services accessibility ■ heart failure ■ hypertension ■ LDL cholesterol ■ diabetes mellitus ■ lifestyle ■ lipids ■ measurement ■ myocardial infarction ■ nicotine ■ nonpharmacological treatment ■ nutrition ■ physical activity ■ prejudice ■ primary prevention ■ psychosocial deprivation ■ public health ■ quality indicators ■ quality measurement ■ risk assessment ■ risk-enhancing factors ■ risk factors ■ risk reduction ■ risk reduction discussion ■ risk treatment discussion ■ secondhand smoke ■ sleep ■ smoking ■ smoking cessation ■ social determinants of health ■ socioeconomic factors ■ statin therapy ■ systems of care ■ tobacco ■ tobacco smoke pollution ■ treatment adherence ■ treatment outcomes ■ type 2 diabetes mellitus ■ waist circumference ■ weight loss

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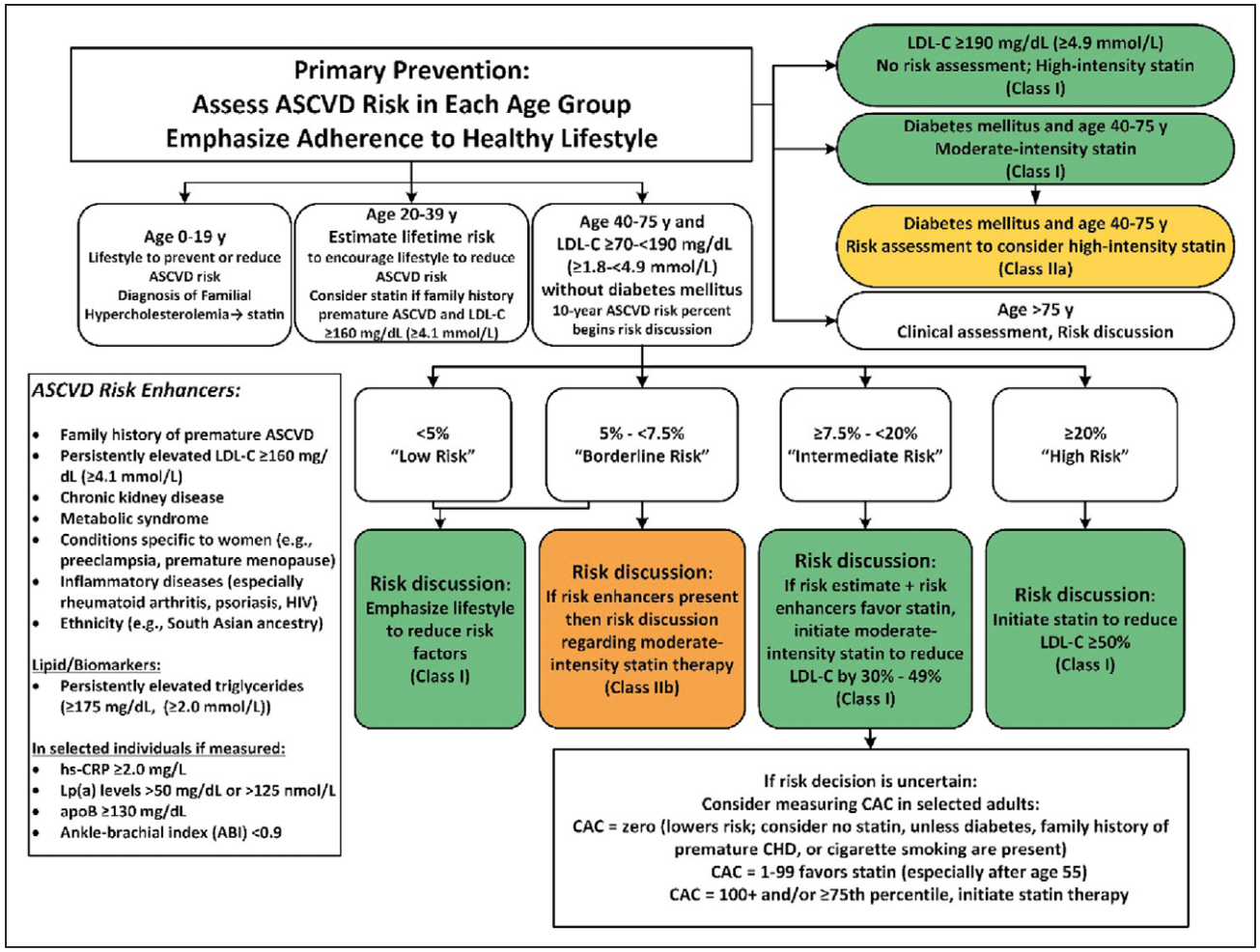

Figure 3. Primary prevention.
Colors correspond to Class of Recommendation in Table 1. ABI indicates ankle-brachial index; apoB, apolipoprotein B; ASCVD, atherosclerotic cardiovascular disease; CAC, coronary artery calcium; CHD, coronary heart disease; HIV, human immunodeficiency virus; hs-CRP, high-sensitivity C-reactive protein; LDL-C, low-density lipoprotein cholesterol; and Lp(a), lipoprotein (a). Reproduced with permission from Grundy et al.[S4.3-1] Copyright © 2018, American Heart Association, Inc., and American College of Cardiology Foundation.

Synopsis

Primary ASCVD prevention requires attention to ASCVD risk factors beginning early in life (Figure 3). This guideline addresses major issues related to cholesterol management and primary ASCVD prevention, which are also addressed in the recently published 2018 Cholesterol Clinical Practice Guidelines.[S4.3-1] Therefore, the relevant subset of those recommendations is presented here, along with its accompanying supportive text. This writing committee agrees that for young adults (20 to 39 years of age), priority should be given to estimating lifetime risk and promoting a healthy lifestyle. Only in select patients with moderately high LDL-C (≥160 mg/dL) or those with very high LDL-C (≥190 mg/dL) is drug therapy indicated. In adults 40 to 75 years of age, 10-year ASCVD risk should guide therapeutic considerations. The higher the estimated risk, the more likely the patient is to benefit from statin treatment. For patients >75 years of age, assessment of risk status and a clinician patient risk discussion are needed to decide whether to continue or initiate statin treatment. For a detailed discussion of statin safety and management of statin-associated side effects, please refer to Section 5 of the 2018 Cholesterol Clinical Practice Guidelines.[S4.3-1]

Recommendation-Specific Supportive Text

1. Large-scale RCTs in primary prevention demonstrated ASCVD risk reduction with moderate-intensity[S4.3-6,S4.3-36] and high-intensity statin therapy[S4.3-7] that outweighed the observable risks. Subsequently, a large-scale RCT in an ethnically and racially diverse population confirmed statin benefit from a moderate-intensity statin therapy, as compared with placebo, in intermediate-risk patients. That RCT enrolled men ≥55 years of age and women ≥65 years of age with at least 1 cardiovascular risk factor. In the placebo

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CLINICAL PRACTICE GUIDELINE

2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

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This document was approved by the American College of Cardiology Clinical Policy Approval Committee, the American Heart Association Science Advisory and Coordinating Committee, American Association of Cardiovascular and Pulmonary Rehabilitation, American Academy of Physician Assistants, Association of Black Cardiologists, American College of Preventive Medicine, American Diabetes Association, American Geriatrics Society, American Pharmacists Association, American Society for Preventive Cardiology, National Lipid Association, and Preventive Cardiovascular Nurses Association in October 2018, and the American Heart Association Executive Committee in October 2018.

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modest differences in LDL-C levels associated with the postprandial state, use of a nonfasting sample is effective to document baseline lipid levels before initiation of statin therapy in individuals with clinical ASCVD (S2.2-1—S2.2-6). In adults with a family history of premature ASCVD or genetic hyperlipidemia, a fasting lipid profile is reasonable for initial evaluation.

2. Given relatively modest differences in LDL-C levels between fasting and non-fasting samples, the latter is generally adequate to document baseline lipid levels prior to initiation of statin therapy (S2.2-1—S2.2-6).
3. The unreliability of the Friedewald-calculated LDL-C levels rises at lower levels of LDL-C, particularly <70 mg/dL (<1.8 mmol/L). If accurate measurements of LDL-C levels are needed at very low LDL-C, calculation adjustments can be used (S2.2-7—S2.2-9). Measurement of apoB may be useful in determining whether hypertriglyceridemia is an atherogenic condition (S2.2-12, S2.2-13).
4. In adults with a family history of premature ASCVD or genetic hyperlipidemia, a fasting lipid profile is reasonable for initial evaluation to aid in the understanding and identification of familial lipid disorders (S2.2-12, S2.2-13).

2.3. Measurements of Apolipoprotein B and Lipoprotein (a)

Two lipoprotein entities related to LDL-C are apoB and lipoprotein (a) [Lp(a)]. Because apoB is the major apolipoprotein embedded in LDL and VLDL, several investigators identify strength of association between apoB and ASCVD (S2.3-1). Others report a high correlation between apoB and non-HDL-C (S2.3-2). Under certain circumstances, particularly in patients with hypertriglyceridemia, the measurement of apoB may have advantages (S2.3-3). Nevertheless, apoB measurement carries extra expense, and its measurement in some laboratories may not be reliable (S2.3-4). A relative indication for its measurement would be triglyceride ≥200 mg/dL. A level >130 mg/dL corresponds to an LDL-C level ≥160 mg/dL and constitutes a risk-enhancing factor. A persistent elevation of apoB can be considered a risk-enhancing factor. Separately, Lp(a) is a modified form of LDL that appears to possess atherogenic potential (S2.3-5). Relative indications for its measurement are family history of premature ASCVD or personal history of ASCVD not explained by major risk factors. Lp(a) increases ASCVD risk especially at higher levels. Thus, if a decision is made to measure Lp(a), an Lp(a) ≥50 mg/dL or ≥125 nmol/L, Lp(a) may be considered a risk-enhancing factor (S2.3-6). Current evidence shows that it should be considered in women only in the presence of hypercholesterolemia and with the understanding that the improvement in risk prediction in adult women in a large clinical trial was minimal (S2.3-7). In the present document, an elevation of Lp(a) is considered to be a risk-enhancing factor (S2.3-6). This is especially in those with higher Lp(a) values and, if used in women, only in the presence of hypercholesterolemia (S2.3-7).

2.4. Monitoring Response of LDL-C to Statin Therapy

In large RCTs of cholesterol-lowering therapy, LDL-C lowering has been consistently shown to reduce the risk of ASCVD. One large meta-analysis (S2.4-1) of statin clinical trials showed a progressive reduction in risk of major ASCVD events with lower on-treatment LDL-C levels. In another larger meta-analysis (S2.4-2) of 14 statin trials, it was observed that a 38.7-mg/dL (1-mmol/L) reduction of LDL-C levels is accompanied by a 21% reduction in ASCVD risk. In clinical practice, however, absolute responses in LDL-C to statin therapy depend on baseline LDL-C concentrations. A given dose of statins produces a similar percentage reduction in LDL-C levels across a broad range of baseline LDL-C levels. For this reason, a more reliable indicator of statin efficacy is percentage reduction. In the present document, the percentage reduction is used in follow-up monitoring of patients to estimate the efficacy of statin therapy. As a rough guide, a lowering of LDL-C levels of 1% gives an approximate 1% reduction in the risk of ASCVD— somewhat more at higher baseline LDL-C levels and somewhat less at lower baseline levels (S2.4-1).

3. THERAPEUTIC MODALITIES

3.1. Lifestyle Therapies

3.1.1. Diet Composition, Weight Control, and Physical Activity

For many years, the AHA and ACC have recommended essentials of a healthy diet for the general public and for patients at risk for ASCVD. The current document supports evidence-based recommendations provided in the 2013 AHA/ACC guidelines on lifestyle management (S3.1.1-1, S3.1.1-2). Patients should consume a dietary pattern that emphasizes intake of vegetables, fruits, whole grains, legumes, healthy protein sources (low-fat dairy products, low-fat poultry (without the skin), fish/seafood, and nuts), and nontropical vegetable oils; and limits intake of sweets, sugar-sweetened beverages, and red meats. This dietary pattern should be adjusted to appropriate calorie requirements, personal and cultural food preferences, and nutritional therapy for other medical conditions including diabetes. Caloric intake should be adjusted to avoid weight gain, or in overweight/obese patients, to promote weight loss. In general, adults should be advised to engage in aerobic physical activity 3-4 sessions per week, lasting on average 40 minutes per session and involving moderate-to vigorous-intensity physical activity.

2023 CPT Code Review: Coronary Lithotripsy

Plain Language Summary:

Coverage question: Should OHP cover a medical procedure to help open blocked blood vessels to the heart?

Should OHP cover this treatment? No. It has not been compared to more common treatments and no studies found evidence of it working well.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should the new CPT code for coronary lithotripsy be covered?

Question source: VBBS

Background:

Coronary artery disease (CAD) is a condition in which there is insufficient blood flow in the arteries that feed the heart. CAD can be treated with percutaneous interventions such as coronary artery stenting. Calcium frequently builds up in the coronary arteries and makes interventions like stenting more difficult. To help stent deployment in these cases, several specialty balloons have been developed which cut or score the calcium lining the artery. Intravascular lithotripsy (IVL) is a recently introduced therapeutic modality in managing calcified coronary lesions (CCL). Lithotripsy enhances the fragmentation of CCL via delivery of circumferential sonic pressure waves to the vessel wall and applying pulsatile shockwaves to the surrounding plaque.

Coronary lithotripsy was discussed at the November 2023 VBBS and HERC meetings. The staff evidence review included a 2020 NICE technology review that concluded that this procedure was experimental, based on 3 case series (N=60, 71 and 120) and a 2022 systematic review and meta-analysis (Mhanna 2022) that included 8 cohort studies (980 patients) that concluded "IVL seems to have excellent efficacy and safety in the management of severe CCL lesions. However, adequately powered RCTs are needed to evaluate IVL compared to other calcium/plaque modifying techniques." The **ACC/AHA/SCAI 2021** guideline for coronary artery revascularization included use of this technique for patients with fibrotic or heavily calcified lesions [2b (weak recommendation), level of evidence B-NR (moderate quality evidence from 1 or more well designed nonrandomized studies)] and listed intracoronary lithotripsy listed as a "potentially emerging modality." All private payers surveyed considered this procedure to be experimental and were not covering (NICE, Aetna Cigna, Providence Health Plans, Premara BCBS).

At the November meeting, Dr. David Saenger stated that he had had discussions with colleagues who found this procedure to be helpful in certain clinical situations and noted that it is currently being used in practice. He said that some private insurers are covering the procedure. He notes that it is used in patients who have more severe arterial disease, so a higher rate of complications would be expected

with this procedure that standard coronary artery stenting. This procedure makes the time required to do coronary catheterization significantly longer, so there is minimal risk of it being abused.

Current Prioritized List/Coverage status:

New Code
92972 Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
Previous code:
0715T Percutaneous transluminal coronary lithotripsy

Additional code: HCPCS **C1761** Catheter, transluminal intravascular lithotripsy, coronary

Coronary catheterization and stenting procedure codes are on lines
45 CORONARY ARTERY ANOMALY
69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
97 HEART FAILURE
188 CHRONIC ISCHEMIC HEART DISEASE
283 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

Evidence:

See November 2023 CPT code summary for the following systematic review summaries: NICE 2020 and Mhanna 2022

Submitted literature:

1) Ali 2023, pooled analysis from the DISRUPT CAD trials
    a. Included in Mhanna 2022 systematic review
2) Ali 2023
    a. Letter that summarized the DISRUPTS CAD trials
3) Ali 2019, DISRUPT CAD II trial
    a. Included in Mhanna 2022 systematic review
4) Barbato 2017
    a. Unable to locate in MEDLINE or through the OHSU library
5) Hill 2020, DISRUPT CAD III trial
    a. Included in Mhanna 2022 systematic review
6) Kereiakes 2021
    a. All included studies also in the Mhanna 2022 systematic review
7) Hussain 2022, patient level analysis of sex-specific outcomes in the Disrupt CAD studies
    a. All included studies also in the Mhanna 2022 systematic review
8) Payor Executive Summary, Intravascular Lithotripsy (IVL)
    a. Shockwave manufacturer device brief
9) Tepe 2022, DISRUPT CAD III trial
    a. Included in Mhanna 2022 systematic review

2023 CPT Code Review: Coronary Lithotripsy

Expert guidelines:

ACC/AHA/SCAI 2021 guideline for coronary artery revascularization

1) In patients with fibrotic or heavily calcified lesions, plaque modification with orbital atherectomy, balloon atherotomy, laser angioplasty, or intracoronary lithotripsy may be considered to improve procedural success [2b (weak recommendation), level of evidence B-NR (moderate quality evidence from 1 or more well designed nonrandomized studies)]
2) Despite promising results from hundreds of small mechanistic studies, dozens of large, randomized trials have shown that the routine use of atheroablative devices does not improve clinical or angiographic outcomes. However, the use of atheroablative devices may enhance procedural success in specific circumstances
3) Intracoronary lithotripsy listed as a "potentially emerging modality"

Expert input:

Dr. Sudeshna Banerjee, Peace Health cardiology

Used for highly calcified lesions. Safer compared with previous modalities.
IVL Use in PCI – IVL is now the largest calcium vessel prep device in PCI. Approximately 9% penetrated into PCI procedures.

Sex Specific Outcomes – Signal toward similar safety in women compared with higher event rates with other therapies. (ie high pressure BDC, Atherectomy)

Also, the interventionalists at OHSU are strong advocates.

Currently the Noridian MAC covers all the peripheral IVL as well as the C1761:
Catheter, transluminal intravascular lithotripsy, coronary use TPT code.

Cost:

The new MS-DRG codes and payments became effective on Oct. 1, 2023. Per the manufacturer, the new CPT code 92972 will add an additional $140 to the physician payment for the percutaneous coronary intervention (https://shockwavemedical.com/wp-content/uploads/2023/11/Coronary-IVL-Physician-Reimbursement-Coding-Guide.pdf).

Utilization

Since 1/2023, the previous temporary CPT 0715T was billed 5 times, each encounter was paid but some had a zero allowed amount which may indicate they were paid under an alternative payment methodology.

Other payer policies:

a. Reviewed in November 2020: NICE, Aetna and Cigna all consider coronary lithotripsy to be experimental
b. CMS 2023: is covering coronary lithotripsy
c. Regence BCBS 2023: Coronary intravascular lithotripsy is considered investigational for all indications.
d. Providence Health Plans 2023

2023 CPT Code Review: Coronary Lithotripsy

a. CDT 92972 (Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure) is listed as experimental

HERC staff summary:

Intravascular coronary artery lithotripsy has been studied only in cohort studies. No studies exist comparing lithotripsy to other types of coronary artery stenting procedures which report on outcomes such as avoidance of major adverse cardiac events (MACE). A recent NICE review found evidence of harms, although it is unknown how these rates of harm compare to other types of coronary artery interventions. A highly trusted evidence source (NICE) did not find sufficient evidence of effectiveness for this procedure. Private insurers are not covering this procedure currently. As pointed out by commenters, CMS is covering this procedure for Medicare.

Local experts and multiple comments support the use of this procedure as an option for treating patients with complicated conditions. The procedure prolongs the time required for coronary catheterization; however, CMS has recently increased the payment for the procedure. Therefore, it is unknown whether this procedure is likely to be overutilized.

This topic received 10 public comments, all in support of coverage. One comment was from the manufacturer and 9 were from practicing cardiologist who felt that this procedure is needed for successful treatment of difficult cases.

HERC staff recommend discussing two options. The first would be continued non-coverage. This option is consistent with the evidence of safety and effectiveness of this procedure, with is based solely on non-randomized, single arm, manufacturer sponsored trials (the DISRUPT CAD trials) with small sample sizes. It is also consistent with private payer coverage. The second option would be to add coverage as recommended by experts and public commenters as an option for difficult cases, and reassessing utilization to monitor for possible abuse.

HERC staff recommendation:

1) **Option 1**: do not cover intravascular lithotripsy
    a. Place CPT **92972** (Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)) on line 654
    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 654

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

Procedure Code	Intervention Description	Rationale	Last Review
92972	Coronary intravascular lithotripsy	Insufficient evidence of effectiveness	January 2024

2023 CPT Code Review: Coronary Lithotripsy

2) **Option 2:** add coverage for intravascular lithotripsy
    a. Place CPT **92972** (Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)) on the following lines:
        i. 45 CORONARY ARTERY ANOMALY
        ii. 69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
        iii. 97 HEART FAILURE
        iv. 188 CHRONIC ISCHEMIC HEART DISEASE
        v. 283 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

Coronary Lithotripsy

Disposition of Public Comments

Table of Contents

Discussion Table

IDs/#s	Summary of Issue	HERC Staff Response
All	Coronary lithotripsy is a tool that can help to successfully treat coronary stenosis in difficult cases	The evidence in this area is developing, and the technology has only been studied in relatively small cohort studies. Expert societies give this technology a 2b (weak) recommendation. While local expert input is valuable in making coverage decisions, OHP coverage of a procedure requires evidence that it is effective based on published literature.
A	Other payers are covering coronary lithotripsy	HERC staff were not able to identify any local private payers who are currently covering this procedure. CMS is covering coronary lithotripsy.

Commenters

Identification	Stakeholder
A	Ryan Sheffer – Shockwave Medical *[Submitted December 19, 2023]*
B	Jeffrey Marbach –OHSU provider *[Submitted December 19, 2023]*

Disposition of Public Comments

C	Judd Salamat, DO, FACC, FSCAI – Adventist Health *[Submitted December 19, 2023]*
D	Ethan Korngold, MD – OHP provider *[Submitted December 19, 2023]*
E	Richard Sohn, MD – OHP provider *[Submitted December 19, 2023]*
F	Joshua Roark – OHP provider *[Submitted December 20, 2023]*
G	Michael Wilson MD – OHP provider *[Submitted December 20, 2023]*
H	Timo Dygert, MD – cardiologist, OHP provider *[Submitted December 20, 2023]*
I	Jaekyoung Hong – OHP provider *[Submitted December 20, 2023]*
J	Keval Patel, MD – OHP provider *[Submitted December 20, 2023]*

Public Comments

ID/#	Comment	Disposition
A	Shockwave Medical is entering in our comments during your Open Comment period in support of Option 2 – in placing CPT 92972 into the same status as any PCI procedure for coronary artery anomaly, acute and subacute ischemic heart disease, MI [myocardial infarction] and HF [heart failure]. IVL should be seen as a simple to use procedure to treat severely calcified lesions prior to stent placement. IVL should be seen as a treatment option for only a small percentage of patients where atherectomy is not the best option based on the anatomy and are mainly for lesions in the left main, that present with nodular calcium lesions, long and multiple lesions that could be of both eccentric and concentric types. These types of hard-to-treat lesions in the coronary space need a safe modality that is highly reproducible. This is what IVL brings to the treatment algorithm and practitioners that are in your network. By preventing them this option would be short sited, especially with as much safety and efficacy data that we have published in highly reputable journals. With this we have achieved coverage at both your Medicare MAC Noridian, and well as the largest Medicaid plan in the country in Medi-CAL. We also have coverage policies across the country for both commercial and Medicare Advantage	*Thank you for your comments. HERC staff could not independently verify that Medi-Cal covers coronary lithotripsy. However, CMS is covering this procedure. HERC staff have searched for additional private payer coverage and found that Regence BCBS and Providence consider this technology to be experimental.*

Disposition of Public Comments

ID/#	Comment	Disposition
	plans (Humana, BCBS Plans and Medica) that have members in Oregon. Yes, we still have not removed non-coverage with all commercial payors across the country, but we are moving towards this in 2024. We also assume that your state Medicaid plan would follow the Federal Mandates (see citation reference) of benefits coverage laid out by CMS. In the United States, according to federal law, Part C providers must provide their beneficiaries with all services and supplies that Original Medicare Parts A and B cover. They must also provide any additional benefits proclaimed in their Part C policy. Policies can provide additional benefits that are approved by the Centers for Medicare & Medicaid Services (CMS). These must be services that are not covered by Original Medicare Parts A and B. In some policies, the additional benefits may also include the reduction of premiums, deductibles, and coinsurance payments found in Original Medicare (Parts A and B) coverage. If not, then we help that we can at least meet to discuss coverage of IVL for a very select group of coronary patients that you would feel comfortable in covering prior to a stent placement. We would appreciate any additional correspondence in reviewing our clinical and safety data with these types of members, as well as assisting in putting together a patient selection criteria that would suite your Medicaid plan as well as your interventional cardiologists and vascular surgeons that would like to utilize IVL for select patients. Thank you for this comprehensive process in order to have a more open discussion around your current and future medical policy coverage decisions.	
B	Coronary Lithotripsy is a novel technology that has become indispensable in the cath lab. With the aging population we are seeing more extensive coronary artery disease in recent years, which is sure to continue to grow. The main driver of failure of coronary stents is poor stent expansion and stent apposition. The main limiting factor causing stent incomplete stent expansion and apposition is heavily calcified coronary arteries. Coronary Lithotripsy	*Thank you for your comments. Your clinical experience is valuable for the HERC to consider.*

Disposition of Public Comments

ID/#	Comment	Disposition
	addresses this problem by providing a low risk therapy that can address the extensive coronary calcification that we are seeing. The benefits of this technology have been recognized by the FDA and CMS. In order to continuing to provider Oregonians with first class care it is essential that the Oregon tax payers have access to this therapy.	*The HERC does not consider FDA approval to be sufficient evidence of effectiveness by itself.*
C	I am an interventional cardiologist and Medical Director of the cardiac catheterization lab at Adventist Health Portland. I have been in practice for almost 7 years performing a high volume of coronary and peripheral vascular interventions. Intravascular lithotripsy is becoming an important tool in treating complex coronary and peripheral vascular disease in a safe and effective manner. It allows treatment of heavily calcified, high-risk lesions with low rates of vessel dissection, perforation, or no-reflow complications that can occur with rotational or orbital atherectomy devices. In my practice, it is particularly beneficial in patients who are severely ill or frail and would not tolerate atherectomy. Denying coverage of this treatment modality would be a disservice to our patients, as it limits our ability to provide safe and effective care with tools that are currently available. There is ample evidence supporting its safety and effectiveness, and it is widely being used across the US and Europe	*Thank you for your comment.* *All literature submitted were trials that were included in the systematic reviews already reviewed by HERC*
D	I urge you to support reimbursement for coronary lithotripsy. This is a safe, proven, and effective modality for treating calcified coronary artery disease. This is an important option for treating patients in the Oregon Health Plan. Thank you for your consideration.	*Thank you for your comment.*
E	Coronary stent placement is a mainstay of heart disease therapy, especially for treatment of heart attacks and chronic chest pains due to coronary artery blockages. The most difficult type of blockage to treat are those with large amounts of calcium. Calcium can prevent optimized stent deployment which can then lead to increased risk of stent complications and stent failure. In	*Thank you for your comment. Your clinical perspective is valuable for the HERC in their deliberations.*

Disposition of Public Comments

ID/#	Comment	Disposition
	some cases, the calcium would prevent stent placement altogether, thereby leaving the patient at risk for recurrent heart attacks and/or debilitating persistent symptoms leading to poor quality of life. While there are already specialized tools for dealing with calcium in order to allow for optimized stent placement, there are situations for which coronary lithotripsy is especially well-suited and at times cannot be treated without coronary lithotripsy. Examples include very thick calcium that wraps all the way around the circumference of a coronary artery as well as bulky rock-like calcium nodules that protrude into the middle of a coronary artery. These are not uncommon scenarios, and without full treatment of the calcium, coronary stent placement is likely to be unsuccessful and possibly impossible in some cases. As an interventional cardiologist, I make the decision of whether to place a stent based on the patient's condition. Once a decision is made to place a stent, it is critical that we have all the tools we need to ensure a safe, successful, and durable result in order to achieve the best outcomes for our patients. Otherwise, we cannot offer the patient the best treatments for their condition. So that we can achieve the best outcomes for our patients, I strongly support OHP coverage for coronary lithotripsy.	*HERC staff agree with the commenter that we all want the best outcomes for our patients; however, best outcomes are obtained using evidence based treatments.*
F	I am an interventional cardiologist and this therapy has become integral to my practice. IVL helps to treat calcified lesions that were previously untreatable or required higher risk procedures to restore bloodflow to the heart. Please consider supporting this therapy for the people of Oregon.	*Thank you for your comment. Your clinical perspective is valuable for the HERC in their deliberations.*
G	I am a high volume interventional cardiologist and Quality Director for such procedures. The treatment of heavily calcified and resistant lesions is one the most difficult and hazardous interventions we often encounter. Coronary IVL has made it possible to treat these lesions with a lower initial risk of perforation/pericardial tamponade and thus allow full stent expansion to reduce the risk of recurring blockage (restenosis). IVL is a critically important	*Thank you for your comment. Your clinical perspective is valuable for the HERC in their deliberations.*

Disposition of Public Comments

ID/#	Comment	Disposition
	tool and is currently used selectively in such cases. I strongly favor reimbursement for this device.	
H	This procedure is a fundamental tool for treating certain patients with acute and chronic complex coronary artery disease. Removing this treatment option would have a detrimental effect on some of our most vulnerable patients who do not have viable alternatives.	*Thank you for your comment. This therapy is currently not covered, so the HERC is not considering removal of coverage.*
I	Coronary lithotripsy is a vital tool for interventional cardiologists in treating heavily calcified coronary vessels. There are multiple cases that I have done where stenting would not have been possible without lithotripsy balloons. In addition, I have used IVL in multiple transcatheter aortic valve replacements (TAVR) cases. We use IVL to treat severe iliac disease and this technology allows me to deliver the stent valve through transfemoral access. These are VERY DIFFERENT than regular balloons. Please reconsider your decision.	*Thank you for your comment. Your clinical perspective is valuable for the HERC in their deliberations.*
J	i'm a cardiologist and for patients with calcified plaque coronary lithotripsy helps with delivery of the stent and overall better angiographic results post pci [percutaneous coronary intervention]	*Thank you for your comment. Your clinical perspective is valuable for the HERC in their deliberations.*

References Provided by Commenters

ID	References
A	Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections 10.2 – Basic Rule (Rev. 121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Disposition of Public Comments

ID	References
B	None provided
C	Ali ZA, Kereiakes DJ, Hill JM, Saito S, Di Mario C, Honton B, Gonzalo N, Riley RF, Maehara A, Matsumura M, Shin D, Stone GW, Shlofmitz RA. Impact of Calcium Eccentricity on the Safety and Effectiveness of Coronary Intravascular Lithotripsy: Pooled Analysis From the Disrupt CAD Studies. Circ Cardiovasc Interv. 2023 Oct;16(10):e012898. doi: 10.1161/CIRCINTERVENTIONS.123.012898. Epub 2023 Oct 17. PMID: 37847770; PMCID: PMC10573097. Ali, Z, Kereiakes, D, Hill, J. et al. Safety and Effectiveness of Coronary Intravascular Lithotripsy for Treatment of Calcified Nodules. J Am Coll Cardiol Intv. 2023 May, 16 (9) 1122–1124. https://doi.org/10.1016/j.jcin.2023.02.015 Ali ZA, Nef H, Escaned J, Werner N, Banning AP, Hill JM, De Bruyne B, Montorfano M, Lefevre T, Stone GW, Crowley A, Matsumura M, Maehara A, Lansky AJ, Fajadet J, Di Mario C. Safety and Effectiveness of Coronary Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Stenoses: The Disrupt CAD II Study. Circ Cardiovasc Interv. 2019 Oct;12(10):e008434 Barbato E, Shlofmitz E, Milkas A, Shlofmitz R, Azzalini L, Colombo A. State of the art: evolving concepts in the treatment of heavily calcified and undilatable coronary stenoses - from debulking to plaque modification, a 40-year-long journey. EuroIntervention. 2017 Aug 25;13(6):696-705 Gunnar Tepe, Marianne Brodmann, William Bachinsky, Andrew Holden, Thomas Zeller, Sarang Mangalmurti, Claus Nolte-Ernsting, Renu Virmani, Sahil A. Parikh, William A. Gray. Intravascular Lithotripsy for Peripheral Artery Calcification: Mid-term Outcomes from the Randomized Disrupt PAD III Trial, Journal of the Society for Cardiovascular Angiography & Interventions, Volume 1, Issue 4, 2022, 100341, ISSN 2772-9303, https://doi.org/10.1016/j.jscai.2022.100341.
D	None provided
E	None provided
F	None provided
G	None provided
H	None provided
I	None provided
J	None provided

Section 8.0

New Discussion Items

PSA for Prostate Cancer Screening

Plain Language Summary:

Coverage question: Should OHP cover a test to check for prostate cancer (prostate specific antigen PSA)?

Should OHP cover this treatment? Yes. There are two options to consider:
Option 1: Add the test with no special limits
Option 2: Add the test with a guideline to include the test only for men aged 55-69 years.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should coverage be added for screening PSA tests?

Question source: Brian Duty, OHSU urologist and VBBS member

Background: Prostate specific antigen (PSA) testing can be used to screen for prostate cancer. PSA is a protein produced by normal, as well as malignant, cells of the prostate gland. In addition to prostate cancer, several benign (not cancerous) conditions can cause a person's PSA level to rise, particularly prostatitis (inflammation of the prostate) and benign prostatic hyperplasia (BPH) (enlargement of the prostate).

The United States Preventive Services Task Force (USPSTF) had a "D" recommendation for prostate cancer screening when the procedure code for screening PSA was first prioritized. This recommendation was later changed to an "I" recommendation, and then to a "C" recommendation in 2018 for men under age 70.

Dr. Duty raised concerns about lack of coverage for screening PSA testing. Prostate cancer has a significantly higher incidence in Black men, as well as men with a family history of prostate cancer. In these groups, the discussion between clinician and patient may result in a recommendation for testing. Lack of coverage of screening PSA does not allow such testing to occur.

Currently, PSA testing for symptomatic men (with urinary symptoms, symptoms of enlarged prostate, symptoms of cancer, etc.) is covered on line 3.

Previous HSC/HERC reviews:

The last PSA screening discussion was in 2004. There was a discussion about the prevention tables, and a notation that PSA screening for prostate cancer had been updated to an "I" recommendation (previously was "D"). No changes were made to the prevention table.

PSA for Prostate Cancer Screening

Current Prioritized List/Coverage status:

HCPCS G0103 (Prostate cancer screening; prostate specific antigen test (psa)) is listed as "Never Reviewed"

ICD-10 Z12.5 (Encounter for screening for malignant neoplasm of prostate) is on line 615 PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS

On the Diagnostic Procedures file [note: these tests are for symptomatic patients]:
CPT 84152 PSA (prostate specific antigen) measurement, complexed
CPT 84153 PSA (prostate specific antigen) measurement, total
CPT 84154 PSA (prostate specific antigen) measurement, free

Evidence:

1) **USPSTF 2018** evidence review of PSA screening
    a. N=24 studies
    b. Three fair-quality RCTs (n = 647 906) assessed the effect of PSA screening on prostate cancer morbidity and mortality and all-cause mortality: the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial,27 the European Randomized Study of Screening for Prostate Cancer (ERSPC),28 and the Cluster Randomized Trial of PSA Testing for Prostate Cancer (CAP)1
    c. Prostate Cancer Incidence
        i. Cumulative incidences of prostate cancer in the screening and control groups were 11.1% and 9.9%, respectively, at 13 years of median follow-up in the PLCO trial (RR, 1.12 [95% CI, 1.07-1.17]), 10.2% and 6.0% at 13 years of median follow-up in the ERSPC trial (RR, 1.57 [95% CI, 1.51-1.62]), and 4.3% and 3.6% at 10 years of median follow-up in the CAP trial (RR, 1.19 [95% CI, 1.14-1.25]). Observed risk differences in prostate cancer incidence indicate a number needed to invite of 84 men in the PLCO trial (95% CI, 59- 144), 26 men in the ERSPC trial (95% CI, 24-29), and 154 men in the CAP trial (95% CI, 128-192) for 1 additional man to be diagnosed with prostate cancer.
    d. Prostate cancer mortality
        i. At a median follow-up of 14.8 years in the PLCO trial, the prostate cancer–specific mortality rate was 4.8 per 10 000 person-years among men in the intervention group and 4.6 per 10 000 personyears among men in the control group (RR, 1.04 [95% CI, 0.87- 1.24])
        ii. After median follow-up periods ranging from 10 years in the CAP trial to 14.8 years in the PLCO trial, randomization to screening (relative to control) was not associated with statistically significantly reduced all-cause mortality in any of the 3 trials (CAP trial: RR, 0.99 [95% CI,0.94-1.03]; ERSPC trial: RR, 1.00 [95% CI,0.98-1.02]; PLCO trial: RR, 0.98 [95% CI, 0.95-1.00])
    e. Harms
        i. Of 61 604 men screened in the European trial, 17.8% received false-positive results. In 3 cohorts (n = 15 136), complications requiring hospitalization occurred in 0.5% to 1.6% of men undergoing biopsy after abnormal screening findings. Overdiagnosis was estimated to occur in 20.7% to 50.4% of screen-detected cancers. In an RCT of men with screen-detected prostate cancer (n =

1643), neither radical prostatectomy (hazard ratio [HR], 0.63 [95% CI, 0.21-1.93]) nor radiation therapy (HR, 0.51 [95% CI, 0.15-1.69]) were associated with significantly reduced prostate cancer mortality vs active monitoring, although each was associated with significantly lower risk of metastatic disease. Relative to conservative management, radical prostatectomy was associated with increased risk of urinary incontinence (pooled RR, 2.27 [95% CI, 1.82-2.84]; 3 trials; n = 1796) and erectile dysfunction (pooled RR, 1.82 [95% CI, 1.62-2.04]; 2 trials; n = 883). Relative to conservative management (8 cohort studies; n = 3066), radiation therapy was associated with increased risk of erectile dysfunction (pooled RR, 1.31 [95% CI, 1.20-1.42])

   f. Conclusions: PSA screening may reduce prostate cancer mortality risk but is associated with false-positive results, biopsy complications, and overdiagnosis. Compared with conservative approaches, active treatments for screen-detected prostate cancer have unclear effects on long-term survival but are associated with sexual and urinary difficulties

2) **Basourakos 2022**, Harm-to-Benefit of Three Decades of Prostate Cancer Screening in Black Men
   a. Modeling study using large US health databases
   b. For men of all races, we estimated 1.5 to 1.9 million (range between estimation approaches) overdiagnosed and 0.9 to 1.5 million overtreated prostate cancers by 2016. Assuming that half of the 270,000 prostate cancer deaths avoided by 2016 were attributable to screening, the NND and the NNT would be 11 to 14 and 7 to 11 for men of all races and 8 to 12 and 5 to 9 for Black men, respectively. Alternative estimates incorporating a lag between incidence and mortality resulted in a NND and a NNT for Black men that reached well into the low single digits.
   c. Black men have a higher incidence of and mortality from prostate cancer compared with men of other races. Although there is debate about the etiology of this disparity, the NND and NNT for screening in Black men are more favorable than those for the general population. Even under the least optimistic scenarios, the estimated NNTs for Black men were single-digit numbers. This finding is particularly important if we take into consideration that once a man is diagnosed with prostate cancer, Black race does not appear to be associated with inferior long-term outcomes as long as there is equal access to care and standardized treatment. Considering the poor representation of Black men in randomized PSA screening studies, our findings provide reason to rethink current guidelines on PSA screening in this population.
   d. Conclusions: We also estimate that the net benefit of PSA screening is greater for Black men than the general population. The potential for overdiagnosis and overtreatment remains, although these harms may be mitigated by contemporary protocols for triaging men before biopsy and active surveillance for men with low-risk disease. These data should prompt policy makers to reconsider the utility of PSA-based prostate cancer screening, particularly for Black men.

Expert guidelines:

1) USPSTF 2018
   a. Men aged 55 to 69 years
      i. For men aged 55 to 69 years, the decision to undergo periodic prostate-specific antigen (PSA)-based screening for prostate cancer should be an individual one. Before deciding whether to be screened, men should have an opportunity to

discuss the potential benefits and harms of screening with their clinician and to incorporate their values and preferences in the decision. Screening offers a small potential benefit of reducing the chance of death from prostate cancer in some men. However, many men will experience potential harms of screening, including false-positive results that require additional testing and possible prostate biopsy; overdiagnosis and overtreatment; and treatment complications, such as incontinence and erectile dysfunction. In determining whether this service is appropriate in individual cases, patients and clinicians should consider the balance of benefits and harms on the basis of family history, race/ethnicity, comorbid medical conditions, patient values about the benefits and harms of screening and treatment-specific outcomes, and other health needs. Clinicians should not screen men who do not express a preference for screening.

ii. Grade C

b. Men 70 years and older

iii. The USPSTF recommends against PSA-based screening for prostate cancer in men 70 years and older.

iv. Grade D

Other payer policies:

2) CMS NCD 2006: covers prostate specific antigen (PSA) blood tests once every 12 months for men over 50
3) Aetna 2023
    a. Prostate-specific antigen (PSA) screening
        i. As a preventive service for men 45 years of age and older who are considered average-risk for prostate cancer, and for men 40 years of age and older who are considered at high-risk for prostate cancer. Risk groups include African-American men and men with a family history of prostate cancer.
        Note: Routine prostate cancer screening for members 75 years of age or older is considered not medically necessary unless life expectancy is greater than or equal to 10 years.
        ii. Annual PSA screening when used for routine screening in men with previously elevated PSAs or signs or symptoms of disease.
    b. PSA testing for men of all ages with signs or symptoms of prostate cancer, and for follow-up of men with prostate cancer.
4) Cigna 2023
    a. Covers all PSA procedure codes with no guidelines/restrictions
5) Premara BCBS 2023: covers all PSA procedure codes
    a. Comment: The USPSTF recommends that informing men aged 55 to 69 years about the potential benefits and harms of prostate-specific antigen (PSA)–based screening for prostate cancer

PSA for Prostate Cancer Screening

HERC staff summary:

PSA screening has been "upgraded" from a "D" recommendation to a "C" recommendation by the USPSTF since the last HERC review. There is evidence that screening has a more favorable benefit/harm ratio in Black men and men with a family history of prostate cancer. The current prioritization of prostate cancer screening below the funding line does not allow individualized clinician-patient decision making in this area. All private payers surveyed cover prostate cancer screening. When surveyed, the CCO medical directors did not feel that a guideline was needed for PSA screening as it was low cost and not an item for which they would require prior authorization.

HERC staff recommends moving prostate cancer screening diagnosis and procedure codes to coverage As PSA screening is not necessarily a "Preventive Service with Evidence of Effectiveness," coverage could be added in one of two ways: 1) add the procedure and diagnostic code to the Diagnostic Procedures file (consistent with CCO medical director input) or 2) add the procedure and diagnostic code to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS and modify the preventive services guideline to align with USPSTF recommendations. Option 2 would likely not result in any denials as the CCO medical directors we consulted have indicated no plans to review or restrict this test; however, it would be consistent with the evidence and USPSTF guidance.

HERC staff recommendations:

1) **Option 1**: add screening PSA coverage with no guideline note changes
    a. Add HCPCS G0103 (Prostate cancer screening; prostate specific antigen test (psa)) to the Diagnostic Procedures File
    b. Remove ICD-10 Z12.5 (Encounter for screening for malignant neoplasm of prostate) from line 615 PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS
        i. Add ICD-10 Z12.5 to the Diagnostic Procedures File
2) **Option 2**: add screening PSA coverage with a guideline
    a. Add HCPCS G0103 (Prostate cancer screening; prostate specific antigen test (psa)) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
    b. Add ICD-10 Z12.5 (Encounter for screening for malignant neoplasm of prostate) to line 3
    c. Modify GN106 as shown below

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,615

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2023
    1) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations/
        a) Treatment of falls prevention with exercise interventions is included on Line 292.
    2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.
B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
        a) http://brightfutures.aap.org. Periodicity schedule available at https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf Plan.
    2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child

PSA for Prostate Cancer Screening

between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.

C) Health Resources **and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines (revised December 2022**). Available at https://www.hrsa.gov/womens-guidelines as of October 30, 2023.

D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf

1) COVID-19 vaccines are intended to be included on this line even if the specific administration code(s) do not yet appear on the line when the vaccine has both 1) FDA approval or FDA emergency use authorization (EUA) and 2) ACIP recommendation.
2) Other ACIP recommended vaccines not on the routine vaccine schedule are included on Line 3 when administered according to recommendations specified in the Morbidity and Mortality Weekly Review (MMWR) as required by federal law: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html (retrieved 8/8/2023).

Colorectal cancer screening is included on Line 3 for average-risk adults aged 45 to 75, using one of the following screening programs:

A) Colonoscopy every 10 years
B) Flexible sigmoidoscopy every 5 years
C) Fecal immunochemical test (FIT) every year
D) Guaiac-based fecal occult blood test (gFOBT) every year

CT colonography (CPT 74263), FIT-DNA (CPT 81528) and mSEPT9 (HCPCS G0327) are included on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS.
Colorectal cancer screening for average-risk adults aged 76 to 85 is covered after informed decision making between patients and clinicians which includes consideration of the patient's overall health, prior screening history, and preferences.
Supervised evidence-based exercise programs for fall prevention for persons aged 65 or older OR younger patients who are at increased risk of falls are included on Line 3 using CPT 98961 or 98962 or HCPCS S9451. HCPCS S9451 is only included on Line 3 for the provision of supervised exercise therapy for fall prevention. Programs should be culturally tailored/culturally appropriate when feasible.

Note: CPT 96110 (Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument) can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.

PSA testing (HCPCS G0103) is included on line 3 for men 55-69 years of age who have had a risk benefit discussion with their provider. PSA testing is included on line 615 PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS for men under age 55 or over 70 years of age.

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

JAMA | US Preventive Services Task Force | EVIDENCE REPORT

Prostate-Specific Antigen–Based Screening for Prostate Cancer
Evidence Report and Systematic Review for the US Preventive Services Task Force

Joshua J. Fenton, MD, MPH; Meghan S. Weyrich, MPH; Shauna Durbin, MPH; Yu Liu, MS; Heejung Bang, PhD; Joy Melnikow, MD, MPH

IMPORTANCE Prostate cancer is the second leading cause of cancer death among US men.

OBJECTIVE To systematically review evidence on prostate-specific antigen (PSA)–based prostate cancer screening, treatments for localized prostate cancer, and prebiopsy risk calculators to inform the US Preventive Services Task Force.

DATA SOURCES Searches of PubMed, EMBASE, Web of Science, and Cochrane Registries and Databases from July 1, 2011, through July 15, 2017, with a surveillance search on February 1, 2018.

STUDY SELECTION English-language reports of randomized clinical trials (RCTs) of screening; cohort studies reporting harms; RCTs and cohort studies of active localized cancer treatments vs conservative approaches (eg, active surveillance, watchful waiting); external validations of prebiopsy risk calculators to identify aggressive cancers.

DATA EXTRACTION AND SYNTHESIS One investigator abstracted data; a second checked accuracy. Two investigators independently rated study quality.

MAIN OUTCOMES AND MEASURES Prostate cancer and all-cause mortality; false-positive screening results, biopsy complications, overdiagnosis; adverse effects of active treatments. Random-effects meta-analyses were conducted for treatment harms.

RESULTS Sixty-three studies in 104 publications were included (N = 1 904 950). Randomization to PSA screening was not associated with reduced risk of prostate cancer mortality in either a US trial with substantial control group contamination (n = 76 683) or a UK trial with low adherence to a single PSA screen (n = 408 825) but was associated with significantly reduced prostate cancer mortality in a European trial (n = 162 243; relative risk [RR], 0.79 [95% CI, 0.69-0.91]; absolute risk reduction, 1.1 deaths per 10 000 person-years [95% CI, 0.5-1.8]). Of 61 604 men screened in the European trial, 17.8% received false-positive results. In 3 cohorts (n = 15 136), complications requiring hospitalization occurred in 0.5% to 1.6% of men undergoing biopsy after abnormal screening findings. Overdiagnosis was estimated to occur in 20.7% to 50.4% of screen-detected cancers. In an RCT of men with screen-detected prostate cancer (n = 1643), neither radical prostatectomy (hazard ratio [HR], 0.63 [95% CI, 0.21-1.93]) nor radiation therapy (HR, 0.51 [95% CI, 0.15-1.69]) were associated with significantly reduced prostate cancer mortality vs active monitoring, although each was associated with significantly lower risk of metastatic disease. Relative to conservative management, radical prostatectomy was associated with increased risk of urinary incontinence (pooled RR, 2.27 [95% CI, 1.82-2.84]; 3 trials; n = 1796) and erectile dysfunction (pooled RR, 1.82 [95% CI, 1.62-2.04]; 2 trials; n = 883). Relative to conservative management (8 cohort studies; n = 3066), radiation therapy was associated with increased risk of erectile dysfunction (pooled RR, 1.31 [95% CI, 1.20-1.42]).

CONCLUSIONS AND RELEVANCE PSA screening may reduce prostate cancer mortality risk but is associated with false-positive results, biopsy complications, and overdiagnosis. Compared with conservative approaches, active treatments for screen-detected prostate cancer have unclear effects on long-term survival but are associated with sexual and urinary difficulties.

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Harm-to-Benefit of Three Decades of Prostate Cancer Screening in Black Men

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Abstract

BACKGROUND—Prostate-specific antigen screening has profoundly affected the epidemiology of prostate cancer in the United States. Persistent racial disparities in outcomes for Black men warrant re-examination of the harms of screening relative to its cancer-specific mortality benefits in this population.

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Author disclosures and other supplementary materials are available at evidence.nejm.org.

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METHODS—We estimated overdiagnoses and overtreatment of prostate cancer for men of all races and for Black men 50 to 84 years of age until 2016, the most recent year with treatment data available, using excess incidence relative to 1986 based on the Surveillance, Epidemiology, and End Results registry and U.S. Census data as well as an established microsimulation model of prostate cancer natural history. Combining estimates with plausible mortality benefit, we calculated numbers needed to diagnose (NND) and treat (NNT) to prevent one prostate cancer death.

RESULTS—For men of all races, we estimated 1.5 to 1.9 million (range between estimation approaches) overdiagnosed and 0.9 to 1.5 million overtreated prostate cancers by 2016. Assuming that half of the 270,000 prostate cancer deaths avoided by 2016 were attributable to screening, the NND and the NNT would be 11 to 14 and 7 to 11 for men of all races and 8 to 12 and 5 to 9 for Black men, respectively. Alternative estimates incorporating a lag between incidence and mortality resulted in a NND and a NNT for Black men that reached well into the low single digits.

CONCLUSIONS—Complementary approaches to quantifying overdiagnosis indicate a harm-benefit tradeoff of prostate-specific antigen screening that is more favorable for Black men than for men of all races considered together. Our findings highlight the need to account for the increased value of screening in Black men in clinical guidelines. (Funded by the Patient-Centered Outcomes Research Institute, the National Cancer Institute, the Bristol Myers Squibb Foundation, and the Damon Runyon Cancer Research Foundation.)

Introduction

The adoption of prostate-specific antigen (PSA) screening in the United States beginning around 1987 has profoundly changed the epidemiology of prostate cancer, with a rapid doubling of incidence and, by 2015, a 50% decrease in annual prostate cancer mortality.[1] Randomized trial data support a significant mortality benefit to PSA screening.[2,3] However, uncertainty remains regarding how much PSA screening (as opposed to advances in the therapeutic armamentarium) is responsible for declining mortality rates[4] as well as how the benefits of screening measure up to the harms of finding and treating cancers that never would have caused morbidity or mortality (i.e., overdiagnosis and overtreatment). This uncertainty is even greater for Black men, who have historically been underrepresented in diagnostic and therapeutic clinical trials despite having nearly double the risk of prostate cancer death compared with the general population. This difference in mortality is one of the largest racial disparities in any cancer.[5]

In 2009, Welch and Albertsen,[6] using data from the Surveillance, Epidemiology, and End Results (SEER) program and the U.S. Census, calculated that the number needed to diagnose (NND; defined as the number of men overdiagnosed with prostate cancer per prostate cancer death prevented) and the number needed to treat (NNT; defined as the number of patients with prostate cancer overtreated per prostate cancer death prevented) for men of all races were 23 and 18, respectively. Their calculations used the excess number of men diagnosed each year over the period from 1986 to 2005 relative to 1986 as proxies for the number overdiagnosed.[6] For benefit, they assumed that all observed decreases in prostate cancer mortality were secondary to screening, which was an admittedly optimistic assumption.

Peristeen Transanal Irrigation System

Plain Language Summary:

Coverage question: Should OHP cover a system to assist with bowel problems by using anal irrigation?

Should OHP cover this treatment? Yes, medical studies show this systems helps certain patients.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should the Peristeen Anal irrigation system be covered for certain types of constipation and bowel dysfunction?

Question source: Coloplast Corp.

Background: Peristeen Plus (Coloplast) is a transanal irrigation system for managing bowel dysfunction. It instills water into the colon through a rectal catheter. The manufacturer recommends consideration of Peristeen when medications and other conservative bowel measures pair to provide symptom relief, as a way of avoiding more invasive surgical procedures. It is approved for treatment of neurogenic bowel dysfunction that results in fecal incontinences or chronic constipation.

Neurogenic bowel dysfunction can result from a variety of causes, including spinal cord injury, spina bifida, muscular dystrophy, Parkinson's disease, injury to the rectum, or slow transit constipation. Conservative measures include laxatives, fiber, diet changes, and over the counter enemas. Severe cases may require surgery.

Previous HSC/HERC reviews: none

Current Prioritized List/Coverage status:

Listed as never reviewed:
HCPCS A4459 Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type
HCPCS A4453 Rectal catheter for use with the manual pump-operated enema system, replacement only

ICD-10-CM K59.2 (Neurogenic bowel, not elsewhere classified) is on line 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES

Peristeen Transanal Irrigation System

Evidence:

1) **NICE 2022**, Peristeen Plus transanal irrigation system for managing bowel dysfunction https://www.nice.org.uk/guidance/mtg36/resources/peristeen-plus-transanal-irrigation-system-for-managing-bowel-dysfunction-pdf-64371998671045
    a. N=13 studies in adults, N=11 studies in children, N=3 studies on adverse events
        i. 1 RCT (Christensen 2006), all other studies were observational
    b. Christensen et al. (2006) was a randomized controlled trial in adults (n=87) that showed statistically significant improvements in bowel-related patient-reported outcomes for Peristeen compared with standard bowel care over 10 weeks' follow up
    c. 12 observational studies in adults at high risk of bias. Despite these uncertainties, the evidence showed that adults who choose to continue using Peristeen report improved clinical outcomes.
    d. All the studies in children were non-comparative, observational case series (6 observational and 5 retrospective). The studies showed improvements in some outcomes for children using Peristeen but NICE considered the overall published evidence in children to be of low quality
    e. Bowel perforation is a serious adverse event that is potentially linked to the use of Peristeen. It was a rare complication (2 in 1 million irrigations) reported in the global audit by Christensen et al. (2016)
    f. Conclusion: The case for adopting Peristeen Plus for transanal irrigation in people with bowel dysfunction is supported by the evidence. Peristeen Plus can reduce the severity of constipation and incontinence, improve quality of life and promote dignity and independence.

Expert guidelines:

1) **Johns 2020,** management of neurogenic bowel dysfunction (NBD) in adults after spinal cord injury
    a. Paralyzed Veterans of America and the Consortium of Spinal Cord Medicine
    b. Transanal irrigation (TAI) is recommended in individuals with NBD who have insufficient results with basic bowel management. (Level - I; Strength - A; Agreement - strong)
        i. Experts recommend TAI for individuals who are refractory to conservative methods, and who have a low rectal volume at defecation urge and at maximal capacity
        ii. absolute contraindications for TAI: anal or rectal stenosis, active inflammatory bowel disease, acute diverticulitis, colorectal cancer, ischemic colitis, rectal surgery within the previous 3 months, or endoscopic polypectomy within the previous 4 weeks. Relative contraindications for TAI are severe diverticulosis; dense sigmoid disease; history of diverticulitis, diverticular abscess, or rectal surgery; long-term steroid medication; fecal impactions; painful anal conditions; planned or current pregnancy; bleeding diathesis or anticoagulant therapy (except aspirin or clopidogrel); and severe autonomic dysreflexia
        iii. Evidence supports the success of TAI in treating constipation (40% to 63% of cases), fecal incontinence (47% to 72.7% of cases), and prolonged defecation time. In addition, TAI improves symptom-related quality of life (QOL), with 2 studies indicating increased satisfaction and opinion of intestinal function. In an observational study, TAI reduced or eliminated pharmaceutical use in 28.6% of subjects. Although TAI is considered a second-line treatment for conservative

bowel management, it outperformed or matched conservative treatment in all parameters in a comparative RCT

iv. The most common adverse events in the single TAI RCT were abdominal pain (15.7% of all bowel observations), sweating (10.5%), chills (7.0%), dizziness (5.4%), and pronounced general discomfort (5.9%). A global audit of TAI (Peristeen)-related bowel perforation found the overall average risk to be 6 per million procedures, with 83% of perforations resulting in emergency surgery

Other payer policies:

1) Medicare LCD 2021
    a. Manual pump enema systems (e.g., Peristeen - Coloplast, Minneapolis, MN) or gravity-administered enema systems do not meet the Durable Medical Equipment (DME) benefit because these devices do not meet the requirement of durability. In addition, these devices do not meet the Prosthetic Benefit because they do not replace a non-functioning internal body organ
    b. Enema systems (gravity and manual pump), codes A4458 and A4459 respectively, will be denied as statutorily non-covered
2) Oklahoma Medicaid
    a. The Peristeen Plus Anal Irrigation System will be considered medically necessary as part of a bowel management program when all the following criteria are met:
        i. Used for the management of neurogenic bowel dysfunction; and
        ii. Member is age 2 years or older; and
        iii. Member suffers from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures that significantly impact the individual's quality of life (i.e. inability to participate fully in school or work); and
        iv. Initial management involving diet, bowel habit, laxatives, or constipating medications has failed; and
        v. For reauthorization requests only, there is documentation in the provider notes that:
            1. The member is consistently using the system as directed by their provider; and
            2. The system has shown to be effective in managing fecal incontinence and/or chronic constipation.
    b. The Peristeen Plus Anal Irrigation System is contraindicated in the following scenarios:
        i. Known anal or colorectal stenosis
        ii. Colorectal cancer, radiotherapy to the pelvis, and recent abdomino-perineal surgery
        iii. Active inflammatory bowel disease, diverticulitis, and ischemic colitis
        iv. Chronic and complex diverticular disease
        v. Abdominal, anal, or colorectal surgery within the last 3 months
        vi. Within 4 weeks of endoscopic polypectomy, recent colonic biopsy, recent endoscopic mucosal resection and recent endoscopic sub-mucosal dissection
        vii. Severe autonomic dysreflexia, or during spinal cord shock phase
        viii. In patients who are pregnant and have not used the system before (if the individual is pregnant and has never used anal irrigation before, the individual should not start the irrigation procedure during pregnancy).
3) Connecticut Medicaid

a. The PAI system may be considered medically necessary as part of a bowel management program when the following criteria are met:
    i. The system is used for the management of chronic neurogenic bowel dysfunction;
    ii. The individual is age 2 years or older;
    iii. The individual suffers from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures that significantly impact the individual's quality of life (i.e. inability to participate fully in work or school);
    iv. Initial management involving diet, bowel habit, laxatives or constipating medications have failed;
    v. The individual has no known contraindications (see below); and
    vi. For reauthorizations requests only, there is documentation in the physician notes that: 1. The individual is consistently using the system as directed by their physician; and 2. The system has shown to be effective in managing fecal incontinence and/or chronic constipation.
    vii. PAI is contraindicated in the following scenarios: • Known anal or colorectal stenosis • Colorectal cancer, radiotherapy to the pelvis, and recent abdomino-perineal surgery • Active inflammatory bowel disease, diverticulitis and ischemic colitis

4) Aetna 2023
    a. Aetna considers the following bowel management devices medically necessary:
        i. Manual pump enema systems (e.g., Peristeen Anal Irrigation System, Coloplast, Minneapolis, MN) for the management of chronic neurogenic bowel when initial management involving diet, bowel habit, laxatives or constipating mediations has failed.

Peristeen Transanal Irrigation System

HERC staff summary:

Peristeen anal irrigation has been found to be an evidenced-supported method to treat neurogenic bowel dysfunction in patients who do not respond to conservative measures. This system has been found to have evidence of effectiveness by a highly trusted evidence source (NICE) and is covered by some other payers.

Five public comments were received regarding this topic that all recommended coverage. These comments were from manufacturers, providers, and families of patients.

HERC staff recommending pairing the codes for pump enema systems with neurogenic bowel dysfunction. HERC staff recommends considering a new guideline for this technology.

HERC staff recommendations:

1) Add the following HCPCS codes to line 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
    a. HCPCS A4459 Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type
    b. HCPCS A4453 Rectal catheter for use with the manual pump-operated enema system, replacement only
2) Add a new guideline to line 71 as shown below

GUIDELINE NOTE XXX ANAL IRRIGATION SYSTEMS

Line 71

Anal irrigation systems (HCPCS A4459, A4453) are included on this line as part of a bowel management program when all the following criteria are met:

1) The patient has neurogenic bowel dysfunction; and
2) The patient suffers from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures that significantly impact the individual's quality of life (i.e. inability to participate fully in school or work); and
3) Initial management involving diet, bowel habit, laxatives, or constipating medications has not benefitted the patient; and
4) For reauthorization requests only, there is documentation in the provider notes that:
    a. The member is consistently using the system as directed by their provider; and
    b. The system has shown to be effective in managing fecal incontinence and/or chronic constipation.
5) There are no contraindications to an anal irrigation system, such as anal or colorectal stenosis, colorectal cancer, radiotherapy to the pelvis, recent abdomino-perineal surgery, active inflammatory bowel disease, diverticulitis and ischemic colitis.

Peristeen Plus

Disposition of Public Comments

Table of Contents

Discussion Table

IDs/#s	Summary of Issue	HERC Staff Response
All	All commenters supported coverage of Peristeen Plus.	The staff recommendation is for coverage. There were no comments regarding the proposed guideline.

Commenters

Identification	Stakeholder
A	Susana Hernandez-Mata – parent of OHP member *[Submitted December 19, 2023]*
B	Rachel Wilson, PA-C –OHP provider *[Submitted December 19, 2023]*
C	Julie McKee, CPNP – OHSU provider *[Submitted December 19, 2023]*
D	Lorraine Padilla– OHP member and family member of OHP member *[Submitted December 20, 2023]*
E	Kathryn Vaughn, PT, DPT Director of Market Access, Coloplast *[Submitted December 20, 2023]*

Peristeen Plus

Disposition of Public Comments

Public Comments

ID/#	Comment	Disposition
A	My son was born with Hirschsprung's disease and suffered from chronic constipation and diarrhea. Due to this condition, his perianal skin breakdown since he was 7 months old until date. Recently the GI surgery team from OHSU recommended the Peristeen treatment and this is a miracle, his life is changing and after 17 years of skin break down around his anus finally starts to heal up. Peristeen is being a blessing for our child.	Thank you for your comments. Thank you for the patient perspective.
B	We have seen the benefit of introducing Peristeen Plus Transanal irrigation system to some of our Pediatric patients. This system has been life-changing for some patients, giving them an easy way to administer irrigations. Prior to using this system, the only option for these patients to achieve fecal continence is via a surgical procedure or parent/caregiver-administered enemas. The Peristeen Plus system is easy to learn and use and can eventually give some of our patients independence in their bowel care. Patients and their caregivers have generally been very happy with the use of the system and the results they are getting. This system can help give patients an option for bowel care that can avoid the pain, cost and resources of surgery, as well as the confidence and ability for selfcare. The system is sustainable for long-term bowel management and should be considered an option for bowel care for appropriate patient populations.	Thank you for your comments.
C	I am a pediatric nurse practitioner working in pediatric surgery at OHSU, Doernbecher Children's Hospital. I have had patients utilize the Peristeen system for their bowel management. Prior to this system, they needed to have a caregiver administer an enema, to keep them from becoming constipated and sick. The Peristeen system allows the patient to gain independence in administering a regimen for their constipation. This has been	Thank you for your comment.

Disposition of Public Comments

ID/#	Comment	Disposition
	extremely beneficial to the teenagers who want to have that independence in taking care of their body. I have also seen this increase their compliance in the bowel regimen therapy and make them feel better overall.	
D	As a person who has family member on Peristeen Plus, I have seen the benefits of this product. I highly recommend that OHP committee approves coverage for Peristeen Plus. This product has given life back to my family member and has allowed them to be more independent with their bowel management. After doing some research, I see that all the surrounding states around Oregon to Utah, have covered Peristeen Plus. Isn't it about time we here in Oregon cover this product too?! We should no longer be denying children and adults alike from receiving this lifesaving product. Please approve this product for coverage.	Thank you for your comment.
E	Coloplast thanks Oregon Medicaid and supports the recommendations to adopt coverage for Peristeen Plus. Peristeen Plus Transanal Irrigation is indicated for patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. Neurogenic bowel dysfunction develops among patients with spina bifida, spinal cord injury or patients with neurological problems. These patients suffer from motor, sensory or autonomic functional deficiencies, with permanent and profound neurological deficits and accompanying disability. Transanal Irrigation systems are specifically designed and FDA-approved for such bowel conditions, which significantly improves these patients' quality of life, reduces UTIs, and avoids unnecessary surgeries. Clinicians have been prescribing Peristeen Plus for individuals with neurogenic bowel as part of their bowel management program since FDA clearance in 2015. Peristeen Plus provides a treatment option when first line treatment has failed and avoids more invasive surgical options. There are National Clinical Practice Guidelines published by the Paralyzed Veterans of America	Thank you for your comment.

Disposition of Public Comments

ID/#	Comment	Disposition
	and the Spina Bifida Association that include Peristeen as a second line treatment option for individuals with neurogenic bowel. There is precedent for Peristeen Plus coverage as it is covered by most payors including Anthem Blue Cross and Blue Shield, Aetna, Cigna, HCSC, the Veteran's Administration, Tricare, UnitedHealthcare and most state Medicaid plans. Coloplast thanks Oregon Medicaid for the preliminary recommendation to adopt a coverage and reimbursement policy that supports Peristeen Plus as a covered item so that it would be available as a treatment for patients suffering from neurogenic bowel dysfunction. We believe the evidence establishes the medical necessity of Transanal Irrigation; members covered under Oregon Medicaid with neurogenic bowel conditions would improve their health conditions while avoiding invasive treatment options.	

References Provided by Commenters

ID	References
A	None provided
B	None provided
C	None provided
D	None provided
E	None provided

Review report of MTG36: Peristeen transanal irrigation system for managing bowel dysfunction

This medical technology guidance was published in February 2018.

All medical technology guidance is usually reviewed 3 years after publication, unless NICE become aware of significant new information before the expected review date.

This review report summarises new evidence and information that has become available since this medical technology guidance was published, and that has been identified as relevant for the purposes of this report. This report will be used to inform NICE's decision on whether this guidance will be updated, amended, remain unchanged (static list) or withdrawn.

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1. Original objective of guidance

To assess the clinical and cost effectiveness of Peristeen anal irrigation system to manage bowel dysfunction.

2. Current guidance recommendations

The current recommendations as outlined in NICE MTG36 (NICE 2018) are:

1.1 The case for adopting Peristeen for transanal irrigation in people with bowel dysfunction is supported by the evidence. Peristeen can reduce the severity of constipation and incontinence, improve quality of life and promote dignity and independence.

1.2 Peristeen may not be suitable for all people with bowel dysfunction. It may take several weeks before a person is comfortable with using Peristeen, and some people may choose to stop using it. Peristeen is therefore most effective when it is offered with specialist training for users, carers and NHS staff, and structured patient support.

1.3 Cost modelling for Peristeen is uncertain, but it is likely that Peristeen provides additional clinical benefits without costing more than standard bowel care.

3. Methods of review

Update searches, based on the original EAC searches for this guidance, were conducted by information specialists at NICE on 23rd June 2021 and covered the period March 2017 to June 2021. Details are provided in Appendix D.

NICE gIS searches identified 566 records, from which duplicates were removed (n=138). Search results provided to Cedar were imported into Endnote (n=428). The company submitted a list of 25 potentially relevant studies, and clinical experts identified 13. The company results included 5 references which had not been identified by the literature searches, and 2 more were added by clinical experts. Following de-duplication, a total of 435 publications were included for title and abstract sift. References provided by the company and clinical experts were cross-checked against the Endnote library.

One researcher reviewed all records and 52 were selected as being relevant for full review. A second researcher reviewed the 52 selected publications to confirm relevance. Following review by second researcher, 11 studies were considered relevant for inclusion. The full text of all 11 studies was obtained; outcomes were reviewed and are summarised in Appendix C, together with EAC comments.

introducing a large volume into the rectum.[166] The following information pertains to the use of soapsuds enemas in the adult general population reported by Schmelzer et al.[166,167] Because of the lack of consensus on the administration of soapsuds enemas even in the general population, a description is included here. In these studies, soapsuds enemas were prepared by using 6 g of castile soap per 1,000 g of deionized water.[166,167] Schmelzer described warming the enema solution to 40° C (105° F) prior to administration to avoid hypothermia.

Soapsuds enemas are primarily used to treat constipation; however, in Schmelzer et al.,[166,167] soapsuds enemas were used for colonic cleansing. Although there are no clear contraindications for these enemas, it is uncertain whether they produce a greater stool output than tap water enemas of equivalent volume.1[66] Nonetheless, the single administration of a soapsuds enema produced significantly greater net mean stool output than a PEG enema did.

Milk and Molasses Enemas

A description of these enemas was provided from the study of a population treated in a hospital emergency department, although no SCI-related studies were extracted regarding milk and molasses enemas. Sugars present in milk and molasses enemas are speculated to interact with the intestinal lining to produce gas, facilitating defecation by increasing intestinal pressure, distension, and peristalsis.[168] Vilke et al.[168] reported this prospective cohort study conducted at the University of California Emergency Department. Additional information, including how to prepare this enema, can be found in the article by Vilke et al.[168]

6.5 Transanal irrigation (TAI) is recommended in individuals with NBD who have insufficient results with BBM.

During TAI, irrigation fluid is electrically or gravity pumped from a reservoir into the colon via a rectal cone or rectal catheter that has been inserted into the anus.[169] Experts recommend performing TAI 20 to 30 minutes after a meal to take advantage of the gastrocolic reflex.[170] TAI should also begin after the user is positioned over a toilet or commode, so that the rectum can be emptied or digitally checked for emptiness if the user has lost sensory awareness. After the device has been inserted, a user or caregiver should hold it in place for the duration of irrigation.[169] Balloon catheters, if used, should be inflated with care to avoid triggering reflex contractions or AD. Repeated catheter expulsion and balloon bursting are the 2 most commonly cited reasons for individuals to reject TAI.[55,171,172,173,174,175] Experts suggest that irrigation fluid should be clean water at 36 to 38°C pumped at a rate of 200 to 300 mL/min.[170,175] Starting at 500 mL, the total volume can be increased by 100-mL increments during each session until irrigation is successful without leakage.[175] If electrolyte balance is a concern, saline should be used instead of water. In the event of cramping, discomfort, or pain during irrigation, pumping should be paused and then continued at a slower rate.[170] When single irrigation sessions fail, 2 half sessions with a 10- to 15-minute break in between is recommended. If pain or fecal incontinence persists, constipation should be investigated, along with reducing the irrigation volume or using constipation agents.[176] No clear parameters for TAI frequency have been defined.

Indications and Contraindications

Experts recommend TAI for individuals who are refractory to conservative methods, and who have a low rectal volume at defecation urge and at maximal capacity.[170] Faaborg et al.[173] demonstrated that the following factors positively influence TAI success: male gender, dual constipation and incontinence symptoms, and prolonged colorectal transit. Individuals with full or restricted hand function experienced improvements with TAI. It is unclear whether a user's dependence on assistance during bowel care or SCI etiology affects the success of TAI.[55,172] Emmanuel et al.[170] suggest the following absolute contraindications for TAI: anal or rectal stenosis, active inflammatory bowel disease, acute diverticulitis, colorectal cancer, ischemic colitis, rectal surgery within the previous 3 months, or endoscopic polypectomy within the previous 4 weeks. Relative contraindications for TAI are severe diverticulosis; dense sigmoid disease; history of diverticulitis, diverticular abscess, or rectal surgery; long-term steroid medication; fecal impactions;

Treatment of Liver Metastases

Plain Language Summary:

Coverage question: Liver metastases are tumors that started out in some other part of the body and have spread to the liver. Should OHP cover treatments for this condition?

Should OHP cover these treatments? Yes, certain types of treatments should be covered in limited cases.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: What treatments should be covered for cancer that is metastatic to the liver?

Question source: Kristin Garrett, CCO medical director

Background: Many cancers can metastasize to the liver, but the most common liver metastases is colorectal cancer. There are many treatments for cancer that has metastasized to the liver, including chemotherapy, surgical resection, radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, and electro-coagulation.

Currently, Guideline Note 78 HEPATIC METASTASES limits treatment of liver metastases to hepatectomy/resection of the liver (CPT codes 47120, 47122,47125 or 47130). The CPT codes for other treatments, such as RFA, are on line 315 CANCER OF LIVER, but appear to be reserved for primary hepatocellular carcinoma. Guideline Note 78 was written in 2009, and the field of oncology has made vast strides in treatment of liver metastases since that time.

Dr. Garrett is requesting clarification of what treatments are actually intended to be paired with liver metastases (specifically colorectal cancer metastases).

In addition to Dr. Garrett's question, staff have reviewed the various treatments for liver metastases, and cryoablation of liver tumors (CPT 47383) was last reviewed in 2014 and placed on line 662/GN173 and should be re-reviewed as it has been almost 10 years since the last review.

Dr. Max Kaiser, CCO medical director and HERC member, has asked HERC staff to look at use of Yttrium-90 (Y-90) for treatment of metastatic disease to the liver for indications other than hepatocellular carcinoma (HCC) or colorectal cancer (CRC) metastatic to the liver. Since the last review of Y-90, the CPT code for this treatment has had a major description change. In 2019, CPT 79445 was specific for HCC or CRC metastatic to the liver. Currently, CPT 79445 is "Radiopharmaceutical therapy, by intra-arterial particulate administration."

Previous HSC/HERC reviews:

April 2006

Treatment of Liver Metastases

Discussion

Treatment of Liver Cancer: [Alison] Little explained that the Commission previously considered embolization for tumor destruction using yttrium and elected not to place it on the list; however, the code for embolization remains. A case at OMAP resulted in her questioning whether appropriate treatments were listed on this line. [Kevin] Olson explained the different treatments, as follows: Radiofrequency ablation is insertion of an ultrasound catheter with use of heat to kill tissue, cryotherapy is the same thing except using a liquid nitrogen probe, chemoembolization is when a catheter is inserted into an artery that feeds the tumor, chemotherapy is infused then the artery is embolized with gel foam. The yttrium procedure does not involve embolization. All of these are used to treat both primary liver cancer and metastatic colon cancer. [Somnath] Saha asked if any of these treatments were controversial except the yttrium. Olson stated that for colon cancer metastatic only to the liver, resection can result in 25% long-term survival. Hepatic artery infusion with 5-FU improved outcomes as well. The data on RFA and cryotherapy is weaker. Chemoembolization results in shrinkage of tumor, but causes severe side-effects. RFA and yttrium have fewer side effects. Hepatic artery infusion is also effective, but systemic chemotherapy has improved to the point that it is rarely done anymore. Saha clarified that the task today is to determine if any of these treatments should be removed from the List. Olson stated that there are some cases where an isolated metastasis is too close to the bile duct to operate, and in those cases it makes sense to use RFA or cryo. He also said that yttrium treatment costs approximately $70,000

Actions: Do not delete any of the following codes from Line 489:
36260 - Insertion of implantable intra-arterial infusion pump
36262 - Removal of implanted intra-arterial infusion pump
37204 - Transcatheter occlusion or embolization
47370 - Laparoscopy, surgical, ablation of one or more liver tumors, RFA
47371 - Laparoscopy, surgical, ablation of one or more liver tumors, cryosurgical
47380 - Ablation, open, one or more liver tumors; RFA
47381 - Ablation, open, one or more liver tumors; cryosurgical 47382 - Ablation, percutaneous, one or more liver tumors; RFA Do not delete CPT code
36261, Revision of implanted intra-arterial infusion pump

Delete 79445 - Radiopharmaceutical therapy, by intra-arterial particulate administration, from Line 489.

June 2009

Discussion

Hepatic metastases Livingston introduced the summary document on liver metastases. The recommendation was to move 197.7 (Secondary malignant neoplasm of the liver) from Line 613 SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS to Line 338 CANCER OF LIVER, to pair with 47120-47130 (Hepatectomy, resection of liver), with a coding specification to avoid inappropriate pairings: “Hepatic metastases (ICD-9 code 197.7) are covered in this line only when paired with CPT code 47120-47130 and only when no other extrahepatic metastases are present.” Saha asked whether this diagnosis could have the cancer care statement of intent criteria applied to it. Livingston reported that the 5 year survival is not reported. Historically, survival is 3-25 month survival without treatment and 14-17 months with treatment. [Carla] Mckelvey asked whether survival was affected by type of primary cancer; [Cat] Livingston

replied that all studies reviewed were on colorectal cancer. Saha noted that based on the 5 year survival data, it appears that treatment of solitary liver metastases meets the criteria in the SOI of improvement of 30%. Historically, best survival 2 yrs, this data shows 3 years, which is 50% increase in survival. The suggestion was made that solitary liver metastases be moved to the colon cancer line, as this was where the evidence for treatment was strongest. Smits noted that CPT treatment codes would also need to be added to this line. Coffman cautioned that moving CPT codes would allow them to pair with other types of cancer as the ICD-9 code for liver metastases is generic/not specific for metastatic colorectal cancer. Saha asked whether the HSC could make a guideline restricting use of this code for metastatic colon/rectal cancer if this diagnosis was added to the liver cancer line; the answer from HSC staff was yes. Suggested wording for a guideline was: "Hepatic metastases (ICD-9 code 197.7) are covered in this line only for 1) a covered primary cancer treatment of which meets our statement of intent for cancer treatment, 2) when paired with CPT code 47120-47130 and 3) when no other extrahepatic metastases are present." Gubler disagreed, that thought that the solitary liver metastases diagnosis should be left under the liver cancer line, with treatment left to clinical judgment. Saha noted that in this situation, rare cases of other diagnoses could be treated under the exceptions process. Shaffer stated that DMAP don't grant exceptions when the HSC has a clear guideline stating limitations to coverage. Kirk objected as well, noting that the hearings/exceptions process for such exceptions are a strain to the plans. A patient with a terminal cancer below the line who has a hepatic met above the line will get an argument that the lower diagnoses (the terminal cancer) should be covered to help benefit the covered diagnosis (the liver metastases), as counterintuitive as that may be. Saha noted that some cases may involve an unknown primary cancer. He noted that in this case, there is no evidence that you would prolong life by treating the solitary metastasis. The decision was to consider placing on either the colorectal or the liver cancer line, with a guideline to be developed by HSC staff and sent to Saha for comment. This topic will be revisited at the December meeting.

Action: HSC staff to develop a guideline restricting treatment of solitary hepatic metastases to evidence based situations, and to determine whether placement should be on the colorectal or liver cancer lines. Staff will forward this guideline/ recommendation to Saha and return to the December meeting for further discussion

December 2009

Solitary liver metastases Livingston introduced a summary regarding solitary liver metastases. There was minimal discussion.

Action
Move 197.7 (Secondary malignant neoplasm of the liver) from Line 612 to Line 338. Guideline adopted as shown in Appendix A. [This guideline later became Guideline Note 78]

GUIDELINE NOTE XXX, HEPATIC METASTASES
Line 338
Hepatic metastases (ICD-9 code 197.7) are covered in this line only when:
1) Treatment of the primary tumor is covered on a funded line in accordance with the criteria in guideline note XX Treatment of Cancer With Little or No Benefit Provided Near the End of Life;
2) There are no other extrahepatic metastases; and,

3) The only treatment covered is hepatectomy/resection of liver (CPT codes 47120, 47122, 47125 or 47130)

November 2014

Cryoablation of liver tumors (CPT 47383)

1) Cryoablation of liver tumors is a minimally invasive treatment of either primary hepatocellular carcinoma or metastatic disease to the liver
2) Radiofrequency ablation of liver tumors (CPT 47382) is covered on the liver cancer line
3) Evidence
    a. **NICE 2010,** guidance for treatment of liver metastases
        i. Current evidence on the safety of cryotherapy for the treatment of liver metastases appears adequate in the context of treating patients whose condition has such a poor prognosis, but the evidence on efficacy is inadequate in quality. Therefore cryotherapy for the treatment of liver metastases should only be used with special arrangements for clinical governance, consent and audit or research.
    b. **Bala 2013**, Cochrane review of cryotherapy for liver metastases
        i. 1 RCT, with high risk of bias
            1. 123 patients, randomized to cryotherapy or conventional surgery
            2. The patients were followed for up to 10 years (minimum five months). Mortality at the last follow-up was 81% (51/63) in the cryotherapy group and 92% (55/60) in the conventional surgery group (RR 0.88; 95% CI 0.77 to 1.02); that is, no statistically significant difference was observed.
            3. Recurrence in the liver was observed in 86% (54/63) of the patients in the cryotherapy group and 95% (57/60) of the patients in the conventional surgery group (relative risk (RR) 0.9; 95% CI 0.8 to 1.01); that is, no statistically significant difference was observed.
        ii. **Authors' conclusions** On the basis of one randomised clinical trial with high risk of bias, there is insufficient evidence to conclude if in patients with liver metastases from various primary sites cryotherapy brings any significant benefit in terms of survival or recurrence compared with conventional surgery. In addition, there is no evidence for the effectiveness of cryotherapy when compared with no intervention. At present, cryotherapy cannot be recommended outside randomised clinical trials.
    c. **Awad 2009**, Cochrane review of cryotherapy for hepatocellular carcinoma
        i. No trials identified
        ii. **Authors' conclusions** At present, there is no evidence to recommend or refute cryotherapy for patients with hepatocellular carcinoma. Randomised clinical trials with low-risk of bias may help in defining the role of cryotherapy in the treatment of hepatocellular carcinoma.
4) HERC staff recommendation: **Non-covered List**
    a. Experimental for both hepatocellular carcinoma and metastatic disease

November 2019

Treatment of Liver Metastases

Yttrium 90 therapy was discussed in 11/2019. High level evidence for the use of Yttrium 90 (RCT level evidence) exists only for use of Y90 as first line treatment for HCC. Y-90 treatment was limited to HCC only in GN185. The codes for Y-90 were added to the liver cancer line. Since 2019, the code descriptions have changed. In 2019, CPT 79445 was specific for HCC or CRC metastatic to the liver. Currently, CPT 79445 is "Radiopharmaceutical therapy, by intra-arterial particulate administration."

Current Prioritized List/Coverage status:

Line 157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS
Contains no liver lesion treatment CPT codes

Diagnosis included on line 315 CANCER OF LIVER:
ICD-10-CM C22.9 Malignant neoplasm of liver, not specified as primary or secondary
ICD-10-CM C78.7 Secondary malignant neoplasm of liver and intrahepatic bile duct

Treatments included on line 315 CANCER OF LIVER:

CPT 36260-36262: placement, revision and removal of implantable intra-arterial infusion pump (eg, for chemotherapy of liver)
CPT 37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
CPT 47120-47130: Hepatectomy, resection of liver
CPT 47370 Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency
CPT 47371 Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
CPT 47380 Ablation, open, of 1 or more liver tumor(s); radiofrequency
CPT 47381 Ablation, open, of 1 or more liver tumor(s); cryosurgical
CPT 47382 Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency

GUIDELINE NOTE 78, HEPATIC METASTASES

Line 315

ICD-10-CM C78.7 Hepatic metastases are included on this line only when:

A) Treatment of the primary tumor is covered on a funded line in accordance with the criteria in Guideline Note 12 PATIENT-CENTERED CARE OF ADVANCED CANCER;
B) There are no other extrahepatic metastases; and,
C) The only treatment covered is hepatectomy/resection of liver (CPT codes 47120, 47122,47125 or 47130).

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

Line 662

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

Treatment of Liver Metastases

Procedure Code	Intervention Description	Rationale	Last Review
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation No evidence of effectiveness for both hepatocellular carcinoma and metastatic disease	No evidence of effectiveness for both hepatocellular carcinoma and metastatic disease	November, 2014

GUIDELINE NOTE 185, YTTRIUM-90 THERAPY

Line 315

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

A) Downsizing tumors in patients who could become eligible for curative treatment (transplant, ablation, or resection), OR

B) Palliative treatment of incurable patients with unresectable or inoperable tumors that are not amenable to ablation therapy and

1) who have good liver function (Child-Pugh class A or B) and
2) good performance status (ECOG performance status 0-2), and
3) who have intermediate stage disease with tumors > 5 cm OR advanced stage HCC with unilateral (not main) portal vein tumor thrombus

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

Treatment of Liver Metastases

Evidence:

Ablation vs liver resection

1) **NICE 2020**, treatment for metastatic colorectal cancer in the liver amenable to treatment with curative intent
   https://www.ncbi.nlm.nih.gov/books/NBK559927/pdf/Bookshelf_NBK559927.pdf
   a. Evidence on ablation vs resection
      i. Very low quality evidence from 1 retrospective cohort study (N=138) showed no clinically important difference in overall survival between people who received RFA alone and those who underwent resection alone for metastatic colorectal cancer in the liver.
      ii. Quality of life
         1. No evidence was identified to inform this outcome.

Cryotherapy

1) **Bala 2019**, Cochrane review of cryotherapy for liver metastases
   a. Included only RCTs in their search strategy
   b. We found no randomized clinical trials comparing cryotherapy versus no intervention or versus systemic treatments
   c. We identified one randomized clinical trial comparing cryotherapy with conventional surgery. The trial included 123 participants with solitary, or multiple unilobar or bilobar liver metastases; 63 participants received cryotherapy and 60 received conventional surgery. The primary sites for the metastases were colon and rectum (66.6%), stomach (7.3%), breast (6.5%), skin (4.9%), ovaries (4.1%), uterus (3.3%), kidney (3.3%), intestines (1.6%), pancreas (1.6%), and unknown (0.8%). The trial was not reported sufficiently enough to assess the risk of bias of the randomization process, allocation concealment, or presence of blinding. It was also not possible to assess incomplete outcome data and selective outcome reporting bias. The certainty of evidence was low because of risk of bias and imprecision. The participants were followed for up to 10 years (minimum five months). The trial reported that the mortality at 10 years was 81% (51/63) in the cryotherapy group and 92% (55/60) in the conventional surgery group. The calculated by us relative risk (RR) with 95% Confidence Interval (CI) was: RR 0.88, 95% CI 0.77 to 1.02. We judged the evidence as low-certainty evidence.
   d. Regarding adverse events and complications, separately and in total, our calculation showed no evidence of a difference in recurrence of the malignancy in the liver: 86% (54/63) of the participants in the cryotherapy group and 95% (57/60) of the participants in the conventional surgery group developed a new malignancy (RR 0.90, 95% CI 0.80 to 1.01; low-certainty evidence). The frequency of reported complications was similar between the cryotherapy group and the conventional surgery group, except for postoperative pain. Both insignificant and pronounced pain were reported to be more common in the cryotherapy group while intense pain was reported to be more common in the conventional surgery group. There were no intervention-related mortality or bile leakages. We identified no evidence for health-related quality of life, cancer mortality, or time to progression of liver metastases.
   e. Authors' conclusions: The evidence for the effectiveness of cryotherapy versus conventional surgery in people with liver metastases is of low certainty. We are uncertain about our estimate and cannot determine whether cryotherapy compared with conventional surgery is beneficial or harmful. We found no evidence for the

benefits or harms of cryotherapy compared with no intervention, or versus systemic treatments

2) **Khanmohammadi 2023**, systematic review and meta-analysis of percutaneous cryoablation for liver metastases
    a. N=15 articles (692 patients)
        i. 9 retrospective cohort studies, 6 prospective cohort studies
        ii. Any type of metastatic cancer, colon cancer being the most common diagnosis
    b. Mean overall survival ranged from 14.5–29 months. The rate of local recurrence in the included studies ranged from 9.4% to 78%, and local control progression-free survival ranged from 1 to 31 months. One-year disease-free survival rate ranged from 58.3 to 63.6%, and the mean disease-free survival was between 3.67 and 7.74 months. One-, two-, and three-year overall survival rates were 56.3–92.3%, 31.3–71.9%, and 18.8–41% among the studies, and the mean overall survival ranged from 14.5–29 months
    c. The total QoL decreased one week after the cryoablation procedure (-3.08 [95% Confidence interval: -4.65, -1.50], p-value 7.39], p-value <0.01) and three months (3.75 [2.25, 5.24], p-value <0.01) after the procedure
    d. Increased liver enzymes (144), pain (140), fever (134), thrombocytopenia (59), pleural effusion (31), malaise (6), self-limited liver bleeding (2), grade1/2 complications (2), freezing sensation (1) pneumothorax (1), and biliary leak (1) were among the post-procedure complications
    e. Conclusion: Cryoablation is an effective procedure for the treatment of liver metastases, especially in cases that are poor candidates for liver resection. It could significantly improve QoL with favorable local recurrence.

Expert guidelines:

Colorectal cancer

1) **NCCN 2.2023** Colon cancer
    a. Resection is the standard approach for the local treatment of resectable metastatic disease. However, patients with liver or lung oligometastases can also be considered for tumor ablation therapy, particularly in cases that may not be optimal for resection. Ablative techniques include radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, and electro-coagulation (irreversible electroporation). There is extensive evidence on the use of RFA as a reasonable treatment option for non-surgical candidates and for recurrent disease after hepatectomy with small liver metastases that can be treated with clear margins.
    b. Data on ablative techniques other than RFA are growing. However, in a comparison of RFA with MWA, outcomes were similar with no local tumor progression for metastases ablated with margins greater than 10 mm (A0) and a relatively better control of perivascular tumors with the use of MWA (P = .021). Similarly, two studies and a position paper by a panel of experts indicated that ablation may provide acceptable oncologic outcomes for selected patients with small liver metastases that can be ablated with sufficient margins. In the same way, a 2018 systematic review confirmed that MWA provides oncologic outcomes similar to resection. Several publications have indicated that the significance of margin creation is particularly important for RAS-mutant metastases.
    c. Yttrium-90

i. When hepatic metastatic disease is not optimally resectable based on insufficient remnant liver volume, approaches using preoperative portal vein embolization, staged liver resection, or yttrium-90 radioembolization can be considered. Arterially directed catheter therapy, and in particular yttrium-90 microsphere selective internal radiation, is an option in highly selected patients with chemotherapy-resistant/-refractory disease and with predominant hepatic metastases

2) **Morris 2023**, ASCO guideline on the treatment of metastatic colorectal cancer
   a. Cytoreductive surgery (CRS) plus systemic chemotherapy may be recommended for selected patients with colorectal peritoneal metastases (Type: Evidence-based, benefits outweigh harms; Evidence quality: Moderate; Strength of recommendation: Weak).
      i. This recommendation applies to patients who have been deemed amenable to complete resection of colorectal peritoneal metastases, regardless of previous treatment, and who have no extraperitoneal metastases.
   b. Surgery with or without perioperative chemotherapy should be offered to patients with mCRC who are candidates for potentially curative resection of liver metastases (Type: Evidence-based, benefits outweigh harms; Evidence quality: Moderate; Strength of recommendation: Weak).

Ovarian cancer

1) **NCCN 2.2023** Ovarian Cancer
   a. Does not mention treatment of liver metastases

Neuroendocrine tumors

1) **NCCN 1.2023** Neuroendocrine and adrenal tumors
   a. For patients with locoregional advanced, liver-predominant, progressive disease or patients with poorly controlled carcinoid syndrome, liver-directed therapies are recommended, mainly with the palliative goals of extending life and relieving hormonal symptoms
   b. Cytoreductive surgery or ablative therapies such as radiofrequency ablation (RFA) or cryoablation may be considered if near-complete treatment of tumor burden can be achieved (category 2B). Ablative therapy in this setting is non-curative. Data on the use of these interventions are emerging. For unresectable liver metastases, hepatic regional therapy (arterial embolization, chemoembolization, or radioembolization [category 2B]) is recommended. No single modality of embolization therapy has been shown to be superior to another, but there is a difference in both long-term and short-term toxicities among the different modalities
   c. Liver-directed therapy consists of four categories of treatment:
      i. Surgical resection (which may include intraoperative thermal ablation of lesions);
      ii. Hepatic arterial embolization, including bland transarterial embolization [TAE], chemoembolization [TACE], and radioembolization [TARE]
      iii. Percutaneous thermal ablation
      iv. RT (SBRT/SABR)
   d. Percutaneous thermal ablation, often using microwave energy (radiofrequency and cryoablation are also acceptable), can be considered for oligometastatic liver disease, generally up to four lesions each smaller than 3 cm. Feasibility considerations include safe percutaneous imaging-guided approach to the target lesions, and proximity to

vessels, bile ducts, or adjacent non-target structures that may require hydro- or aero-dissection for displacement.

e. Cytoreductive surgery of >90% of metastatic disease may provide symptomatic relief, prevent future symptoms, and improve progression-free survival for patients with functioning tumors. This strategy is particularly appropriate for patients with relatively indolent metastatic small bowel NETs, and less appropriate for patients in whom rapid progression of disease is expected after surgery. Patients who are symptomatic from hormonal syndromes, such as carcinoid syndrome, typically derive palliation from cytoreductive surgery.
f. Liver-directed therapies (eg, liver resection, thermal ablation, chemoembolization) for hepatic metastases from NETs following pancreatoduodenectomy are associated with increased risk for cholangitis and liver abscess.

Hepatocellular carcinoma

1) **NCCN 2.2023** Hepatocellular carcinoma
    a. Ablation (radiofrequency, cryoablation, percutaneous alcohol injection, microwave):
        i. All tumors should be amenable to ablation such that the tumor and, in the case of thermal ablation, a margin of normal tissue is treated.
        ii. Tumors should be in a location accessible for percutaneous/laparoscopic/open approaches for ablation.
        iii. Caution should be exercised when ablating lesions near major vessels, major bile ducts, diaphragm, and other intra-abdominal organs.
        iv. Ablation alone may be curative in treating tumors less than or equal to 3 cm. In well-selected patients with small properly located tumors, ablation should be considered as definitive treatment in the context of a multidisciplinary review. Lesions 3 to 5 cm may be treated to prolong survival using arterially directed therapies, or with combination of an arterially directed therapy and ablation as long as tumor location is accessible for ablation.
        v. Unresectable/inoperable lesions greater than 5 cm should be considered for treatment using arterially directed therapy, systemic therapy, or RT

Other payer policies:

1) Aetna 2023

a. Aetna considers the following as medically necessary when the following criteria are met:
b. Cryosurgery, microwave, or radiofrequency ablation for members with isolated colorectal cancer liver metastases or isolated hepatocellular cancer who are not candidates for open surgical resection when the selection criteria specified below are met. Members must fulfill *all* of the following criteria. Particular emphasis should be placed on criteria 2 and 3, which ensure that cryosurgery, microwave, or radiofrequency ablation is performed with curative intent.
    i. Members must either have hepatic metastases from a colorectal primary cancer or have a hepatocellular cancer; *and*
    ii. Members must have isolated liver disease. Members with nodal or extra-hepatic systemic metastases are not considered candidates for these procedures; *and*

iii. All tumors in the liver, as determined by pre-operative imaging, would be potentially destroyed by cryotherapy, microwave, or radiofrequency ablation; *and*
iv. Because open surgical resection is the preferred treatment, members must be unacceptable open surgical candidates due to the location or extent of the liver disease or due to co-morbid conditions such that the member is unable to tolerate an open surgical resection; *and*
v. Liver lesions must be 4 cm or less in diameter and occupy less than 50 % of the liver parenchyma. Lesions larger than this may not be adequately treated by these procedures.

c. Aetna considers cryosurgery, microwave, or radiofrequency ablation of hepatic lesions experimental and investigational when these criteria are not met.
d. The following procedures are considered experimental and investigational because the effectiveness of these approaches has not been established
i. Cryosurgery, microwave, or radiofrequency ablation as a treatment of hepatic metastases from non-colonic primary cancers;
ii. Cryosurgical, microwave or radiofrequency ablation as a palliative treatment of either hepatic metastases from colorectal cancer or hepatocellular cancer

2) **Anthem BCBS 2023**, Locoregional Techniques for Treating Primary and Metastatic Liver Malignancies
a. Medically Necessary:
i. *Treatment of Hepatic Tumors (Primary or Metastatic)*
1. Any of the following locally ablative techniques are considered medically necessary for individuals with *any* of the following conditions when *all* of the criteria below have been met:
a. Techniques
i. Cryosurgical ablation; **or**
ii. Microwave ablation (MWA); **or**
iii. Percutaneous ethanol injection (PEI); **or**
iv. Radiofrequency (RFA)
and
b. Conditions
i. Hepatocellular carcinoma; **or**
ii. Liver metastases from colorectal cancer; **or**
iii. Functioning neuroendocrine tumors
and
c. Criteria
i. A poor candidate for surgical resection or unwilling to undergo surgical resection; **and**
ii. Each lesion measures no more than 5 cm in diameter; **and**
iii. No or minimal extra-hepatic metastases; **and**
iv. All foci of disease are amenable to ablative therapy or surgical resection.

Treatment of Liver Metastases

Expert input:

Dr. Brett Sheppard, OHSU surgery

I just wanted to be sure we are reviewing metastatic disease to the liver (CRC, PNET) [Colorectal cancer, pancreatic/small bowel neuroendocrine tumors] and differentiate this from primary HCC or intra-hepatic cholangiocarcinoma.

For common metastatic disease to the liver (CRC, PNET), I would concur with you that OHP would be providing the best care possible by funding surgical resection and/or ablation (most of us have moved to microwave, some irreversible electroporation).

There is good data that shows even for non-functional PNET and NET that if they are able to have surgical debulking of at least 75% of their tumor they will reap a significant survival benefit. This can be completed with surgery +/- microwave ablation (MWA). It would be something to consider for our OHP patients.

I concur with you that cryoablation does not need to be covered. MWA can now generally accomplish the same and has a lower side effect profile than cryoablation and may be less expensive as procedure time may be shorter.

I agree with the revised guidelines. If you agree, after appropriate literature search, about my statement in regards to non-functional PNEt/NET then they would need to be modified

Treatment of Liver Metastases

HERC staff summary:

Expert guidelines recommend various interventions to treat liver metastases for colorectal tumors when a patient is not a good candidate for surgical resection. Such interventions are recommended when there are no metastases outside of the liver. Ablative techniques include radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, and electro-coagulation (irreversible electroporation). The best evidence for ablative techniques per NCCN is for RFA and MWA.

NCCN mentions ablation of liver metastases from neuroendocrine cancer as a "can be considered" option, noting that it is a palliative rather than curative treatment. However, NCCN mentions ablation of such liver metastases as being helpful for patients who are symptomatic from hormonal syndromes caused by the neuroendocrine tumor. Local experts recommend coverage for neuroendocrine tumors liver metastases that are functional (i.e. producing hormones that are causing symptoms).

Percutaneous cryotherapy of liver metastases has some evidence of effectiveness, but it consists only of relatively small prospective and retrospective cohorts. There is one small RCT on any type of cryoablation of liver metastases (cryoresection, cryoreduction, croyextirpation). However, cryoablation is listed in several NCCN guidelines as a treatment option, and is covered by private insurers.

Private insurers cover treatment of certain types of cancer with liver metastases (colorectal, with some covering neuroendocrine as well) with cryosurgery, microwave, or radiofrequency ablation. This coverage is limited to metastatic disease isolated to the liver when the patient is a poor candidate for surgical resection.

HERC staff recommend clarifying GN78. First, the intent appears to be to allow surgical resection of any type of liver metastases (any primary tumor) as long as the metastases are isolated to the liver. Second, additional ablative procedures (radiofrequency ablation, microwave ablation) should be allowed only for hepatocellular carcinoma, colorectal cancer metastatic to the liver, and functional neuroendocrine tumors metastatic to the liver. In the case of metastatic disease, coverage should be limited to patients who have only liver metastases present and only when the patient is not a candidate for surgical resection.

HERC staff recommend continuing non-coverage of percutaneous cryoablation, and adding surgical cryoablation to the line 662/GN173 entry as the evidence of effectiveness is poor. NCCN notes that RFA and MWA are generally considered the treatments of choice for ablative procedures for hepatocellular carcinoma and colorectal cancer metastatic in the liver.

Yttrium-90 treatment only has high level of evidence of effectiveness for treatment of HCC. NCCN includes as an option in certain clinical scenarios with metastatic colorectal cancer.

HERC staff recommendations:

1) Add CPT 47383 (Ablation, 1 or more liver tumor(s), percutaneous, cryoablation) to line 315 CANCER OF LIVER and remove from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    a. Delete the GN173 entry
2) Modify GN78 as shown below

Treatment of Liver Metastases

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
~~47383~~	~~Ablation, 1 or more liver tumor(s), percutaneous, cryoablation~~	~~No evidence of effectiveness for both hepatocellular carcinoma and metastatic disease~~	~~November, 2014~~

GUIDELINE NOTE 78, HEPATIC METASTASES

Line 315

~~ICD-10-CM C78.7~~ Hepatectomy/resection (CPT codes 47120, 47122,47125 or 47130) of hepatic metastases (ICD-10-CM C22.9 Or C78.7) are included on this line only when there are no extrahepatic metastases.

~~A) Treatment of the primary tumor is covered on a funded line in accordance with the criteria in Guideline Note 12 PATIENT-CENTERED CARE OF ADVANCED CANCER;~~

~~B) There are no other extrahepatic metastases; and,~~

~~C) The only treatment covered is hepatectomy/resection of liver (CPT codes 47120, 47122,47125 or 47130).~~

Microwave and radiofrequency ablation and cryoablation (CPT 37243, 47340, 47370, 47371, 47380-47383, 47389) are included on this line only when ALL of the following criteria are met:

A) Treatment is for colorectal cancer liver metastases, functioning neuroendocrine tumors or hepatocellular cancer; AND

B) There are no extrahepatic metastases; AND

C) The patient is not a candidate for open surgical resection due to the location or extent of the liver disease or due to co-morbid conditions such that the member is unable to tolerate an open surgical resection; AND

D) All tumors in the liver, as determined by pre-operative imaging, would be potentially destroyed by cryotherapy, microwave, or radiofrequency ablation; AND

E) Liver lesions must be 4 cm or less in diameter and occupy less than 50 % of the liver parenchyma.

Yttrium-90 therapy (CPT 79445) is only covered for treatment of hepatocellular carcinoma as specified in GUIDELINE NOTE 185, YTTRIUM-90 THERAPY.

Cochrane Library

Cochrane Database of Systematic Reviews

Cryotherapy for liver metastases (Review)

Bala MM, Riemsma RP, Wolff R, Pedziwiatr M, Mitus JW, Storman D, Swierz MJ, Kleijnen J

Bala MM, Riemsma RP, Wolff R, Pedziwiatr M, Mitus JW, Storman D, Swierz MJ, Kleijnen J.
Cryotherapy for liver metastases.
Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD009058.
DOI: 10.1002/14651858.CD009058.pub3.

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WILEY

[Intervention Review]

Cryotherapy for liver metastases

Malgorzata M Bala[1], Robert P Riemsma[2], Robert Wolff[2], Michal Pedziwiatr[3], Jerzy W Mitus[4], Dawid Storman[5], Mateusz J Swierz[6], Jos Kleijnen[2,7]

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Editorial group: Cochrane Hepato-Biliary Group.
Publication status and date: Edited (no change to conclusions), published in Issue 10, 2019.

Citation: Bala MM, Riemsma RP, Wolff R, Pedziwiatr M, Mitus JW, Storman D, Swierz MJ, Kleijnen J. Cryotherapy for liver metastases. *Cochrane Database of Systematic Reviews* 2019, Issue 7. Art. No.: CD009058. DOI: 10.1002/14651858.CD009058.pub3.

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ABSTRACT

Background

The liver is affected by two of the most common groups of malignant tumours: primary liver tumours and liver metastases from colorectal carcinoma. Liver metastases are significantly more common than primary liver cancer and long-term survival rates reported for patients after radical surgical treatment is approximately 50%. However, R0 resection (resection for cure) is not feasible in the majority of patients. Cryotherapy is performed with the use of an image-guided cryoprobe which delivers liquid nitrogen or argon gas to the tumour tissue. The subsequent process of freezing is associated with formation of ice crystals, which directly damage exposed tissue, including cancer cells.

Objectives

To assess the beneficial and harmful effects of cryotherapy compared with no intervention, other ablation methods, or systemic treatments in people with liver metastases.

Search methods

We searched The Cochrane Hepato-Biliary Group Controlled Trials Register, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE Ovid, Embase Ovid, and six other databases up to June 2018.

Selection criteria

Randomised clinical trials assessing beneficial and harmful effects of cryotherapy and its comparators for liver metastases, irrespective of the location of the primary tumour.

Data collection and analysis

We used standard methodological procedures expected by Cochrane. We extracted information on participant characteristics, interventions, study outcomes, and data on the outcomes important for our review, as well as information on the design and methodology of the trials. Two review authors independently assessed risk of bias in each study. One review author performed data extraction and a second review author checked entries.

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Main results

We found no randomised clinical trials comparing cryotherapy versus no intervention or versus systemic treatments; however, we identified one randomised clinical trial comparing cryotherapy with conventional surgery. The trial was conducted in Ukraine. The trial included 123 participants with solitary, or multiple unilobar or bilobar liver metastases; 63 participants received cryotherapy and 60 received conventional surgery. There were 36 women and 87 men. The primary sites for the metastases were colon and rectum (66.6%), stomach (7.3%), breast (6.5%), skin (4.9%), ovaries (4.1%), uterus (3.3%), kidney (3.3%), intestines (1.6%), pancreas (1.6%), and unknown (0.8%). The trial was not reported sufficiently enough to assess the risk of bias of the randomisation process, allocation concealment, or presence of blinding. It was also not possible to assess incomplete outcome data and selective outcome reporting bias. The certainty of evidence was low because of risk of bias and imprecision.

The participants were followed for up to 10 years (minimum five months). The trial reported that the mortality at 10 years was 81% (51/63) in the cryotherapy group and 92% (55/60) in the conventional surgery group. The calculated by us relative risk (RR) with 95% Confidence Interval (CI) was: RR 0.88, 95% CI 0.77 to 1.02. We judged the evidence as low-certainty evidence. Regarding adverse events and complications, separately and in total, our calculation showed no evidence of a difference in recurrence of the malignancy in the liver: 86% (54/63) of the participants in the cryotherapy group and 95% (57/60) of the participants in the conventional surgery group developed a new malignancy (RR 0.90, 95% CI 0.80 to 1.01; low-certainty evidence). The frequency of reported complications was similar between the cryotherapy group and the conventional surgery group, except for postoperative pain. Both insignificant and pronounced pain were reported to be more common in the cryotherapy group while intense pain was reported to be more common in the conventional surgery group. However, the authors did not report whether there was any evidence of a difference. There were no intervention-related mortality or bile leakages.

We identified no evidence for health-related quality of life, cancer mortality, or time to progression of liver metastases. The study reported tumour response in terms of the carcinoembryonic antigen level in 69% of participants, and reported results in the form of a graph for 30% of participants. The carcinoembryonic antigen level was lower in the cryotherapy group, and decreased to normal values faster in comparison with the control group ($P < 0.05$).

Funding: the trial did not provide information on funding.

Authors' conclusions

The evidence for the effectiveness of cryotherapy versus conventional surgery in people with liver metastases is of low certainty. We are uncertain about our estimate and cannot determine whether cryotherapy compared with conventional surgery is beneficial or harmful. We found no evidence for the benefits or harms of cryotherapy compared with no intervention, or versus systemic treatments.

PLAIN LANGUAGE SUMMARY

Cryotherapy for liver metastases

Review question

Is cryotherapy (cooling) beneficial or harmful for local destruction of cancer (tumours) spread to the liver?

Background

When cancer spreads in the body (metastasis), one of the most common sites is the liver. Besides cancers of the liver (primary liver cancer), liver metastases from colorectal cancer are the most common cancer affecting the liver. More than half of people who have cancer spread to the liver die from complications. Cryotherapy is one of methods, used to destroy metastases in the liver. This method requires placing a special probe near the cancer site. The probe is used to deliver extreme cold to the site, which is produced by liquid nitrogen or argon gas. Placement of the probe can be guided using ultrasound or computed tomography (a special x-ray). The rapid freezing process kills the cancer cells, and the size of the cancer is reduced. However, it is not clear if this treatment prolongs life or increases quality of life of affected people.

We reviewed the evidence about the effect of cryotherapy in destroying cancer metastases in the liver. We searched for studies assessing the effect of cryotherapy in comparison with no treatment or any other treatment in people with liver metastases from cancer of any location. We aimed to assess the effect of cryotherapy on the risk of death, quality of life, and adverse events (side effects caused by the treatment).

Study characteristics

We last searched for evidence in June 2018. We included only one trial conducted in Ukraine, and participants' primary cancer was colorectal (bowel) cancer in 66% of instances, but there were also people with stomach, breast, skin, and other tumours. All of them had cancer spread to the liver. In this trial, 123 participants were allocated at random to receive either cryotherapy (63 people) or conventional surgery (affected parts of the liver were removed; 60 people).

Funding

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The trial did not provide information on funding.

Key results

The trial was at high risk of bias. The participants were followed for up to 10 years (minimum five months). The trial reported that the mortality at 10 years was 81% (51/63) in the cryotherapy group and 92% (55/60) in the conventional surgery group. We judged the evidence as low-certainty evidence. We found no evidence of a difference in proportion of participants with recurrence of the malignancy in the liver: 86% (54/63) of the participants in the cryotherapy group and 95% (57/60) of the participants in the conventional surgery group developed a new malignancy (low-certainty evidence). The frequency of reported complications was similar between the cryotherapy group and the conventional surgery group, except for postoperative pain. Both insignificant and pronounced pain were reported to be more common in the cryotherapy group while intense pain was reported to be more common in the conventional surgery group. However, it was not reported whether there was any evidence of a difference. The frequency of unwanted effects (adverse events or complications) was mostly similar in both groups, but pain intensity and frequency seemed to differ between the groups. There were no intervention-related mortality or bile leakages. The trial did not provide data on quality of life; cancer mortality, and time to progression of liver metastases.

Reliability of the evidence

The evidence for the effectiveness of cryotherapy versus conventional surgery in people with liver metastases is of low certainty. We are uncertain about our estimate and cannot determine whether cryotherapy compared with conventional surgery is beneficial or harmful. We found no evidence for the benefits or harms of cryotherapy compared with no intervention, or versus systemic treatments.

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PLOS ONE

RESEARCH ARTICLE

Survival outcomes and quality of life after percutaneous cryoablation for liver metastasis: A systematic review and meta-analysis

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Funding: The author(s) received no specific funding for this work.

Competing interests: The authors have declared that no competing interests exist.

Abstract

Background

Liver metastasis is present in a wide range of malignancies, with colorectal cancer as the most common site. Several minimally invasive treatments have been suggested for managing hepatic metastases, and cryoablation is among them, yet not widely used. In this systematic review, we aimed to assess the effectiveness of percutaneous cryoablation in all types of liver metastases.

Methods

A systematic search was performed in international databases, including PubMed, Scopus, Embase, and Web of Science, to find relevant studies reporting outcomes for percutaneous cryoablation in liver metastasis patients. In addition to baseline features such as mean age, gender, metastasis origin, and procedure details, procedure outcomes, including overall survival, local recurrence, quality of life (QoL), and complications, were extracted from the studies. Random-effect meta-analysis was performed to calculate the mean difference (MD) and 95% confidence interval for comparison of QoL.

Results

We screened 2131 articles. Fifteen studies on 692 patients were included. Mean overall survival ranged from 14.5–29 months. The rate of local recurrence in the included studies ranged from 9.4% to 78%, and local control progression-free survival ranged from 1 to 31 months. The total QoL decreased one week after the cryoablation procedure (-3.08 [95% Confidence interval: -4.65, -1.50], p-value <0.01) but increased one month (5.69 [3.99,

7.39], p-value <0.01) and three months (3.75 [2.25, 5.24], p-value <0.01) after the procedure.

Conclusion

Cryoablation is an effective procedure for the treatment of liver metastases, especially in cases that are poor candidates for liver resection. It could significantly improve QoL with favorable local recurrence.

1. Introduction

The liver is a common site for metastasis from various malignancies such as colorectal cancer, lung cancer, melanoma, and breast cancer, among which colorectal cancer is the most common primary site [1]. In the United States, about 5.1% of all patients diagnosed with malignancy have synchronous liver metastases at the time of diagnosis [2], while it reaches 50% in patients with colorectal cancer origin [3]. Several clinical modalities have been established for liver metastases treatment, including liver resection, systemic and local chemotherapy, and radiotherapy [4]. While liver resection is still the main curative option for colorectal liver metastases [5], this is not the case for many others, such as breast cancer and esophageal cancer [6,7].

In recent years, interventional oncology has become very popular for managing primary and secondary liver malignancies due to its ability to improve survival, reduce tumor burden, and low complication rate [8]. So, the emerging role of interventional oncology as a treatment alone, as a bridge to transplantation, or in association with other approaches could not be denied [9,10].

Thermal ablation, including radiofrequency ablation (RFA) or microwave ablation (MWA), is the most popular local minimally invasive method with many publications and studies. However, cold ablation is less considered in the liver and is not extensively available. Percutaneous cryoablation is in situ destruction of tumor cells with low temperatures. Mechanistically, cellular dehydration, protein denaturation, and microcirculatory failure in thawing and freezing cycles are the main pathways the cryoablation affects the tumor [11]. The current method of cryoablation is the administration of probes with the use of circulating cooled fluid or gas, such as nitrogen or argon, which then expands into a gas, creating low temperatures, including the Joule-Thomson effect [12]. It was first suggested that cryoablation might only be used in cases of liver metastases from colorectal cancer; however, several other studies have assessed the procedure's effects in other types of metastases [13–15]. Many of these studies have shown the efficacy of cryoablation in improving survival and quality of life (QoL). To date, there is no systematic review investigating the role of cryoablation in liver metastases from different origins. In the present systematic review, we aimed to investigate the effectiveness of percutaneous cryoablation in treating liver metastases through a systematic search in the literature and finding relevant studies.

2. Methods and materials

This review was conducted in compliance with the review protocol registered on PROSPERO, 2023 CRD42023390082. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement was followed in this study [16]. An ethics statement is not applicable because this study is based exclusively on published literature.

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ASCO special articles

Treatment of Metastatic Colorectal Cancer: ASCO Guideline

Van K. Morris, MD[1]; Erin B. Kennedy, MHSc[2]; Nancy N. Baxter, MD, PhD[3]; Al B. Benson III, MD[4]; Andrea Cercek, MD[5]; May Cho, MD[6]; Kristen K. Ciombor, MD, MSCI[7]; Chiara Cremolini, MD, PhD[8]; Anjee Davis, MPPA[9]; Dustin A. Deming, MD[10]; Marwan G. Fakih, MD[11]; Sepideh Gholami, MD[12]; Theodore S. Hong, MD[13]; Ishmael Jaiyesimi, DO[14]; Kelsey Klute, MD[15]; Christopher Lieu, MD[16]; Hanna Sanoff, MD, MPH[17]; John H. Strickler, MD[18]; Sarah White, MD[19]; Jason A. Willis MD, PhD[1]; and Cathy Eng, MD[7]

abstract

PURPOSE To develop recommendations for treatment of patients with metastatic colorectal cancer (mCRC).

METHODS ASCO convened an Expert Panel to conduct a systematic review of relevant studies and develop recommendations for clinical practice.

RESULTS Five systematic reviews and 10 randomized controlled trials met the systematic review inclusion criteria.

RECOMMENDATIONS Doublet chemotherapy should be offered, or triplet therapy may be offered to patients with previously untreated, initially unresectable mCRC, on the basis of included studies of chemotherapy in combination with anti–vascular endothelial growth factor antibodies. In the first-line setting, pembrolizumab is recommended for patients with mCRC and microsatellite instability-high or deficient mismatch repair tumors; chemotherapy and anti–epidermal growth factor receptor therapy is recommended for microsatellite stable or proficient mismatch repair left-sided treatment-naive *RAS* wild-type mCRC; chemotherapy and anti–vascular endothelial growth factor therapy is recommended for microsatellite stable or proficient mismatch repair *RAS* wild-type right-sided mCRC. Encorafenib plus cetuximab is recommended for patients with previously treated *BRAF* V600E–mutant mCRC that has progressed after at least one previous line of therapy. Cytoreductive surgery plus systemic chemotherapy may be recommended for selected patients with colorectal peritoneal metastases; however, the addition of hyperthermic intraperitoneal chemotherapy is not recommended. Stereotactic body radiation therapy may be recommended following systemic therapy for patients with oligometastases of the liver who are not considered candidates for resection. Selective internal radiation therapy is not routinely recommended for patients with unilobar or bilobar metastases of the liver. Perioperative chemotherapy or surgery alone should be offered to patients with mCRC who are candidates for potentially curative resection of liver metastases. Multidisciplinary team management and shared decision making are recommended. Qualifying statements with further details related to implementation of guideline recommendations are also included.

Additional information is available at www.asco.org/gastrointestinal-cancer-guidelines.

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ASSOCIATED CONTENT

Appendix

Data Supplement

Author affiliations and support information (if applicable) appear at the end of this article.

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Evidence Based Medicine Committee approval:

July 15, 2022.

INTRODUCTION

Colorectal cancer (CRC) is the third most common type of cancer diagnosed worldwide.[1] Almost 150,000 new cases and more than 50,000 deaths from CRC are reported each year in the United States.[2] In recent decades, the overall incidence of CRC has decreased among older adults because of screening and lifestyle factors; however, at the same time, incidence is increasing among younger adults.[3] The 5-year relative overall survival (OS) for patients with metastatic colorectal cancer (mCRC) is approximately 15%.[4] Approximately 33% of patients with CRC will develop metastases either at presentation or follow-up.[5] Evaluating treatment options is complex because of the heterogeneity of the patient population, including different molecular subtypes. Treatment has included conventional fluorouracil (FU)–based chemotherapy, and more recently, targeted therapies have been developed for specific molecular subtypes and primary tumor sidedness.[6] This guideline provides a review of the evidence for areas of uncertainty in the treatment of mCRC, including indications for targeted therapy, and treatment options for oligometastatic and liver-limited disease.

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Rectal Sensation, Tone, and Compliance Test

Plain Language Summary:

Coverage question: Should OHP cover a test to check how strong and flexible the muscles in the rectum are?

Should OHP cover this treatment? Yes, this routine test checks bowel movement issues.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should coverage be added for the rectal sensation, tone and compliance test?

Question source: Holly Jo Hodges, CCO medical director

Background:

This test helps to evaluate the cause of fecal incontinence or constipation. The rectal sensation, tone, and compliance test measures the sensory, motor and biomechanical function of the rectum. The physician performs a rectal sensation tone and compliance test using graded balloon distention to evaluate anorectal pathology. Tone tests for relaxation or rigidity in the rectum. Compliance tests the distensibility of the rectum. Sensation tests for fullness and discomfort upon distention. The patient is asked to empty his or her bowels.

Previous HSC/HERC reviews:

December 2004: 91120 Rectal sensation, tone and compliance test: purpose and clinical impact of the test was obscure. Added to the non-covered services list. Later moved to line 662/GN173

Similar procedure: 91122 (Anorectal manometry) is on the diagnostic procedures file

Current Prioritized List/Coverage status:

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS
Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
91120	Rectal sensation, tone, and compliance test	Insufficient evidence of effectiveness	December 2004

Rectal Sensation, Tone, and Compliance Test

Expert guidelines:

1) American Gastroenterological Association position statement on constipation
    a. Anorectal manometry and a rectal balloon expulsion should be performed in patients who fail to respond to laxatives (strong recommendation, moderate-quality evidence).
2) American College of Gastroenterology guideline on management of benign anorectal disorders
    a. Anorectal tests are necessary because symptoms alone do not discriminate between defecation disorders (DD) and other causes of constipation. The diagnostic tests assess rectal sensation and anorectal pressures (manometry), rectal balloon expulsion (BET), external anal sphincter and pelvic floor muscle activity (EMG), or rectal evacuation (barium or MRI defecography)
    b. Anorectal manometry and balloon expulsion are required to diagnose DD.

Other payer policies:

Aetna 2023 and United Healthcare 2023 cover rectal sensation testing

HERC staff summary: Rectal sensation testing is part of the standard evaluation of constipation and other defecation disorders and is included in expert guidelines.

HERC staff recommendation:

1) Add 91120 (Rectal sensation, tone, and compliance test) to the Diagnostic Procedures File
2) Remove 91120 from line 654 and delete the guideline 173 entry 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 654

The following Interventions are prioritized on Line 654 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
~~91120~~	~~Rectal sensation, tone, and compliance test~~	~~Insufficient evidence of effectiveness~~	~~December 2004~~

AGA

American Gastroenterological Association Medical Position Statement on Constipation

The AGA Institute Medical Position Panel consisted of the lead technical review author (Adil E. Bharucha, MBBS, MD, AGAF), a Clinical Practice and Quality Management Committee representative and content expert (Spencer D. Dorn, MD, MPH), and two gastroenterologists and content experts (Anthony Lembo, MD, and Amanda Pressman, MD).

Podcast interview: www.gastro.org/gastropodcast. Also available on iTunes.

This document presents the official recommendations of the American Gastroenterological Association (AGA) on constipation. It was drafted by the AGA Institute Medical Position Panel, reviewed by the Clinical Practice and Quality Management Committee, and approved by the AGA Institute Governing Board. This medical position statement is published in conjunction with a technical review[1] on the same subject, and interested readers are encouraged to refer to this publication for in-depth considerations of topics covered by these questions. The technical review was begun before the AGA's decision to adopt the GRADE system. However, a GRADE methodologist worked with the authors and panel to rank the quality of the evidence and strength of recommendations.

The medical position statement presents information by addressing clinically related questions and summarizing key points from the technical review. When specific recommendations about medical interventions or management strategies for patients with constipation are stated, the "strength of recommendation" and the "quality of evidence" are provided. The strength of recommendation is either judged as "weak" or "strong" and quality of evidence is ranked as high, moderate, low, or very low in accordance with GRADE criteria. Recommendations are highlighted by appearing within a text box. A strong recommendation implies that, based on available evidence, the benefits outweigh risks and there is less variability in patient's values and preferences. A weak recommendation implies that benefits, risks, and the burden of intervention are more closely balanced, or appreciable uncertainty exists in regards to patient's values and preferences. Applying this approach, high-quality evidence does not always result in strong recommendations and, conversely, strong recommendations may emerge from lower-quality evidence.

Symptoms of constipation are extremely common; the prevalence is approximately 16% in adults overall and 33% in adults older than 60 years. Many people seek medical care for constipation, but fortunately most do not have a life-threatening or disabling disorder and the primary need is for control of symptoms, although rare, life-threatening, or treatable conditions must be excluded. If therapeutic trials of laxatives fail, specialized testing should be considered. We suggest the following practice guidelines for the symptom of constipation; our rationale for these guidelines is supported by the accompanying technical review.

Constipation is a symptom that can rarely be associated with life-threatening diseases. Current recommendations will relate to (1) rational and, where possible, more judicious diagnostic approaches and (2) more rational and efficacious therapies that will improve symptoms, both of which should have beneficial fiscal and logistic impacts on the health care system. Although the overall classification of chronic constipation into 3 categories (ie, normal transit, isolated slow transit, and defecatory disorders) and several recommendations in this version are similar to the prior version, there are 3 substantive changes. First, these guidelines recommend assessment of colonic transit at a later stage, that is, only for patients who do not have a defecatory disorder or patients with a defecatory disorder that has not responded to pelvic floor retraining. Second, the evidence supporting these recommendations has been evaluated using the GRADE system, in which the strength of recommendation is rated as strong or weak and the quality of evidence is rated as high, moderate, low, or very low. Third, therapeutic recommendations have been updated to include newer agents and delete certain older agents.

Definitions

Although physicians often regard constipation to be synonymous with infrequent bowel movements, typically fewer than 3 per week, patients have a broader set of symptoms, including hard stools, a feeling of incomplete evacuation, abdominal discomfort, bloating, and distention, as well as other symptoms (eg, excessive straining, a sense of anorectal blockage during defecation, and the need for manual

Abbreviations used in this paper: AGA, American Gastroenterological Association; GRADE, Grading of Recommendations Assessment, Development and Evaluation; NTC, normal transit constipation; STC, slow transit constipation.

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puborectalis muscle, which should also contract during squeeze. Acute localized tenderness to palpation along the puborectalis is a feature of the levator ani syndrome. Finally, the patient should be instructed to integrate the expulsionary forces by requesting that she or he "expel my finger."

- An examination should then be conducted to evaluate for a rectocele or consideration be given to gynecologic consultation.

Although a careful digital rectal examination is useful for identifying pelvic floor dysfunction, a normal examination does not exclude this diagnosis. After the initial history and physical examination, a set of focused tests should be considered to exclude disorders that are either treatable (eg, hypothyroidism) or important to diagnose early (eg, colon cancer). However, data do not exist to strictly evaluate and define the tests that need to be performed. A complete blood cell count should be performed. Although metabolic tests (thyroid-stimulating hormone, serum glucose, creatinine, and calcium) are often performed, their diagnostic utility and cost-effectiveness have not been rigorously evaluated and are probably low. A structural evaluation of the colon may be appropriate in certain circumstances, especially if the patient has alarm symptoms or has abrupt onset of constipation or is older than 50 years and has not undergone previous screenings for colorectal cancer. Depending on the circumstances, colonoscopy, computed tomographic colonography, or flexible sigmoidoscopy and barium enema will effectively exclude lesions that could cause constipation.

If this evaluation uncovers a secondary cause for constipation, the appropriate treatment can be offered. The patient's medications can be adjusted when possible to avoid those with constipating effects. A trial of fiber and/or over-the-counter laxatives can be instituted.

Clinical Assessment of Constipation

If feasible, discontinue medications that can cause constipation before further testing (strong recommendation, low-quality evidence).

A careful digital rectal examination that includes assessment of pelvic floor motion during simulated evacuation is preferable to a cursory examination without these maneuvers and should be performed before referral for anorectal manometry. However, a normal digital rectal examination does not exclude defecatory disorders (strong recommendation, moderate-quality evidence).

Diagnostic Tests

Patients who do not respond to these measures may benefit from special testing and treatments; these can be presented most simply as an algorithm (Figure 1).

This algorithm starts by recommending anorectal testing for patients who do not respond to a trial of laxatives and/or fiber. Anorectal testing is simple and safe and can potentially modify management; a rectal balloon expulsion test is also inexpensive. There is evidence that pelvic floor retraining is superior to laxatives for defecatory disorders. Hence, anorectal testing may be considered earlier when symptoms or signs strongly suggest pelvic floor dysfunction. Interpretation of any single test must be guarded, because it must be recognized that patient cooperation and understanding comprise an important voluntary component of most tests of anorectal function. The tests themselves must be in a setting as private as possible to reduce embarrassment and facilitate cooperation. Ideal conditions are often not possible. Although anorectal manometry and a rectal balloon expulsion test generally suffice to diagnose or exclude a defecatory disorder, defecography, which is generally performed with barium, or at some centers with magnetic resonance imaging, is useful if results are inconclusive.

Up to 50% of patients with defecatory disorders also have slow colonic transit. Therefore, slow colonic transit does not exclude a defecatory disorder. In addition, coexistent slow colonic transit does not alter the management of defecatory disorders. In contrast to the previous version of this guideline, assessment of colonic transit is recommended only after excluding a defecatory disorder or as shown later during management in Figures 2 and 3. After excluding a defecatory disorder, consideration should be given to assessing colonic transit by radiopaque markers, scintigraphy, or a wireless motility capsule in patients with persistent symptoms while being treated with laxatives. Identifying slow colonic transit may reassure patients about the pathophysiology of their symptoms, serve as an objective marker for documenting the response to therapy, and also provide the physician with the rationale for treating patients with newer, often more expensive treatments. At present, the medical approaches used for managing NTC and STC are similar. However, the major pharmacologic trials in chronic constipation did not assess if the response to therapy is influenced by colonic transit. Although newer agents may also be considered without assessing colonic transit, the long-term side effects, if any, of these agents are unknown and exposure to such potential risks might be more appropriate in patients with more severe forms of constipation associated with slow transit. Hence, we empirically recommend assessing colonic transit in patients with chronic constipation whose symptoms do not respond to laxatives or first-line pharmacologic therapy.

At the conclusion of this initial evaluation, the patient with constipation can be tentatively diagnosed as having (1) NTC or, in patients who also have pain and other features of the disorder, irritable bowel syndrome; (2) STC; (3) defecatory disorder, (4) a combination of STC and defecatory disorder; or (5) secondary constipation (ie, secondary to an organic disease such as mechanical obstruction, systemic disease, or side effect of a drug).

CME

ACG Clinical Guidelines: Management of Benign Anorectal Disorders

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Benign anorectal disorders of structure and function are common in clinical practice. These guidelines summarize the preferred approach to the evaluation and management of defecation disorders, proctalgia syndromes, hemorrhoids, anal fissures, and fecal incontinence in adults and represent the official practice recommendations of the American College of Gastroenterology. The scientific evidence for these guidelines was assessed using the Grading of Recommendations Assessment, Development and Evaluation process. When the evidence was not appropriate for Grading of Recommendations Assessment, Development and Evaluation, we used expert consensus to develop key concept statements. These guidelines should be considered as preferred but are not the only approaches to these conditions.

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INTRODUCTION

Similar to the previous ACG Clinical Guidelines, these updated guidelines summarize the definitions, diagnostic criteria, evaluation, and management of a group of benign disorders of anorectal function and/or structure. Disorders of defecation, proctalgia syndromes, and fecal incontinence (FI) are primarily regarded as disorders of function; some patients also have structural abnormalities. The structural disorders include acute and chronic anal fissures and hemorrhoids. The guidelines consist of individual sections that cover the definitions, epidemiology and/or pathophysiology, diagnostic testing, and treatment recommendations. These reflect a comprehensive search of relevant topics of pertinent English language articles in PubMed, Ovid MEDLINE, and the National Library of Medicine updated to June 2020 using appropriate terms for each subject. As with the earlier guidelines, recommendations for anal fissures, hemorrhoids and surgical interventions for FI also rely on adaptation from the American Society of Colon and Rectal Surgeons Practice parameters from the most recently published guidelines in 2018. We used systematic reviews and meta-analyses when available. The National Library of Medicine was searched for terms that were cross-referenced to the terms that have been used to describe dyssynergic defecation: disordered defecation, pelvic floor dyssynergia, anismus, obstructed defecation, and functional outlet obstruction.

Each section contains key concepts, recommendations, and summaries of the available evidence. Each recommendation statement includes an assessment of the quality of evidence based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) process (1). High-quality evidence indicates that further research is unlikely to change the authors confidence in the estimate of the effect; moderate-quality evidence is defined as moderate confidence in the estimate of effect, although future studies would be likely to impact our confidence of the estimate; low-quality evidence indicates that further study would likely have an important impact on the confidence in the estimate of the effect and would likely change the estimate. Very-low-quality evidence indicates very little confidence in the effect estimate and that the true effect is likely to be substantially different than the estimate of effect.

Largely but not entirely based on the evidence, a strong recommendation is made when the authors agree that the benefits clearly outweigh the negatives and/or the result of no action. A conditional recommendation indicates that some uncertainty remains about the balance of benefits and potential harms. In these guidelines, many treatments have little or no potential for harm and may result in a strong recommendation with low quality of evidence. In contrast, treatments associated with potential for harm may result in a conditional recommendation with similar quality of evidence. Key concepts are statements that are not amenable to the GRADE process either because of the structure of the statement or because of the available evidence. In some instances, key concepts are based on extrapolation of evidence and/or expert opinion.

Each of the key concepts and recommendations were assessed by the 6 authors based on a five-point Likert scale:

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(1) Strongly disagree
(2) Disagree
(3) Neither agree nor disagree
(4) Agree
(5) Strongly agree

Consensus agreement was defined as a composite score of ≥ 25 (maximum of 30).

These guidelines are established to support clinical practice and suggest preferable approaches to a typical patient with a particular medical problem based on the currently-available published literature. When exercising clinical judgment, particularly when treatments pose significant risks, health-care providers should incorporate this guideline in addition to patient-specific medical comorbidities, health status, and preferences to arrive at a patient-centered care approach.

DEFECATION DISORDERS

A systematic review of diagnostic tests for constipation was recently reported as part of a comprehensive guideline concerning the management of constipation (2). These guidelines focus on studies that examined the concordance of the most commonly used diagnostic tests to each other or to an external standard where one is available. The diagnostic tests assessed include symptoms, digital rectal examination, anorectal manometry (ARM) with or without electromyography (EMG) of the pelvic floor, the balloon expulsion test (BET), barium defecography, and MRI of the pelvic floor.

Definition and epidemiology

Defecation disorders (DDs) are defined as difficulty in evacuating stool from the rectum in patients with chronic or recurring symptoms of constipation (2–4). The diagnosis requires both symptoms of constipation and anorectal tests suggestive of impaired rectal evacuation. With the increasing availability of anorectal tests, DDs are increasingly recognized in clinical practice. In the community, the incidence of diagnosis of DD is more common in women than in men and is 3-fold more common than Crohn's disease (5). In women, the incidence is greatest between the ages of 20 and 29 years and then declines with a second peak between the ages of 80 and 89 years. In men, the incidence of DD increases with age until the age of 80–89 years.

Pathophysiology

Maladaptive learning of sphincter contraction, possibly initiated by avoidance of anorectal pain or trauma or neglecting the call to defecate, is thought to underlie the development of DD (6,7). In one-third of children with constipation, severe symptoms persist beyond puberty (8). Evacuation may be impaired because of inadequate rectal propulsive forces and/or increased outlet resistance, resulting from impaired relaxation or paradoxical contraction of the external anal sphincter and/or puborectalis muscle (3,4,9–14). Other abnormalities such as reduced rectal sensation and structural deformities (e.g., rectoceles and excessive perineal descent) may coexist and be primary or secondary to constipation (15–20). Decreased rectal sensation may also reduce the desire to defecate and contribute to DD (16,17). Up to 50% of patients with DD also have delayed colonic transit, which may represent coexistent colonic motor dysfunction or arise secondary to pelvic floor dysfunction (10,21,22). Over time, excessive straining can weaken the pelvic floor, leading to excessive perineal descent, rectal intussusception, solitary rectal ulcer syndrome, and pudendal neuropathy (23–26).

However, several important questions remain. Some asymptomatic people exhibit a dyssynergic pattern when tested, perhaps because it is a challenge to simulate defecation in the laboratory; hence, the extent to which dyssynergia is responsible for impaired evacuation is uncertain (27–29). Among patients who also have structural abnormalities (e.g., a large rectocele), their relative contribution to the symptoms is unclear. Stool form may influence the expression of pelvic floor dysfunction; similar to healthy people, patients with DD strain more to evacuate hard than soft stools (30,31).

Associated conditions. In case series, DDs often begin in childhood; many patients have irritable bowel syndrome (IBS), anxiety, and/or depression (5,32–34). Other associated conditions and possible risk factors include surgery, hospitalization, eating disorders, trauma, and physical or sexual abuse (5,32,35,36). In contrast to FI, obstetric trauma is not associated with DD (37). Secondary causes of DD include Parkinson disease and inflammatory bowel disease before or after ileal pouch–anal anastomosis (5,38–41).

Clinical features. The symptoms of DD include infrequent defecation, hard stools, excessive straining during defecation, sense of anorectal blockage during defecation, use of manual maneuvers to facilitate evacuation, and a sense of incomplete evacuation after defecation (3,4,14,32,42,43). However, these symptoms, including a sense of anal blockage during defecation or anal digitation, do not discriminate between DD and other causes of constipation (42,44–47).

A digital rectal examination (DRE) can identify structural abnormalities (e.g., anal fissures, hemorrhoids, fecal impaction, descending perineum syndrome, or anorectal cancer) and also assess anal sphincter functions that are involved with defecation. A DRE includes perianal inspection followed by digital assessment to assess stool in the rectum, anal tone at rest, during voluntary contraction of the sphincter (squeeze) and simulated evacuation. During the latter, the anal sphincter should relax. Failure to relax with simulated defecation or contraction around the finger may suggest a DD or reflect the challenges of simulating evacuation in healthy people. The examining finger is then inserted more deeply to palpate the puborectalis muscle; the patient is again asked to simulate defecate and the normal response is for the muscle to relax, thus widening the anorectal angle. Regrettably, many health care providers do not perform a DRE in patients with constipation (48). Assessments of anal tone at rest, during squeeze and evacuation, and perineal descent during evacuation with a meticulous DRE are significantly correlated with objective assessments by experienced examiners (15,49,50). Compared with manometry, a DRE was 75% sensitive and 87% specific for identifying dyssynergia in 1 study from a tertiary care center (50). Compared with a rectal BET, which is arguably the most useful diagnostic test for DD, the sensitivity and specificity were 80% and 56%, respectively. Some persons with normal pelvic floor function may find it awkward to simulate defecation during a DRE, which might explain the lower specificity of DRE compared with a BET. Although a normal DRE is probably more useful than an abnormal result (50), all patients with constipation with symptoms refractory to standard therapy should be referred for anorectal testing to exclude the presence of a DD.

Diagnostic tests. Anorectal tests are necessary because symptoms alone do not discriminate between DD and other causes of constipation. The diagnostic tests assess rectal sensation and

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Esophageal Balloon Distention Provocation Study

Plain Language Summary:

Coverage question: Should OHP cover a test with balloon dilation to check if the esophagus is causing chest pain that isn't related to the heart?

Should OHP cover this treatment? No, testing the esophagus with balloon dilation doesn't seem very reliable, it's not commonly recommended and there's no evidence that it can predict how well a treatment will work.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should the esophageal balloon distention provocation study be added for coverage?

Question source: Holly Jo Hodges, CCO medical director

Background: The esophageal balloon distention provocation study is a test to see if the esophagus is the cause of non-cardiac chest pain. Standard testing for non-cardiac chest pain is a trial of proton pump inhibitors (PPIs), upper endoscopy with biopsy, wireless pH capsule endoscopy and esophageal manometry. Balloon distention is one test for esophageal hypersensitivity which has been proposed as one test for evaluation of non-cardiac chest pain. Dr. Hodges is requesting a re-review as the last review of this technology was in 2004.

Previous HSC/HERC reviews:

December 2004: 91040 Esophageal balloon distention provocation study: used for diagnosing chest pain; added only 4% to diagnostic sensitivity. Added to the non-covered list

Current Prioritized List/Coverage status:

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS
Line 654

The following Interventions are prioritized on Line 654 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
91040	Esophageal balloon distension study	Evidence of ineffectiveness	December 2004

Esophageal Balloon Distention Provocation Study

Evidence:

1) **Foss 2019**, diagnosis and management of functional chest pain
    a. Balloon distention was also originally introduced as a tool to discriminate between esophageal and cardiac pain with a limited sensitivity that ranged from 5.0–75.0%. Later, the technique has evolved to assess for the presence of esophageal hypersensitivity. However, as with the acid perfusion test, protocols were not standardized, and different equipment was used. Moreover, the test is invasive, painful and has not been shown to predict therapeutic outcome.
    b. All patients with non-cardiac chest pain should be evaluated for GERD, using the PPI test or empirical PPI trial and pH-impedance test or wireless pH capsule. An upper endoscopy can help to exclude esophageal and gastric mucosal abnormalities, as well as eosinophilic esophagitis using a disease-related biopsy protocol. Esophageal manometry is required to exclude major esophageal motor disorders

Expert guidelines: none identified

Other payer policies:

1) Aetna 2023: considers esophageal balloon distension studies to be experimental

HERC staff summary: Esophageal balloon dilation provocation testing appears to be a test with limited sensitivity, is not part of standard testing recommendations, and has not been shown to predict therapeutic outcomes.

HERC staff recommendation:

1) Update the entry to GN173 regarding esophageal balloon dilation provocation testing 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 654

The following Interventions are prioritized on Line 654 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
91040	Esophageal balloon distension study	Evidence of ineffectiveness	~~December 2004~~ January 2024

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Review

Diagnosis and Management of Functional Chest Pain in the Rome IV Era

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Functional chest pain accounts for about a third of the patients with noncardiac chest pain. It is a very common functional esophageal disorder that remains even today a management challenge to the practicing physician. Based on the definition offered by the Rome IV criteria, diagnosis of functional chest pain requires a negative workup of noncardiac chest pain patients that includes, proton pump inhibitor test or empirical proton pump inhibitor trial, endoscopy with esophageal mucosal biopsies, reflux testing, and esophageal manometry. The mainstay of treatment are neuromodulators that are primarily composed of anti-depressants. Alternative medicine and psychological interventions may be provided alone or in combination with other therapeutic modalities.
(J Neurogastroenterol Motil 2019;25:487-498)

Key Words
Alternative medicine; Chest pain; Endoscopy; Neuromodulators; Proton pump inhibitors

Introduction

Functional gastrointestinal disorders (FGIDs) are disorders of gut-brain interaction, defined as gastrointestinal symptoms that are related to any combination of motility disturbance, visceral hypersensitivity, altered mucosal and immune function, altered gut microbiota, and altered central nervous system processing.[1] In addition, functional esophageal disorders are defined by chronic esophageal symptoms in the absence of identifiable structural, inflammatory, motor, or metabolic mechanism as the etiology.[2] Unlike other FGIDs, esophageal motor abnormalities, except ineffective esophageal motility and fragmented peristalsis, are not considered part of the multi-faceted presentation of a functional esophageal disorder. Rome IV criteria identified 5 functional esophageal disorders, including functional chest pain (FCP), functional heartburn, reflux hypersensitivity, globus, and functional dysphagia. Diagnosis of all functional esophageal disorders requires the exclusion of gastroesophageal reflux disease (GERD), eosinophilic esophagitis, and a major esophageal motor disorder (vide infra).

FCP accounts for more than a third of the patients diagnosed with esophageal related noncardiac chest pain (NCCP). Other underlying mechanisms of esophageal related NCCP include GERD, esophageal dysmotility, psychological comorbidity, and less commonly eosinophilic esophagitis. After GERD, FCP is the second most common cause of NCCP. The pathophysiology of FCP is poorly understood, but most patients demonstrate increased mechano- or chemo-receptor sensitivity to esophageal distention or acid perfusion, respectively. This suggests the presence of esophageal hypersensitivity, which is defined as the perception of

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chest pains were more often acidic. Another advantage of the pH-impedance test is the use of baseline mucosal impedance as a surrogate marker for mucosal permeability. In one study it was demonstrated that baseline mucosal impedance in the distal esophagus of patients with GERD-related NCCP was significantly lower than in subjects with non-GERD-related NCCP.[58] In contrast, there was no difference in baseline mucosal impedance values between the 2 groups in the proximal esophagus, although it was significantly lower than healthy volunteers. However, for diagnosing FCP, the pH-impedance test and metrics like basal mucosal impedance are currently not required.

Esophageal Manometry

Assessment of esophageal function, using high-resolution esophageal manometry, should be pursued prior diagnosing FCP in NCCP patients with normal reflux testing. The purpose of the test is to exclude major esophageal motor disorders, including achalasia, esophagogastric junction outflow obstruction, absent contractility, distal esophageal spasm, and jackhammer esophagus.[2] The presence of ineffective esophageal motility or fragmented peristalsis does not exclude the diagnosis of FCP.

Studies have shown that most NCCP patients undergoing esophageal manometry (up to 70.0%) demonstrate normal esophageal function.[59-61] While hypercontractile esophageal motor disorders have been proposed to be the main underlying cause for esophageal related chest pain, studies have demonstrated that hypotensive esophageal motor disorders are the most common findings in NCCP patients undergoing esophageal manometry. Recently, Akinsiku et al[61] have demonstrated that hypotensive lower esophageal sphincter was the most common motility disorder identified by conventional manometry (27.3%), and ineffective esophageal motility was the most common esophageal motor disorder identified by high-resolution esophageal manometry (25.3%).

The nature of the relationship between identified esophageal motor disorder and chest pain remains to be elucidated. Importantly, patients rarely report chest pain during esophageal manometry, when these motor abnormalities are diagnosed.[11,13] In addition, therapies aimed at improving the identified esophageal motor disorder in NCCP patients have not yielded consistent results.[13] Consequently, it has been hypothesized that the esophageal motility disorders diagnosed in NCCP patients may represent a marker for a general sensory-motor abnormality or possibly just an epiphenomenon.[13,43]

Sensory Testing

The role of sensory testing in FCP has been scarcely studied. Some of the tests were introduced to reproduce patient's chest pain and others to assess for the presence of esophageal hypersensitivity.[62] However, the different sensory tests (Table 3) have not been standardized and various protocols have been used in different studies. Furthermore, the tests are invasive, uncomfortable and we are still devoid of any evidence that a positive test can direct a specific treatment or predict therapeutic outcome.[63]

The original acid perfusion test (Bernstein test) was intended to discriminate between cardiac and esophageal pain.[64] The test has been shown to be highly specific but with a relatively low sensitivity (7.0-60.0%). Later modifications to the test have converted it to a sensory testing, assessing for the presence of esophageal hypersensitivity.[65] Balloon distention was also originally introduced as a tool to discriminate between esophageal and cardiac pain with a limited sensitivity that ranged from 5.0-75.0%.[66,67] Later, the technique has evolved to assess for the presence of esophageal hypersensitivity. However, as with the acid perfusion test, protocols were not standardized, and different equipment was used.[14] Moreover, the test is invasive, painful and has not been shown to predict therapeutic outcome.

Impedance planimetry, using dynamic balloon distensions, has been utilized in FCP to assess esophageal sensory thresholds and biomechanical properties.[68] In one study, the authors demonstrated that FCP patients have lower perception thresholds for pain, larger cross-sectional esophageal area, decreased esophageal wall strain, and reduced distensability.[68]

Electrical stimulation, thermal stimulation, and multimodal techniques that provide a battery of stimulation tests (electrical, acid, balloon, and thermal) have been used primarily as research tools to assess for esophageal hypersensitivity in NCCP patients.[69]

Psychological Evaluation

Psychological comorbidity is very common in patients with FCP, affecting up to 75.0%.[70] Depression, anxiety, neuroticism, and

Table 3. Sensory Testing in Functional Chest Pain

- Acid perfusion test
- Balloon distention test
- Impedance planimetry
- Electrical stimulation
- Thermal stimulation
- Multi-modal stimulation test (thermal, balloon, and electrical)

Intraocular Steroids for Uveitis 2023

Plain Language Summary:

Coverage question: Should OHP remove the part of a guideline about treatments for eye inflammation that says members have to try of oral steroid medication first?

Should OHP cover this treatment? Yes, and remove the whole guideline as it is out of date.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should the intraocular steroid guideline be modified to remove the requirement for systemic steroids to be tried prior to intraocular steroid injections?

Question source: Jeanne Savage, CCO medical director

Background: Uveitis is an inflammatory disease of the eye that can cause loss of vision. It may occur due to infection or may be due to an autoimmune etiology. Several drugs are available for the management of noninfectious uveitis including corticosteroids, immunosuppressive agents, and more recently biologics. Steroids can be administered orally (systemic therapy) or by injecting them into the eye.

This topic was last reviewed almost 10 years ago. At that time, common treatments for uveitis such as adalimumab were not part of the treatment paradigm.

Previous HSC/HERC reviews:

October 2013
Information from P&T and testimony from industry was considered. A new guideline was created for intraocular steroid implants for chronic non-infectious uveitis and a second guideline was added for intraocular steroid implants for central retinal vein occlusion.

A P&T report on dexamethasone intravitreal implants (Ozudex) and fluocinolone intraocular implants (Retisert) were reviewed: “There is low quality evidence that there is no difference in visual acuity outcomes between fluocinolone acetonide intravitreal implant and standard of care with systemic corticosteroids for the treatment of noninfectious uveitis. There is also low quality evidence that fluocinolone intravitreal implant may control inflammation in the eye faster and more frequently than standard of care, although both approaches decrease inflammation.” The initial results of the MUST trial were reviewed that compared intraocular steroid implants to systemic steroids. The conclusion of this review was “some benefit seen with steroid implants; however, systemic steroid therapy appears to be equally effective. High rates of complications seen, including cataracts and increased intraocular pressure.”

Intraocular Steroids for Uveitis 2023

November 2014
The intraocular steroid for chronic non-infectious uveitis guideline was modified to allow treatment for intermediate and pan-uveitis as well as posterior uveitis. The intraocular steroid implants for central retinal vein occlusion guideline was modified to allow treatment for macular edema resulting from branch retinal vein occlusion in certain circumstances. These changes were based on industry testimony.

March 2015
The guideline regarding intraocular steroid injections was modified to include coverage criteria for use in diabetic macular edema

October 2016
The guideline for intraocular steroid implants for retinal vein occlusion was deleted and its content added to the uveitis guideline as a global intraocular steroid treatment guideline.

Current Prioritized List/Coverage status:

CPT 67027 (Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of vitreous) is on lines 95,279,285,318,360,383and 67028 (Intravitreal injection of a pharmacologic agent (separate procedure)) is on lines 95,277,283,315,357,380

Line 95 DIABETIC AND OTHER RETINOPATHY
Line 277 RETINAL DETACHMENT AND OTHER RETINAL DISORDERS
Line 283 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
Line 315 PURULENT ENDOPHTHALMITIS
Line 357 CHORIORETINAL INFLAMMATION
Line 380 CENTRAL SEROUS CHORIORETINOPATHY

GUIDELINE NOTE 116, INTRAOCULAR STEROID TREATMENTS

Lines 95,357,438

Intraocular steroid treatments (CPT 67027, 67028) are included on Line 360 for pairing with uveitis (ICD-10-CM H30.0, H30.1, H30.89, H30.9, H44.11) when the following conditions are met: uveitis is chronic, non-infectious, and there has been appropriate trial and failure, or intolerance of therapy, with local and systemic corticosteroids and/or immunosuppressive agents.

Intraocular steroid treatments (CPT 67027, 67028) are included on Line 95 for treating chronic diabetic macular edema (ICD-10-CM E11.311) only when there has been insufficient response to anti-VEGF therapies, and only when FDA approved treatments are utilized.

Intraocular steroid treatments (CPT 67027, 67028) are only included on Line 441 for treatment of macular edema due to:

A) Central retinal vein occlusion (ICD-10-CM H34.81) in those individuals who have failed anti-VEGF therapy.
B) Branch retinal vein occlusion (ICD-10-CM H34.83) when treatment with laser photocoagulation has not been beneficial, or treatment with laser photocoagulation is not considered suitable

because of the extent of macular hemorrhage in those individuals who have failed anti-VEGF therapy.

Evidence:

1) **Kempen 2017**, MUST trial follow up
    a. 7 yr follow up of MUST RCT
        i. Randomized patients to steroid implant vs systemic steroid therapy
        ii. N=161 uveitic eyes in implant group and 167 eveitic eyes in the systemic group
    b. Change in mean visual acuity from baseline (implant, 61.7; systemic therapy, 65.0) through 7 years (implant, 55.8; systemic therapy, 66.2) favored systemic therapy by 7.2 (95% CI, 2.1-12) letters. Among protocol-specified, prospectively collected systemic adverse outcomes, the cumulative 7-year incidence in the implant and systemic therapy groups, respectively, was less than 10%, with the exceptions of hyperlipidemia (6.1% vs 11.2%), hypertension (9.8% vs 18.4%), osteopenia (41.5% vs 43.1%), fractures (11.3% vs 18.6%), hospitalization (47.6% vs 42.3%), and antibiotic-treated infection (57.4% vs 72.3%)
    c. Conclusions: In 7-year extended follow-up of a randomized trial of patients with severe intermediate, posterior, or panuveitis, those randomized to receive systemic therapy had better visual acuity than those randomized to receive intravitreous fluocinolone acetonide implants. Study interpretation is limited by loss to follow-up.

Expert guidelines:

1) **American Academy of Ophthalmology** 2020-2021 Basic and Clinical Science Course, Chapter 6: Therapy for Uveitis
    a. Available at https://www.aao.org/education/bcscsnippetdetail.aspx?id=724c93e0-b934-4906-8acf-02db787c83e1
        i. Accessed 11/22/23
    b. Corticosteroids are the mainstay of uveitis therapy. They may be administered locally (as topical eyedrops, or periocular or intraocular injections) or systemically (orally or intravenously or, less frequently, intramuscularly).
    c. Sustained-release steroid may be delivered directly into the vitreous cavity or into the periocular space of an eye with noninfectious uveitis when a more posterior effect is needed, or when a patient is nonadherent or only partially responsive to topical or systemic administration. Intermediate- and short-acting local steroid injections may be used intermittently to treat breakthrough inflammation in otherwise well-controlled or mild uveitis. Long-acting intravitreal steroids can be used as alternatives to long-term IMT in certain clinical settings
    d. Systemic corticosteroids are used for vision-threatening chronic uveitis when local corticosteroids are insufficient or contraindicated or when systemic disease also requires therapy.
2) **NICE 2017** Adalimumab and dexamethasone for treating non-infectious uveitis
    a. Dexamethasone intravitreal implant is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults, only if there is:
        i. active disease (that is, current inflammation in the eye) and
        ii. worsening vision with a risk of blindness.

Intraocular Steroids for Uveitis 2023

Other payer policies:

1) Aetna 2023
    a. Retisert (fluocinolone acetonide intravitreal 0.59 mg implant) and Yutiq (fluocinolone acetonide intravitreal 0.18 mg implant) for the treatment of chronic non-infectious uveitis (including birdshot chorioretinopathy) affecting the posterior segment of the eye in persons who do not respond to or are intolerant to conventional treatment (i.e., failed corticosteroid or immunosuppressive therapy)
    b. Iluvien (fluocinolone acetonide intravitreal implant) for the treatment of diabetic macular edema in persons who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.
2) Cigna: appears to cover CPT 67027 without restrictions

Expert input:

Dr. Jonathan Yoken, ophthalmologist

By way of our previous conversation regarding systemic vs local therapy for uveitis, and the requirement for systemic failure PRIOR to local therapy, I had a conversation with Dr Eric Suhler, a Uveitis specialist at Casey Eye Institute (I and my Retina colleagues see numerous Uveiits patients, but Dr Suhler sees almost exclusively those patients). He supported my opinion that one need not, nor should one have to fail systemic therapy prior to local treatment. It's not even clear that it would be a cost savings - if that is in fact the goal. Every patient presentation as you can imagine is unique, and in many cases a combination treatment approach may be appropriate.

If simply removing the guideline solves the problem I would happily support that. The treatment of Uveitis has been evolving with numerous new systemic options as well as local (infra-ocular) therapy. It definitely is not appropriate to require a trial of systemic therapy prior to infra-ocular therapy. For example, sometimes patients present with severe intra-ocular Inflammation involving the retina, vitreous or optic nerve. And certainly one option is to start the patient on oral prednisone (after excluding infectious causes). But sometimes there can be a contraindication to systemic prednisone or the inflammation is primarily in the form of macular edema - which may take time for systemic therapy to take effect. Intraocular injections of steroid containing medications can provide very rapid resolution of the inflammation while sparing the patient from systemic side effects. Also, some systemic immunotherapy may not work at all or have side effects and while trying to find an effective systemic therapy, the untreated inflammation can cause more damage.

I find local therapy can be a very effective initial treatment. Most patients will respond very rapidly, and some may achieve long term remission with one or two treatments. Those requiring more frequent or repeat intraocular treatment will then likely benefit from systemic therapy to achieve longer term control with occasional injections if there is breakthrough inflammation.

Some patients may present with uveitis and have a known autoimmune disease or one may be diagnosed following the uveitis presentation. These patients may benefit from initial systemic therapy.

> I think overall, the guideline probably is not very useful - uveitis is relatively rare, so as a cost savings guideline, I would think at the end of the day it probably doesn't achieve much in the way of cost savings but would severely impact the custom tailoring of therapy - which is essential in such a complex disease.

HERC staff summary:

Uveitis has a variety of treatment options, including topical steroid drops, steroid injections and implants, systemic steroids, and non-steroidal systemic treatments such as adalimumab. Since the last in depth review 10 years ago, the treatment of uveitis has evolved considerably. Expert guidelines now recommend systemic corticosteroids only when there is failure of topical or local steroid treatment. Oregon experts recommend removing the requirement for systemic therapy prior to local therapy for non-infectious uveitis.

When queried, the CCO medical directors indicated that they are not using this guideline. Expert input recommends deleting the guideline, and HERC staff agree.

HERC staff recommendation:

1) Delete Guideline Note 116

~~GUIDELINE NOTE 116, INTRAOCULAR STEROID TREATMENTS~~

~~*Lines 95,357,438*~~

~~Intraocular steroid treatments (CPT 67027, 67028) are included on Line 357 for pairing with uveitis (ICD-10-CM H30.0, H30.1, H30.89, H30.9, H44.11) when the following conditions are met: uveitis is chronic, non-infectious, and there has been appropriate trial and failure, or intolerance of therapy, with local and systemic corticosteroids and/or immunosuppressive agents.~~

~~Intraocular steroid treatments (CPT 67027, 67028) are included on Line 95 for treating chronic diabetic macular edema (ICD-10-CM E11.311) only when there has been insufficient response to anti-VEGF therapies, and only when FDA approved treatments are utilized.~~

~~Intraocular steroid treatments (CPT 67027, 67028) are only included on Line 438 for treatment of macular edema due to:~~

~~A) Central retinal vein occlusion (ICD-10-CM H34.81) in those individuals who have failed anti-VEGF therapy.~~

~~B) Branch retinal vein occlusion (ICD-10-CM H34.83) when treatment with laser photocoagulation has not been beneficial, or treatment with laser photocoagulation is not considered suitable because of the extent of macular hemorrhage in those individuals who have failed anti-VEGF therapy.~~

JAMA | Original Investigation

Association Between Long-Lasting Intravitreous Fluocinolone Acetonide Implant vs Systemic Anti-inflammatory Therapy and Visual Acuity at 7 Years Among Patients With Intermediate, Posterior, or Panuveitis

Writing Committee for the Multicenter Uveitis Steroid Treatment (MUST) Trial and Follow-up Study Research Group

IMPORTANCE A randomized clinical trial comparing fluocinolone acetonide implant vs systemic corticosteroids and immunosuppression for treatment of severe noninfectious intermediate, posterior, and panuveitides did not result in a significant difference in visual acuity at 2 and 4.5 years; longer-term outcomes are not known.

OBJECTIVE To compare the association between intravitreous fluocinolone acetonide implant vs systemic therapy and long-term visual and other outcomes in patients with uveitis.

DESIGN, SETTING, AND PARTICIPANTS Nonprespecified 7-year observational follow-up of the Multicenter Uveitis Steroid Treatment (MUST) randomized clinical trial comparing the alternative treatments. Follow-up was conducted in tertiary uveitis subspecialty practices in the United States (21), the United Kingdom (1), and Australia (1). Of 255 patients 13 years or older with intermediate, posterior, or panuveitis (active within ≤60 days) enrolled in the MUST trial between December 6, 2005, and December 9, 2008, 215 consented to ongoing follow-up through at least 7 years postrandomization (last visit, February 10, 2016).

INTERVENTIONS Participants had been randomized to receive a surgically placed intravitreous fluocinolone acetonide implant or systemic corticosteroids supplemented by immunosuppression. When both eyes required treatment, both eyes were treated.

MAIN OUTCOMES AND MEASURES Primary outcome was change from baseline in best-corrected visual acuity in uveitic eyes (5 letters = 1 visual acuity chart line; potential range of change in letters read, −121 to +101; minimal clinically important difference, 7 letters), analyzed by treatment assignment accounting for nonindependence of eyes when patients had 2 uveitic eyes. Secondary outcomes included potential systemic toxicities of corticosteroid and immunosuppressive therapy and death.

RESULTS Seven-year data were obtained for 161 uveitic eyes (70% of 90 patients assigned to implant) and 167 uveitic eyes (71% of 90 patients assigned to systemic therapy) (77% female; median age at enrollment, 48 [interquartile range, 36-56] years). Change in mean visual acuity from baseline (implant, 61.7; systemic therapy, 65.0) through 7 years (implant, 55.8; systemic therapy, 66.2) favored systemic therapy by 7.2 (95% CI, 2.1-12) letters. Among protocol-specified, prospectively collected systemic adverse outcomes, the cumulative 7-year incidence in the implant and systemic therapy groups, respectively, was less than 10%, with the exceptions of hyperlipidemia (6.1% vs 11.2%), hypertension (9.8% vs 18.4%), osteopenia (41.5% vs 43.1%), fractures (11.3% vs 18.6%), hospitalization (47.6% vs 42.3%), and antibiotic-treated infection (57.4% vs 72.3%).

CONCLUSIONS AND RELEVANCE In 7-year extended follow-up of a randomized trial of patients with severe intermediate, posterior, or panuveitis, those randomized to receive systemic therapy had better visual acuity than those randomized to receive intravitreous fluocinolone acetonide implants. Study interpretation is limited by loss to follow-up.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT00132691

JAMA. 2017;317(19):1993-2005. doi:10.1001/jama.2017.5103
Published online May 6, 2017.

Supplemental content

CME Quiz at jamanetwork.com/learning

Authors/Group Information: Members of the Writing Committee are listed at the end of this article. A complete list of the members of the MUST Trial and Follow-up Study Research Group is available in the eAppendix in Supplement 1.

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Reflectance Confocal Microscopy

Plain Language Summary:

Coverage question: Should OHP cover the use of a specialized tool that takes close-up images of the skin?

Should OHP cover this treatment? No, this is relatively new technology and hasn't been thoroughly researched yet.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should reflectance confocal microscopy continue to be non-covered?

Question sources: Dr. Alexander Wikowski, OHSU dermatology; Holly Jo Hodges, CCO medical director

Background:

Reflectance confocal microscopy (RCM) is a non-invasive diagnostic modality used for imaging the skin with cellular resolution. RCM allows the noninvasive evaluation of a variety of skin conditions and provides a more detailed, magnified evaluation of potential lesions than other microscopic techniques. It is used to help diagnose squamous cell (SCC), basal cell (BCC) and melanoma skin cancers.

The alternative to RCM is clinical skin exam with biopsy of any suspicious lesions with or without dermoscopy. Dermoscopy is on several covered lines on the Prioritized List.

It is estimated that a minimum of 4 to 6 months of training, including the evaluation of several thousands of cases, is required for a clinician to reach an acceptable level of diagnostic accuracy and expertise (**Levine 2018**). RCM imaging takes significantly longer than dermoscopy and therefore should not be used as a replacement to dermoscopy as a screening tool but as an adjunct in selecting equivocal lesions of concern based on dermoscopic findings. Most of the studies calculating diagnostic accuracy include prior clinical and dermoscopic data; therefore, it is optimal to be proficient in dermoscopy to efficiently and effectively decide which lesions should subsequently be referred for RCM imaging and the actual interpretation of these lesions (Levine 2018)

Previous HSC/HERC reviews:

1) Reflectance confocal microscopy was discussed as a new CPT code in October 2015, with one additional code discussed in November 2016 also as a new CPT code. During the 2015 review, one systematic review (Drakaki 2012) was reviewed that found 4 studies on this technology. No private payer was found to be covering this technology. This technology was determined to be experimental.

Reflectance Confocal Microscopy

Current Prioritized List/Coverage status:

Dermoscopy (CPT 96904) is on lines 228 MALIGNANT MELANOMA OF SKIN, 274 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA, and 620 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES.

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS
Line 654

The following Interventions are prioritized on Line 654 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
96931-96935	Reflectance confocal microscopy for non-melanoma skin lesions	Insufficient evidence of effectiveness	November, 2015
96936	Reflectance confocal microscopy (RCM) for cellular and subcellular imaging of skin.	Insufficient evidence of effectiveness	November, 2016

Evidence:

1) **Pellacani 2022,** RCT of RCM for diagnostic accuracy of melanoma in suspect lesions
    a. N=3165 patients
    b. Randomized to standard care (clinical and dermoscopy evaluation) with or without adjunctive RCM
        i. 1455 patients in the standard care diagnostic analysis
        ii. 1536 patients in the RCM diagnostic analysis
    c. In the standard group, all lesions were referred for excision. Of those lesions 18.6% were melanoma
    d. In the RCM group, 720 (45.5%) were referred for excision. Melanoma was confirmed in 278 of 836 (33.2%) excised lesions. 144 of the 278 (51.8%) were classified as melanoma in situ
    e. When compared with standard therapeutic care only, adjunctive RCM was associated with a higher positive predictive value (18.9 vs 33.3), lower benign to malignant ratio (3.7:1.0 vs 1.8:1.0), and a number needed to excise reduction of 43.4% (5.3 vs 3.0). All lesions (n = 15) with delayed melanoma diagnoses were thinner than 0.5 mm.
    f. Conclusions: This randomized interventional trial assessed the applicability of adjunctive RCM for equivocal lesions suspected of melanoma in a clinical setting and proves that unnecessary excisions can be reduced by almost half, with greater accuracy of in vivo identification of benign lesions. This randomized clinical trial shows that adjunctive use of RCM for suspect lesions reduces unnecessary excisions and assures the removal of aggressive melanomas at baseline in a real-life, clinical decision-making application for referral centers with RCM.
2) **Dinnes 2018**, Cochrane review of reflectance confocal microscopy for diagnosing melanoma
    a. N=18 publications reporting on 19 cohorts with 2838 lesions
        i. All studies were at unclear risk of bias

ii. All cohort or case series

b. Across all populations, algorithms and thresholds assessed, the sensitivity and specificity of the Pellacani RCM score at a threshold of three or greater were estimated at 92% (95% confidence interval (CI) 87 to 95) for RCM

c. Conclusion: RCM may have a potential role in clinical practice, particularly for the assessment of lesions that are difficult to diagnose using visual inspection and dermoscopy alone, where the evidence suggests that RCM may be both more sensitive and specific in comparison to dermoscopy. Given the paucity of data to allow comparison with dermoscopy, the results presented require further confirmation in prospective studies comparing RCM with dermoscopy in a real-world setting in a representative population

3) **Dinnes 2018**, reflectance confocal microscopy for diagnosis non-melanoma skin cancer
   a. N=10 studies on 11 cohorts
      i. All studies at high or unclear risk of bias
      ii. All cohort or case series
   b. Meta-analysis found RCM to be more sensitive but less specific for the detection of BCC in studies of participants with equivocal lesions (sensitivity 94%, 95% confidence interval (CI) 79% to 98%; specificity 85%, 95% CI 72% to 92%; 3 studies) compared to studies that included any suspicious lesion (sensitivity 76%, 95% CI 45% to 92%; specificity 95%, 95% CI 66% to 99%; 4 studies), although CIs were wide
   c. Conclusion: There is insufficient evidence for the use of RCM for the diagnosis of BCC or SCC in either population group.

Expert guidelines:

1) **NCCN 3.2023** Cutaneous melanoma
   a. Follow up for patients previously diagnosed with melanoma:
      i. Pre-diagnostic clinical modalities (ie, dermoscopy, total-body photography and sequential digital dermoscopy), noninvasive imaging and other technologies (eg, reflectance confocal microscopy, electrical impedance spectroscopy) may aid in surveillance for new primary melanoma, particularly in patients with high mole count and/or presence of clinically atypical nevi

Other payer policies:

1) Anthem BCBS: Reflectance confocal microscopy for the evaluation of skin lesions is considered **not medically necessary** in all cases
2) Aetna: The following interventions (not an all-inclusive list) for evaluating dysplastic and atypical nevi for early detection of malignant cutaneous melanomas because their clinical value for this indication has not been established:
   a. Reflectance confocal microscopy (RCM)
3) Regence BCBS
   a. Considers reflectance confocal microscopy to be investigational

HERC staff summary:

Reflectance Confocal Microscopy

Reflectance confocal microscopy is a relatively new technology with mostly cohort and case control studies evaluating it. There is one RCT that found that RCM decreased the biopsy rate when used in addition to clinical exam and dermoscopy. RCM requires specialized equipment and specific training. NCCN lists RCM as one possible method for follow up for patients who previously were diagnosed with melanoma. Private insurers consider this technology to be investigational.

Staff recommends continuing non-coverage of reflectance confocal microscopy.

HERC staff recommendation:

1) Update the GN173 entry for reflectance confocal microscopy 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 654

The following Interventions are prioritized on Line 654 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
96931~~-96935~~-96936	Reflectance confocal microscopy ~~for non-melanoma skin lesions~~	Insufficient evidence of effectiveness	~~November, 2015~~ January 2024
~~96936~~	~~Reflectance confocal microscopy (RCM) for cellular and subcellular imaging of skin.~~	~~Insufficient evidence of effectiveness~~	~~November, 2016~~

Introduction to reflectance confocal microscopy and its use in clinical practice

Amanda Levine, MD, and Orit Markowitz, MD, FAAD
New York and Brooklyn, New York

Reflectance confocal microscopy (RCM) is a novel technology that provides noninvasive, in vivo imaging of the skin at nearly histologic resolution. In 2016, the US Centers for Medicare and Medicaid Services (CMS) established reimbursement codes for RCM image acquisition and for the reading and interpretation of images. The combination of RCM imaging with dermoscopy has improved the accuracy of skin cancer diagnosis while reducing the number of biopsies of benign skin lesions. With that, we are starting to see more dermatologists and dermatopathologists using RCM in clinical practice. This editorial is to serve as an introduction on RCM imaging with a focus on its usefulness in both the diagnosis and management of skin cancers. We end by briefly describing the characteristic RCM features of normal skin to serve as a building block for later cases that will explore both the benefits and drawbacks of incorporating RCM imaging for benign and malignant lesions. (J Am Acad Dermatol 2018;4:1014-23.)

Key words: innovative technology; lentigo maligna; melanoma; noninvasive imaging; nonmelanoma skin cancer; reflectance confocal microscopy; skin cancer.

INTRODUCTION

Reflectance confocal microscopy (RCM) is a US Food and Drug Administration–approved optical imaging technology that offers noninvasive visualization of skin lesions in vivo at nearly histologic resolution. In 2016, the Centers for Medicare and Medicaid Services (CMS) granted category I current procedural terminology (CPT) codes (96931-96936) for RCM imaging and evaluation of skin lesions.[1] Physicians can now submit a procedural bill for potential reimbursement for the cellular and subcellular image acquisition or interpretation and report of skin lesions.[1] Although the cost of purchasing a device has previously limited its use to large academic and research centers, now with reimbursement and the option to lease, we predict that this technology will gain more traction in the United States market. With this comes the need to narrow the educational gap hindering dermatologists from using this device in clinical practice.

Abbreviations used:

CMS:	US Centers for Medicare and Medicaid Services
CPT:	current procedural terminology
LM:	lentigo maligna
NNT:	number needed to treat
RCM:	reflectance confocal microscopy

RCM TECHNICAL PROPERTIES

The current commercially available in vivo devices include the wide-probe RCM, VivaScope 1500 (Caliber Imaging and Diagnostics, Rochester, NY) and the handheld RCM, VivaScope 3000 (Caliber Imaging and Diagnostics). RCM imaging provides nuclear and cellular morphology of the skin with a typical lateral (ie, horizontal) resolution of 0.5 to 1 μm and axial resolution (ie, vertical layer thickness) of between 3 and 5 μm, to a depth of about 150 to 200 μm depending on the anatomical site.[2-6] Imaging is in the horizontal (en face) plane, parallel to the skin surface, similar to the field of view obtained in dermoscopy and Mohs sections. The VivaScope 1500 creates individual optical sections in small 0.5- x 0.5-mm fields of view at 30x magnification comparable to histopathology. To image in depth, RCM can create a stack of images at the same horizontal plane

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Conflicts of interest: None disclosed.

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JAMA Dermatology | Original Investigation

Effect of Reflectance Confocal Microscopy for Suspect Lesions on Diagnostic Accuracy in Melanoma
A Randomized Clinical Trial

Giovanni Pellacani, MD; Francesca Farnetani, MD; Silvana Ciardo, BS; Johanna Chester, BA, BSC; Shaniko Kaleci, PhD; Laura Mazzoni, PhD; Sara Bassoli, MD; Alice Casari, MD; Riccardo Pampena, MD; Marica Mirra, MD; Michela Lai, MD; Serena Magi, PhD; Victor D. Mandel, MD; Sergio Di Matteo, MSc; Giorgio Lorenzo Colombo, MSc; Ignazio Stanganelli, MD; Caterina Longo, MD

IMPORTANCE Previous systematic reviews and meta-analyses have concluded that given data paucity, a comparison of reflectance confocal microscopy (RCM) with dermoscopy is complex. They recommend comparative prospective studies in a real-world setting of suspect lesions.

OBJECTIVE To test the hypothesis that RCM reduces unnecessary lesion excision by more than 30% and identifies all melanoma lesions thicker than 0.5 mm at baseline.

DESIGN, SETTING, AND PARTICIPANTS This randomized clinical trial included 3165 patients enrolled from 3 dermatology referral centers in Italy between January 2017 and December 2019, with a mean (SD) follow-up of 9.6 (6.9) months (range, 1.9-37.0 months). The consecutive sample of 3165 suspect lesions determined through dermoscopy were eligible for inclusion (10 patients refused). Diagnostic analysis included 3078 patients (48 lost, 39 refused excision). Data were analyzed between April and September 2021.

INTERVENTIONS Patients were randomly assigned 1:1 to standard therapeutic care (clinical and dermoscopy evaluation) with or without adjunctive RCM. Information available guided prospective clinical decision-making (excision or follow-up).

MAIN OUTCOMES AND MEASURES Hypotheses were defined prior to study initiation. All lesions excised (baseline and follow-up) were registered, including histopathological diagnoses/no change at dermoscopy follow-up (with or without adjunctive RCM). Number needed to excise (total number of excised lesions/number of melanomas) and Breslow thickness of delayed diagnosed melanomas were calculated based on real-life, prospective, clinical decision-making.

RESULTS Among the 3165 participants, 1608 (50.8%) were male, and mean (SD) age was 49.3 (14.9) years. When compared with standard therapeutic care only, adjunctive RCM was associated with a higher positive predictive value (18.9 vs 33.3), lower benign to malignant ratio (3.7:1.0 vs 1.8:1.0), and a number needed to excise reduction of 43.4% (5.3 vs 3.0). All lesions (n = 15) with delayed melanoma diagnoses were thinner than 0.5 mm.

CONCLUSIONS AND RELEVANCE This randomized clinical trial shows that adjunctive use of RCM for suspect lesions reduces unnecessary excisions and assures the removal of aggressive melanomas at baseline in a real-life, clinical decision-making application for referral centers with RCM.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT04789421

Visual Abstract

Supplemental content

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Cochrane Database of Systematic Reviews

Reflectance confocal microscopy for diagnosing cutaneous melanoma in adults (Review)

Dinnes J, Deeks JJ, Saleh D, Chuchu N, Bayliss SE, Patel L, Davenport C, Takwoingi Y, Godfrey K, Matin RN, Patalay R, Williams HC, Cochrane Skin Cancer Diagnostic Test Accuracy Group

Dinnes J, Deeks JJ, Saleh D, Chuchu N, Bayliss SE, Patel L, Davenport C, Takwoingi Y, Godfrey K, Matin RN, Patalay R, Williams HC, Cochrane Skin Cancer Diagnostic Test Accuracy Group.
Reflectance confocal microscopy for diagnosing cutaneous melanoma in adults.
Cochrane Database of Systematic Reviews 2018, Issue 12. Art. No.: CD013190.
DOI: 10.1002/14651858.CD013190.

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[Diagnostic Test Accuracy Review]

Reflectance confocal microscopy for diagnosing cutaneous melanoma in adults

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ABSTRACT

Background

Melanoma has one of the fastest rising incidence rates of any cancer. It accounts for a small percentage of skin cancer cases but is responsible for the majority of skin cancer deaths. Early detection and treatment is key to improving survival; however, anxiety around missing early cases needs to be balanced against appropriate levels of referral and excision of benign lesions. Used in conjunction with clinical or dermoscopic suspicion of malignancy, or both, reflectance confocal microscopy (RCM) may reduce unnecessary excisions without missing melanoma cases.

Objectives

To determine the diagnostic accuracy of reflectance confocal microscopy for the detection of cutaneous invasive melanoma and atypical intraepidermal melanocytic variants in adults with any lesion suspicious for melanoma and lesions that are difficult to diagnose, and to compare its accuracy with that of dermoscopy.

Search methods

We undertook a comprehensive search of the following databases from inception up to August 2016: Cochrane Central Register of Controlled Trials; MEDLINE; Embase; and seven other databases. We studied reference lists and published systematic review articles.

Selection criteria

Studies of any design that evaluated RCM alone, or RCM in comparison to dermoscopy, in adults with lesions suspicious for melanoma or atypical intraepidermal melanocytic variants, compared with a reference standard of either histological confirmation or clinical follow-up.

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Data collection and analysis

Two review authors independently extracted all data using a standardised data extraction and quality assessment form (based on QUADAS-2). We contacted authors of included studies where information related to the target condition or diagnostic threshold were missing. We estimated summary sensitivities and specificities per algorithm and threshold using the bivariate hierarchical model. To compare RCM with dermoscopy, we grouped studies by population (defined by difficulty of lesion diagnosis) and combined data using hierarchical summary receiver operating characteristic (SROC) methods. Analysis of studies allowing direct comparison between tests was undertaken. To facilitate interpretation of results, we computed values of specificity at the point on the SROC curve with 90% sensitivity as this value lies within the estimates for the majority of analyses. We investigated the impact of using a purposely developed RCM algorithm and in-person test interpretation.

Main results

The search identified 18 publications reporting on 19 study cohorts with 2838 lesions (including 658 with melanoma), which provided 67 datasets for RCM and seven for dermoscopy. Studies were generally at high or unclear risk of bias across almost all domains and of high or unclear concern regarding applicability of the evidence. Selective participant recruitment, lack of blinding of the reference test to the RCM result, and differential verification were particularly problematic. Studies may not be representative of populations eligible for RCM, and test interpretation was often undertaken remotely from the patient and blinded to clinical information.

Meta-analysis found RCM to be more accurate than dermoscopy in studies of participants with any lesion suspicious for melanoma and in participants with lesions that were more difficult to diagnose (equivocal lesion populations). Assuming a fixed sensitivity of 90% for both tests, specificities were 82% for RCM and 42% for dermoscopy for any lesion suspicious for melanoma (9 RCM datasets; 1452 lesions and 370 melanomas). For a hypothetical population of 1000 lesions at the median observed melanoma prevalence of 30%, this equated to a reduction in unnecessary excisions with RCM of 280 compared to dermoscopy, with 30 melanomas missed by both tests. For studies in equivocal lesions, specificities of 86% would be observed for RCM and 49% for dermoscopy (7 RCM datasets; 1177 lesions and 180 melanomas). At the median observed melanoma prevalence of 20%, this reduced unnecessary excisions by 296 with RCM compared with dermoscopy, with 20 melanomas missed by both tests. Across all populations, algorithms and thresholds assessed, the sensitivity and specificity of the Pellacani RCM score at a threshold of three or greater were estimated at 92% (95% confidence interval (CI) 87 to 95) for RCM and 72% (95% CI 62 to 81) for dermoscopy.

Authors' conclusions

RCM may have a potential role in clinical practice, particularly for the assessment of lesions that are difficult to diagnose using visual inspection and dermoscopy alone, where the evidence suggests that RCM may be both more sensitive and specific in comparison to dermoscopy. Given the paucity of data to allow comparison with dermoscopy, the results presented require further confirmation in prospective studies comparing RCM with dermoscopy in a real-world setting in a representative population.

PLAIN LANGUAGE SUMMARY

What is the diagnostic accuracy of the imaging test reflectance confocal microscopy (RCM) for the detection of melanoma in adults?

What was the aim of the review?

The aim of this Cochrane Review was to find out how accurate reflectance confocal microscopy (RCM) was on its own and used in addition to dermoscopy compared to dermoscopy alone for diagnosing melanoma. Review authors in Cochrane included 18 publications to answer this question.

Why is improving the diagnosis of melanoma important?

Melanoma is one of the most dangerous forms of skin cancer. Not recognising a melanoma when it is present (called a false negative test result) delays surgery to remove it, risking cancer spreading to other parts in the body and possibly death. Diagnosing a skin lesion as a melanoma when it is not present (called a false positive result) may result in unnecessary surgery, further investigations, and patient anxiety.

What did the review study?

Microscopic techniques are used by skin cancer specialists to allow a more detailed, magnified examination of suspicious skin lesions than can be achieved using the naked eye alone. Currently, dermoscopy (a handheld device using natural light) can be used as part of the clinical examination of suspicious skin lesions. RCM is a new microscopic technique (a handheld device or static unit using infrared light) that can visualise deeper layers of the skin compared to dermoscopy. Both techniques are painless procedures, but RCM is more expensive, time consuming, and requires additional training. Dermoscopy can be used by general practitioners whereas RCM is likely to only be used by secondary care specialists in people who have been referred with a lesion suspicious for skin cancer. We sought to find out whether RCM should be used instead of, or in addition to, dermoscopy, to diagnose melanoma in any suspicious skin lesion or only in particularly difficult to diagnose skin lesions.

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Reflectance confocal microscopy for diagnosing keratinocyte skin cancers in adults (Review)

Dinnes J, Deeks JJ, Chuchu N, Saleh D, Bayliss SE, Takwoingi Y, Davenport C, Patel L, Matin RN, O'Sullivan C, Patalay R, Williams HC, Cochrane Skin Cancer Diagnostic Test Accuracy Group

Dinnes J, Deeks JJ, Chuchu N, Saleh D, Bayliss SE, Takwoingi Y, Davenport C, Patel L, Matin RN, O'Sullivan C, Patalay R, Williams HC, Cochrane Skin Cancer Diagnostic Test Accuracy Group.
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[Diagnostic Test Accuracy Review]

Reflectance confocal microscopy for diagnosing keratinocyte skin cancers in adults

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ABSTRACT

Background

Early accurate detection of all skin cancer types is important to guide appropriate management and improve morbidity and survival. Basal cell carcinoma (BCC) is usually a localised skin cancer but with potential to infiltrate and damage surrounding tissue, whereas cutaneous squamous cell carcinoma (cSCC) and melanoma are higher risk skin cancers with the potential to metastasise and ultimately lead to death. When used in conjunction with clinical or dermoscopic suspicion of malignancy, or both, reflectance confocal microscopy (RCM) may help to identify cancers eligible for non-surgical treatment without the need for a diagnostic biopsy, particularly in people with suspected BCC. Any potential benefit must be balanced against the risk of any misdiagnoses.

Objectives

To determine the diagnostic accuracy of RCM for the detection of BCC, cSCC, or any skin cancer in adults with any suspicious lesion and lesions that are difficult to diagnose (equivocal); and to compare its accuracy with that of usual practice (visual inspection or dermoscopy, or both).

Search methods

We undertook a comprehensive search of the following databases from inception to August 2016: Cochrane Central Register of Controlled Trials; MEDLINE; Embase; CINAHL; CPCI; Zetoc; Science Citation Index; US National Institutes of Health Ongoing Trials Register; NIHR Clinical Research Network Portfolio Database; and the World Health Organization International Clinical Trials Registry Platform. We studied reference lists and published systematic review articles.

Selection criteria

Studies of any design that evaluated the accuracy of RCM alone, or RCM in comparison to visual inspection or dermoscopy, or both, in adults with lesions suspicious for skin cancer compared with a reference standard of either histological confirmation or clinical follow-up, or both.

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Data collection and analysis

Two review authors independently extracted data using a standardised data extraction and quality assessment form (based on QUADAS-2). We contacted authors of included studies where information related to the target condition or diagnostic threshold were missing. We estimated summary sensitivities and specificities using the bivariate hierarchical model. For computation of likely numbers of true-positive, false-positive, false-negative, and true-negative findings in the 'Summary of findings' tables, we applied summary sensitivity and specificity estimates to lower quartile, median and upper quartiles of the prevalence observed in the study groups. We also investigated the impact of observer experience.

Main results

The review included 10 studies reporting on 11 study cohorts. All 11 cohorts reported data for the detection of BCC, including 2037 lesions (464 with BCC); and four cohorts reported data for the detection of cSCC, including 834 lesions (71 with cSCC). Only one study also reported data for the detection of BCC or cSCC using dermoscopy, limiting comparisons between RCM and dermoscopy. Studies were at high or unclear risk of bias across almost all methodological quality domains, and were of high or unclear concern regarding applicability of the evidence. Selective participant recruitment, unclear blinding of the reference test, and exclusions due to image quality or technical difficulties were observed. It was unclear whether studies were representative of populations eligible for testing with RCM, and test interpretation was often undertaken using images, remotely from the participant and the interpreter blinded to clinical information that would normally be available in practice.

Meta-analysis found RCM to be more sensitive but less specific for the detection of BCC in studies of participants with equivocal lesions (sensitivity 94%, 95% confidence interval (CI) 79% to 98%; specificity 85%, 95% CI 72% to 92%; 3 studies) compared to studies that included any suspicious lesion (sensitivity 76%, 95% CI 45% to 92%; specificity 95%, 95% CI 66% to 99%; 4 studies), although CIs were wide. At the median prevalence of disease of 12.5% observed in studies including any suspicious lesion, applying these results to a hypothetical population of 1000 lesions results in 30 BCCs missed with 44 false-positive results (lesions misdiagnosed as BCCs). At the median prevalence of disease of 15% observed in studies of equivocal lesions, nine BCCs would be missed with 128 false-positive results in a population of 1000 lesions. Across both sets of studies, up to 15% of these false-positive lesions were observed to be melanomas mistaken for BCCs. There was some suggestion of higher sensitivities in studies with more experienced observers. Summary sensitivity and specificity could not be estimated for the detection of cSCC due to paucity of data.

Authors' conclusions

There is insufficient evidence for the use of RCM for the diagnosis of BCC or cSCC in either population group. A possible role for RCM in clinical practice is as a tool to avoid diagnostic biopsies in lesions with a relatively high clinical suspicion of BCC. The potential for, and consequences of, misclassification of other skin cancers such as melanoma as BCCs requires further research. Importantly, data are lacking that compare RCM to standard clinical practice (with or without dermoscopy).

PLAIN LANGUAGE SUMMARY

What is the diagnostic accuracy of reflectance confocal microscopy for the detection of basal or squamous cell carcinoma of the skin in adults?

What is the aim of the review?

The aim of this Cochrane Review was to find out how accurate reflectance confocal microscopy (RCM) is on its own or compared to inspection of a skin lesion with the naked eye alone or using a hand-held microscope called dermoscopy for diagnosing two common forms of keratinocyte skin cancer: basal cell carcinoma (BCC) or cutaneous squamous cell carcinoma (cSCC) in adults. Review authors in Cochrane included 10 studies to answer this question.

Why is improving the diagnosis of BCC or cSCC important?

There are a number of different types of skin cancer. BCC and cSCC are usually localised skin cancers. Making the correct diagnosis is important because mistaking one skin cancer for another can lead to the wrong treatment being used or lead to a delay in effective treatment. A missed diagnosis of BCC (known as a false-negative result) can result in the missed BCC growing and causing disfigurement. A missed diagnosis of cSCC is more serious as it could spread to other parts of the body. Diagnosing a skin cancer when it is not actually present (a false-positive result) may result in unnecessary biopsy or treatment and can cause discomfort and worry to patients.

What was studied in the review?

Microscopic techniques are used by skin cancer specialists to provide a more detailed, magnified examination of suspicious skin lesions than can be achieved using the naked eye alone. Currently, dermoscopy is used by doctors as part of the examination of suspicious skin lesions. RCM is a new microscopic technique to increase the magnification. It is a hand-held device or static unit using infrared light that can visualise deeper layers of the skin when compared with dermoscopy. Both techniques are painless procedures, but RCM is more expensive, time consuming, and requires additional specialised training. Dermoscopy can be used by general practitioners (GP) whereas RCM is likely to only be used by hospital specialists for people who have been referred with a skin lesion that is suspected to be a skin cancer. We wanted

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to see if RCM should be used instead of, or as well as, inspection of a skin lesion with the naked eye alone or using dermoscopy to diagnose BCC or cSCC. The accuracy of the test was looked at when used on people with any suspicious skin lesion and also in people with skin lesions that were tricky to diagnose.

What are the main results of the review?

We found 10 studies that included information on 11 groups of people with lesions suspicious for skin cancer. The main results were based on seven of the 11 sets of data: four in any lesion suspicious for skin cancer and three in particularly difficult to diagnose skin lesions.

For the comparison of RCM versus dermoscopy, we found four sets of data that included 912 suspicious skin lesions. The results suggested that in a group of 1000 people with any suspicious lesion, of whom 125 (12.5%) really do have BCC:

- an estimated 139 people will have an RCM result indicating BCC is present;

- of these, 44 (32%) people will not have BCC (false-positive results) including one person with a melanoma mistaken for a BCC;

- of the 861 people with an RCM result indicating that BCC is not present, 30 (3%) will actually have BCC.

The review also included three sets of data on people that had 668 particularly difficult to diagnose skin lesions, one comparing RCM to dermoscopy. The results suggested that if RCM was to be used by skin specialists in a group of 1000 people, of whom 150 (15%) really do have BCC:

- an estimated 269 people will have an RCM result indicating BCC is present;

- of these, 128 (48%) people will not have a BCC (known as a false-positive result), including as many as 19 people with melanomas mistaken for BCCs;

- of the 732 people with an RCM result indicating that BCC is not present, nine (1%) will actually have BCC.

There was not enough evidence to determine the accuracy of RCM for the detection of cSCC in either population group.

How reliable are the results of this review?

There was a lot of variation in the results of the studies in this review. Poor reporting of study conduct made assessment of the reliability of studies difficult. It was unclear whether studies were representative of populations eligible for testing with RCM, and test interpretation was often undertaken using images, remotely from the patient and the interpreter blinded to clinical information that would normally be available in practice. Only one study compared the accuracy of dermoscopy and RCM. Most studies were conducted by specialist research teams with high levels of training and experience with RCM, meaning that RCM may appear better than it would be when used in everyday practice. Most studies reported diagnosis based on observers' subjective views, which might not be the same for people using the technique in everyday practice. In nine studies, the diagnosis of skin cancer was made by a skin biopsy or by following up those people over time to make sure they remained negative for skin cancer*. This is likely to have been a reliable method for deciding whether patients really had skin cancer. In one study, the absence of skin cancer was made by experts looking at the skin, a method that may be less reliable for deciding whether patients really had skin cancer.

Who do the results of this review apply to?

Five studies were carried out in Europe (61%), and the rest in Asia, Oceania, North America, or more than one continent. The average ages of people who took part ranged from 41 to 65 years. The percentage of people with BCC in these studies ranged from 6% to 83% (a middle value of 12% for any suspicious lesion and 15% for difficult to diagnose skin lesions). For studies of RCM used for cSCC, the percentage of people with cSCC ranged between 4% and 13%. In many studies it was not clear what tests people taking part had received before RCM.

What are the implications of this review?

There was not enough good evidence to support the use of RCM for the diagnosis of BCC or cSCC outside of research studies. There was a lot of variation and uncertainty in results and in the ways studies were carried out, reducing the reliability of findings. Using RCM might avoid the need for a diagnostic biopsy in people who see a doctor with a high suspicion of a BCC lesion, but more research is needed to confirm this. Such research should compare RCM to dermoscopy in well-described groups of people with suspicious skin lesions and they must say whether other skin cancers end up being missed or being wrongly classified as BCC.

How up-to-date is this review?

The review authors searched for and used studies published up to August 2016.

*In these studies, biopsy or clinical follow-up were the reference standards (means of establishing final diagnoses).

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CardioMEMS Implantable Wireless Pulmonary Artery Pressure Monitor for Heart Failure

Plain Language Summary:

Coverage question: Should OHP cover a device that gets implanted to keep track of heart rate and pressure in the pulmonary artery (the blood vessel connected to the heart) for some people with heart failure?

Should OHP cover this treatment? No, expert guidelines in this field do not recommend using this device.

STAFF NOTE: The draft recommendation as part of this issue summary is unchanged from the version published for advance public comment on December 7, 2023.

Coverage Question: Should any change be made to the non-coverage of CardioMEMS?

Question source: Holly Jo Hodges, CCO medical director

Background: The CardioMEMS HF System is an implantable device that is used to monitor heart rate and pulmonary artery (PA) pressure in certain individuals with heart failure. A small, paper clip-sized sensor is implanted into the pulmonary artery during a heart catheterization procedure. Once the device is implanted and the individual returns home, the Patient Electronics System uses wireless technology to read the PA pressure measurements and then transmits the information to the physician. On May 28, 2014, the FDA cleared the CardioMEMS Heart Failure System for use in monitoring the heart rates and pulmonary arterial pressures of individuals with NYHA Class III heart failure who have been placed in the hospital for heart failure within the previous 12 months.

Previous HSC/HERC reviews:

CardioMEMS was last reviewed as a new code in October 2018 and was a subject of a 2018 coverage guidance. It is currently on line 654/GN173 as non-covered due to lack of evidence of effectiveness. Dr. Hodges is requesting a re-review due to new evidence that has been published.

The decision factors from the 2018 coverage guidance are shown below.

Balance of benefits and harms: We have low confidence that CardioMEMS™ decreases the rate of heart failure-related hospitalization, very low confidence that it improves quality of life, and very low confidence that there is a mortality benefit. We have very low confidence that it is associated with serious adverse events. While the balance of benefits and harms weighs in favor of the intervention, based on the limited evidence it is unclear that the benefit outweighs the risk.

CardioMEMS Implantable Wireless Pulmonary Artery Pressure Monitor for Heart Failure

Rationale: The balance of benefits and harms weighs in favor of the intervention, but it is very expensive and invasive, and preferences would likely be highly variable. Given that the evidence is derived from only one trial that has concern of bias, a confirmatory trial is necessary to improve the confidence regarding the potential benefit of this intervention.
Recommendation: CardioMEMS™ is not recommended for coverage for heart failure monitoring *(weak recommendation).*

Current Prioritized List/Coverage status:

CPT 33289 Insertion of wireless pressure sensor into lung artery through tube with review by radiologist

CPT 93264 Remote monitoring of pulmonary artery pressure sensor, up to 30 days

HCPCS C2624 Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

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

Line 654

The following Interventions are prioritized on Line 654CONDITIONS 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	CardioMEMS™ – Implantable wireless pulmonary artery pressure monitor for heart failure monitoring	Insufficient evidence of effectiveness	November, 2018 Coverage guidance

Evidence:

1) **Brugts 2023**, MONITOR-HF trial
    a. N=348 patients (176 Cardio-MEMS, 172 control)
        i. Median ejection fraction 30%
        ii. Control was standard care in the Dutch healthcare system
        iii. Non-blinded
    b. The primary efficacy endpoint was the mean change in Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary scores from baseline to 12 months between groups
        i. Scores range from 0 to 100, with higher scores reflecting better health status.
    c. The secondary efficacy endpoint was the total number of heart failure hospitalisations (first and recurrent) and urgent visits with the necessity of intravenous diuretics during follow-up

   d. Patients in both groups had similar mean baseline KCCQ overall summary scores (55.8 [SD 23.3] in the CardioMEMS-HF group and 54.9 [22.3] in the standard care group; p=0.70)
   e. The mean change in KCCQ overall summary scores between baseline and 12 months among patients in the CardioMEMS-HF group was +7.05 (95% CI 2.77 to 11.33; p=0.0014), compared with –0.08 points among those in the standard care group (–3.76 to 3.60; p=0.97
   f. The total number of heart failure hospitalisations was 117 in the CardioMEMS-HF group and 212 in the control group, which corresponded to an event rate of 0.381 per patient-year in the CardioMEMS-HF group and 0.678 per patient-year in the control group. Hence, the rate of total heart failure hospitalisations was reduced by 44% (hazard ratio [HR] 0.56 [95% CI 0.38–0.84; p=0.0053
   g. Conclusions: The MONITOR-HF study showed that haemodynamic monitoring and subsequent individualised adjustment of diuretics and GDMT significantly improved QOL and reduced the number of heart failure hospitalisations.
   h. We acknowledge the limitations of an open-label design, as well as the absence of a device (or sham) in controls, which can be prone to bias in the QOL endpoint by unmasking

2) **Hajduczok 2022**, systematic review and meta-analysis of remote monitoring for heart failure using implantable devices
   a. N=11 RCTs (6196 patients)
      i. Compared implantable remote monitoring devices to standard care
      ii. Endpoints: hospitalization, mortality
   b. When comparing remote monitoring to standard of care, there was no significant reduction in mortality (RR 0.89 [95% CI 0.77–1.03]) or the composite of CV or HF hospitalizations (RR 0.98 [95% CI 0.81–1.19])
   c. Sensitivity analysis examining exclusively HF hospitalizations with data from 8 of the 11 RCTs included revealed no significant reduction in HF hospitalizations in the remote monitoring group compared to control (RR 0.97 [95% CI 0.74–1.24])
   d. Conclusion: Compared to standard of care, remote monitoring of physiologic parameters using implantable devices did not have a significant reduction in mortality or in the composite of CV or HF hospitalizations in patients with HF in the 11 RCTs included in this systematic review and meta-analysis

Expert guidelines:

1) **AHA/ACC/HFSA 2022** CLINICAL PRACTICE GUIDELINE Management of Heart Failure:
   a. In selected adult patients with NYHA class III HF and history of a HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated stable doses of GDMT with optimal device therapy, the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain and provides uncertain value. COR 2b (weak), LOE B-R (moderate quality evidence from one or more RCTs)
   b. The CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure patients) trial reported a significant 28% reduction of HF-related hospitalizations after 6 months in patients randomized to an implanted PA pressure monitor compared with a control group. Patients had to have a

HF hospitalization in the previous year and be on stable doses of a beta blocker and angiotensin-converting enzyme inhibitor (ACEi) (or angiotensin (II) receptor blocker [ARB]) if tolerated. The clinical benefit persisted after longer term follow-up and was seen in both subjects with reduced and preserved LVEF. However, CHAMPION was a nonblinded trial, and there was differential contact of study personnel with patients in the treatment arm, raising methodological concerns about the opportunity for bias to have influenced its results. In the recent GUIDE-HF (Haemodynamic-GUIDEed management of Heart Failure) study, hemodynamic-guided management of patients with NYHA class II to IV heart failure did not significantly reduce the composite endpoint rate of mortality and total HF events. The usefulness of noninvasive telemonitoring or remote monitoring of physiological parameters (eg, patient activity, thoracic impedance, heart rate) via implanted electrical devices (ICDs or CRT-Ds) to improve clinical outcomes remains uncertain. Further study of these approaches is needed before they can be recommended for routine clinical care

Other payer policies:

1) Aetna 2023: considers CardioMEMS to be experimental
2) Cigna 2023: considers CardioMEMS to be experimental
3) Anthem BCBS 2023: The implantation of a pressure sensor into the pulmonary artery for the purpose of wireless ambulatory monitoring of heart failure and all other indications is considered investigational and not medically necessary
4) UHC 2023: unproven intervention

HERC staff summary:

Implantable pulmonary artery pressure monitors have not been shown in meta-analyses to reduce hospitalizations due to heart failure or mortality. One recent study indicates that this technology may improve quality of life, but it is unclear if this finding is generalizable outside of the Dutch health care system. The expert guidelines in this field do not recommend use of this technology. The previous coverage guidance on this topic found concerns for harms. No private payer surveyed is covering these remote monitors.

HERC staff recommendation:

1) Update 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 654

The following Interventions are prioritized on Line 654 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

CardioMEMS Implantable Wireless Pulmonary Artery Pressure Monitor for Heart Failure

Procedure Code	Intervention Description	Rationale	Last Review
33289, 93264, C2624	CardioMEMS™ – Implantable wireless pulmonary artery pressure monitor for heart failure monitoring	Insufficient evidence of effectiveness	~~November, 2018 Coverage guidance~~ January 2024

Remote haemodynamic monitoring of pulmonary artery pressures in patients with chronic heart failure (MONITOR-HF): a randomised clinical trial

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Summary

Background The effect of haemodynamic monitoring of pulmonary artery pressure has predominantly been studied in the USA. There is a clear need for randomised trial data from patients treated with contemporary guideline-directed-medical-therapy with long-term follow-up in a different health-care system.

Methods MONITOR-HF was an open-label, randomised trial, done in 25 centres in the Netherlands. Eligible patients had chronic heart failure of New York Heart Association class III and a previous heart failure hospitalisation, irrespective of ejection fraction. Patients were randomly assigned (1:1) to haemodynamic monitoring (CardioMEMS-HF system, Abbott Laboratories, Abbott Park, IL, USA) or standard care. All patients were scheduled to be seen by their clinician at 3 months and 6 months, and every 6 months thereafter, up to 48 months. The primary endpoint was the mean difference in the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score at 12 months. All analyses were by intention-to-treat. This trial was prospectively registered under the clinical trial registration number NTR7673 (NL7430) on the International Clinical Trials Registry Platform.

Findings Between April 1, 2019, and Jan 14, 2022, we randomly assigned 348 patients to either the CardioMEMS-HF group (n=176 [51%]) or the control group (n=172 [49%]). The median age was 69 years (IQR 61–75) and median ejection fraction was 30% (23–40). The difference in mean change in KCCQ overall summary score at 12 months was 7·13 (95% CI 1·51–12·75; p=0·013) between groups (+7·05 in the CardioMEMS group, p=0·0014, and –0·08 in the standard care group, p=0·97). In the responder analysis, the odds ratio (OR) of an improvement of at least 5 points in KCCQ overall summary score was OR 1·69 (95% CI 1·01–2·83; p=0·046) and the OR of a deterioration of at least 5 points was 0·45 (0·26–0·77; p=0·0035) in the CardioMEMS-HF group compared with in the standard care group. The freedom of device-related or system-related complications and sensor failure were 97·7% and 98·8%, respectively.

Interpretation Haemodynamic monitoring substantially improved quality of life and reduced heart failure hospitalisations in patients with moderate-to-severe heart failure treated according to contemporary guidelines. These findings contribute to the aggregate evidence for this technology and might have implications for guideline recommendations and implementation of remote pulmonary artery pressure monitoring.

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Introduction

Heart failure is a global health problem with high mortality and morbidity and is one of the leading causes of hospital admissions.[1] As hospitals run at full capacity, one of the biggest challenges is in relocating the delivery of care from a passive hospital-centred setting towards a proactive and remote patient-centred approach for a future-proof health-care system. The evidence of telemonitoring modalities for chronic heart failure is inconsistent and limited by the multiple and heterogeneous approaches.[2,3] As haemodynamic congestion precedes overt clinical congestion,[4] invasive parameters could provide a more adequate monitoring target. Responding to haemodynamic congestion can lead to the accurate and timely diagnosis of worsening heart failure and an opportunity for early intervention with decongestive therapies to prevent heart failure hospitalisations, often without symptoms or signs of clinical congestion. This lack of symptoms or signs is probably why many non-invasive telemonitoring modalities fail to achieve this time window because the intervention is much later in the decompensation process.[2–4]

The CardioMEMS-HF system (Abbott Laboratories, Abbott Park, IL, USA) measures pulmonary artery pressure as a clinically intuitive and interpretable haemodynamic parameter and surrogate estimate of left-sided filling pressure.[4] Clinical evidence of remote monitoring with the CardioMEMS-HF system was provided by the CHAMPION trial[5] among patients with New York Heart Association (NYHA) class III heart

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Remote monitoring for heart failure using implantable devices: a systematic review, meta-analysis, and meta-regression of randomized controlled trials

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Abstract

In heart failure (HF) patients, remote monitoring using implantable devices may be used to predict and reduce HF exacerbations and mortality. Data from randomized controlled trials (RCTs) was assessed to determine the effectiveness of implantable remote monitoring on the improvement of outcomes in HF patients. A systematic review and meta-analysis of RCTs testing remote monitoring versus standard of care for management of HF patients was performed. Primary endpoints were all-cause mortality and a composite of cardiovascular (CV) and HF hospitalizations. Rate ratios (RRs) and 95% confidence intervals (CI) were calculated. A secondary analysis tested for heterogeneity of treatment effect (HTE) comparing right ventricular/pulmonary pressure monitoring versus impedance-based monitoring on hospitalization. A regression analysis was performed using the mean follow-up time as the moderator on each primary endpoint. Eleven RCTs ($n=6196$) were identified with a mean follow-up of 21.9 months. The mean age and reported ejection fraction were 64.1 years and 27.7%, respectively. Remote monitoring did not reduce mortality (RR 0.89 [95% CI 0.77, 1.03]) or the composite of CV and HF hospitalizations (RR 0.98 [0.81, 1.19]). Subgroup analysis found significant HTE for hospitalizations between those studies that used right ventricular/pulmonary pressure monitoring versus impedance-based monitoring ($I^2=87.1\%$, $\text{chi}^2=7.75$, $p=0.005$). Regression analysis found no relationship between the log rate ratio of remote monitoring's effect on mortality, CV hospitalization or HF hospitalization, and mean follow-up time. Compared to standard of care, remote monitoring using implantable devices did not reduce mortality, CV, or HF hospitalizations. However, right ventricular/pulmonary pressure monitoring may reduce HF hospitalizations, which will need to be explored in future studies.

Keywords Heart failure · Remote monitoring · Implantable devices · Systematic review · Meta-analysis · Randomized controlled trials

Highlights

- Standard of care in heart failure outpatient monitoring is centered on patient-reported symptoms.
- New methods of monitoring physiologic markers with implantable devices such as cardiac resynchronization therapy device and pulmonary artery pressure sensors have been developed.
- Several randomized controlled trials (RCTs) have been conducted examining whether use of remote monitoring has an effect on mortality and hospitalizations.
- This systematic review and meta-analysis examined 11 RCTs and showed no significant effect with implantable remote monitoring on mortality, heart failure (HF) hospitalizations, or cardiovascular hospitalizations when compared to standard of care.
- A decrease in HF hospitalizations was observed in RCTs using implantable continuous cardiac/pulmonary artery pressure monitoring compared to thoracic impedance-based monitoring strategies.

Extended author information available on the last page of the article

Abbreviations

HF	Heart failure
CV	Cardiovascular
RCT	Randomized controlled trial
CRT-D	Cardiac resynchronization therapy defibrillator
ICD	Implantable cardioverter-defibrillator

Introduction

Heart failure (HF) is a complex clinical syndrome that affects over 26 million people worldwide [1, 2]. The disease poses a tremendous strain on the current medical system due to frequent rehospitalizations, accounting for over 1 million annual hospital admissions [3]. In patients with HF, the standard of care for surveillance of chronic disease has been to monitor symptoms and maintain frequent outpatient

follow-up with patient-initiated phone calls if symptoms worsen. Outpatient diuretic regimens are adjusted in real time to help reduce volume overload and improve heart failure symptoms. Early follow-up for HF hospitalizations, within 7 days of discharge, has been associated with a lower 30-day readmission rate, suggesting a benefit for closer monitoring of HF patients [4]. Continuous remote monitoring of specific metrics in HF patients may lead to earlier interventions and therefore improved outcomes [5, 6].

Randomized controlled trials (RCTs) have tried to replicate this close follow-up and monitoring technique using telemonitoring that transmits metrics such as blood pressure, weights, and symptoms [5, 7, 8]. Individual studies have not shown a large benefit in reducing HF hospitalizations using telemonitoring, but meta-analysis of these RCTs suggests that there may be a role for telemonitoring in reducing mortality and HF hospitalizations [8–10].

In addition to telemonitoring, a new method of surveillance for disease severity has emerged in the form of remote monitoring of implantable devices [7, 11]. Such devices, which include implanted cardiac defibrillators, dual chamber pacemakers, cardiac resynchronization therapy devices, and implantable hemodynamic pressure sensors, can measure physiologic parameters such as intrathoracic impedance, tachyarrhythmias, and intracardiac or pulmonary artery pressure, thereby providing actionable data to guide therapy [1, 5, 11].

The physiologic measures these devices are able to monitor theoretically correlate with heart failure exacerbation states [11], but their utilization for heart failure management with mortality benefit remains to be seen [12]. Ongoing research is being conducted to determine whether monitoring of this physiologic data can be utilized to make medication adjustments in the outpatient setting and control heart failure symptoms to prevent hospitalization [13]. This was based on previous observational studies that utilized hemodynamic-based heart failure management strategies, which improved New York Heart Association (NYHA) class and decreased HF hospitalizations [14, 15].

Due to the inconclusive RCT and meta-analysis data about the effectiveness of telemonitoring, additional research has been performed to assess objective measures that correlate with worsening HF, specifically via implantable remote monitoring devices [12, 13, 16–28]. Whereas the current standard of care relies on patient-reported symptoms for intervention, utilization of remote monitoring would give more objective clinical data to help drive management, and may improve outcomes [11, 12, 17]. Given the burden of heart failure hospitalizations on the individual patient as well as the larger healthcare system, prevention of HF exacerbation is a critical goal [1–3].

We aimed to review and analyze the current literature on invasive remote monitoring in HF patients to assess whether remote monitoring of physiologic markers of disease severity leads to a reduction in mortality, cardiovascular-related hospitalization, or heart failure hospitalization rates when compared to standard of care (routine outpatient follow-up).

Methods

Literature search strategy, selection criteria, and outcomes of interest

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) document was used as a guide and followed [29, 30]. Medline/PubMed, Embase, and Cochrane databases were searched for English language studies published between January 1, 1990 and August 9, 2019. Studies of interest included prospective randomized controlled trials (RCTs) testing remote monitoring versus control (standard of care) in adult (> 18 years) patients with HF and analyzed various outcomes using implantable remote monitoring modalities that were able to directly or indirectly report hemodynamic information. "Standard of care" was defined as usual or routine follow-up for heart failure, based on clinician discretion, including outpatient visits and bloodwork, but not using remote monitoring or electronic transmission of data to guide management. Outcomes of interest for this analysis included all-cause mortality and heart failure hospitalization. If an RCT did not report an outcome of interest, it was not included in this analysis. Remainder of inclusion criteria included subjects with New York Heart Failure (NYHA) HF classes I–IV and use of an implantable remote monitoring device that had remote monitoring capabilities (intracardiac pressures, pulmonary artery pressures, thoracic impedance, continuous arrhythmia monitoring, or a combination of these parameters). Exclusion criteria included studies that only utilized remote telemonitoring that did not transmit information from an implantable device or studies that only transmitted arrhythmia data from ICD or CRT-D devices. Initial keywords that were used included "Heart Failure, remote monitoring, wearable technology, heart sensor, implantable hemodynamic monitoring, randomized controlled trial, mortality, and hospital stay."

Data extraction and quality assessment

Data extraction was done in two phases: a practical review and a methodological review. In the practical review, the title and abstract of each of the 1604 articles retrieved in the search were reviewed independently for inclusion by a team of two reviewers (AH and SM), after removing duplicates. Gray literature was also searched, with revealed no additional articles.

Disagreements were resolved by consensus and resulted in 105 articles selected for full review. In the full-text review, inclusion/exclusion criteria were applied again, yielding 25 articles eligible for methodological review. These 25 studies were then further narrowed to 11 randomized controlled trials (RCTs) after eliminating duplicate datasets and studies that did not have the primary outcomes of mortality and cardiovascular (CV) hospitalizations or HF hospitalizations, or included the proper forms of remote monitoring (Fig. 1).

Data were independently recorded in a standardized manner for each RCT. Supplemental appendices were also searched if data were incomplete. Any inconsistencies were reassessed by all parties until the data were determined to be accurate.

All included studies were graded for bias using the Cochrane Handbook for Systematic Review of Interventions by two authors (AH and SM). Bias was assessed on predetermined criteria including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other (i.e., predetermined outcome of trial, financial consideration) [31, 32].

Statistical analysis

The primary analysis was performed using the Mantel–Haenszel method, and summary rate ratios (RRs) and 95% confidence interval (CI) were calculated using a random effect model for each endpoint. Total patient-years were calculated using trial duration and number of patients in each arm of the included studies. Examination of heterogeneity across the RCTs was assessed using Q statistics and I^2 [33]. The 95% CIs were estimated using a binominal distribution. A sensitivity analysis was performed which excluded the 3 studies that only reported all-cause hospitalizations [23, 24, 26] and included those that reported HF hospitalization specifically [17, 19–22, 25, 27, 34]. A random effect model was utilized given the inherent variability in patient population, device types, remote monitoring protocols, variation in control arm oversight, and follow-up times of the included studies. Publication bias was visually assessed using funnel plots.

An exploratory subgroup analysis was performed comparing implanted right ventricular/pulmonary pressure monitoring versus impedance-based monitoring on each hospitalization outcome. This was also performed for clinician-based versus patient-based alerts and reported for both hospitalization outcomes. In both

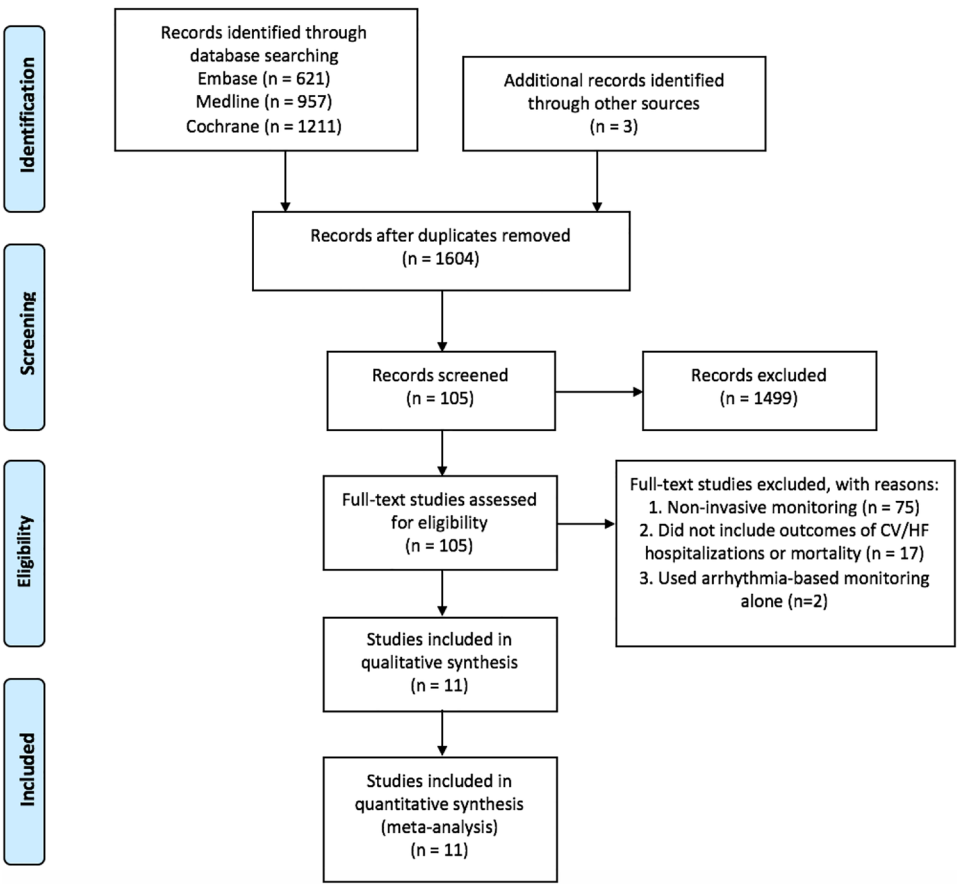

Fig. 1 Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram of systematic review, which represents the number of studies screened, assessed, and included in the meta-analysis. One thousand six hundred four references were reviewed, yielding a total of 11 randomized controlled trials for final analysis

cases, summary RRs with 95% CI were calculated. Each subgroup was assessed for heterogeneity, and the test for subgroup differences was performed using chi^2 and I^2 tests to assess for heterogeneity of treatment effect (HTE) [35].

A random effect meta-regression was performed using the mean follow-up time in months of each RCT as the moderator to determine if this continuous variable contributed to the heterogeneity in the mortality, HF or CV hospitalization, and HF hospitalization outcome. Meta-regression linear graphs were created by plotting the moderator variable (mean follow-up time) on the *x*-axis and the treatment effect of remote monitoring on the *y*-axis (the log of the rate ratio of remote monitoring's treatment effect of mortality, HF or CV hospitalization, and HF hospitalization for each RCT). When interpreting meta-regression, the log of the rate ratio used is on the *y*-axis. A log value of zero corresponds to a rate ratio of one; a negative log value corresponds to a rate ratio less than one, and a positive log value corresponds to a rate ratio greater than one. Each circle in the regression represents an included RCT, and the size of the circle is proportional to the weight of each RCT in the regression. The darker line in the center is the regression line, and the outer lighter colored lines represent the 95% CI. The following statistical tests were used in the regression: Tau^2 which estimates the true variance among trials, I^2 which represents the ratio of heterogeneity to total observed variation in the RCTs, and R^2 index which is the proportion of between study variance explained by the moderator (in this analysis mean follow-up time). Regression coefficients and 95% CIs were calculated and describe how remote monitoring's treatment effect will change with a unit change in the moderator variable.

Statistical analyses were conducted, and forest plots were created with Review Manager (RevMan [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). The meta-regression was performed using Comprehensive Meta-Analysis Version 3, Biostat, Englewood, NJ, 2013.

Results

Eleven RCTs were identified comparing remote monitoring of implantable devices with hemodynamic monitoring capabilities to standard of care for heart failure management. These RCTs had a total of 6196 participants with weighted mean follow-up time of 21.9 months (10,667 patient-years of follow-up). The mean age and reported ejection fraction were 64.1 years and 27.7%, respectively (Fig. 1 and Table 1). There was some variation in primary endpoints between the studies, with 8 measuring HF hospitalizations and the remaining 3 measuring the broader measure of CV hospitalizations, which were defined as any hospitalizations with a cardiovascular diagnosis as the reason for admission (Table 2). All 11 RCTs had mortality data included as either primary or secondary endpoints (Tables 1 and 2 and Appendix 1). When comparing remote monitoring to standard of care, there was no significant reduction in mortality (RR 0.89 [95% CI 0.77–1.03]) or the composite of CV or HF hospitalizations (RR 0.98 [95% CI 0.81–1.19]) (Figs. 2 and 3). Statistically significant heterogeneity existed among the RCTs analyzing CV or HF hospitalization ($I^2 = 90\%$, chi$^2 = 101.02$, $p < 0.0001$). Minimal, although statistically insignificant, heterogeneity existed amongst the RCTs when analyzing all-cause mortality ($I^2 = 7\%$, chi$^2 = 10.7$, $p = 0.38$). On visual evaluation of the funnel plot, there was no evidence of publication bias for both of the measured primary outcomes (Supplementary Figs. 3, 4).

Sensitivity analysis examining exclusively HF hospitalizations with data from 8 of the 11 RCTs included revealed no significant reduction in HF hospitalizations in the remote monitoring group compared to control (RR 0.97 [95% CI 0.74–1.24]). Statistically significant heterogeneity was observed among these 8 RCTs (chi$^2 = 64.9$, $p < 0.0001$, $I^2 = 89\%$) (Fig. 4).

Given the significant heterogeneity observed when analyzing the hospitalization outcome, exploratory subgroup analyses were performed based on type of remote monitoring and alert type (clinician versus patient). Subgroup analysis showed that there was a statistically significant difference in the composite of CV or HF hospitalizations and HF hospitalizations alone when comparing studies using implanted right ventricular/pulmonary pressure monitoring versus impedance-based monitoring, favoring the intracardiac pressure monitoring (RR 0.75 [95% CI 0.59–0.95] vs. RR 1.10 [95% CI 0.96–1.26]) and test for subgroup differences: $I^2 = 87.1\%$, chi$^2 = 7.75$, $p = 0.005$ (Fig. 5, Supplemental Fig. 5). When RCTs were stratified by alert type (clinician versus patient alerts), there was an increase in both CV or HF hospitalizations and HF hospitalizations alone when studies used devices with patient alerts (RR 1.55 [95% CI 1.28–1.89]) compared to clinician alerts (RR 0.91 [95% CI 0.75–1.09]) and test for subgroup differences: $I^2 = 93.7\%$, chi$^2 = 15.87$, $p < 0.0001$ (Fig. 6, Supplemental Fig. 6).

The overall risk of bias in the included RCTs was judged to be low, as 11/88 (12.5%) of the domains were graded as moderate or high (Supplementary Table 1).

The meta-regression analysis found no statistically significant relationship between the log rate ratio of remote monitoring's effect on mortality and the mean follow-up time [Tau$^2 = 0.01$, $I^2 = 17.1\%$ and $R^2 = 0.00$, regression coefficient = 0.004 (95% CI − 0.02–0.03)] (Fig. 7). In addition, there was no statistically significant linear relationship between the log rate ratio of remote monitoring's effect on CV or HF hospitalization and mean follow-up time [Tau$^2 = 0.07$, $I^2 = 78\%$ and $R^2 = 0.00$, regression

Table 1 Baseline characteristics

Author, year	Study name	Number of patients (RM/SoC)	Follow-up (months)	Age (mean ± SD)	Male (%)	Mean LVEF (% mean ± SD)	Ischemic (%)	NYHA class (% I, II, III, IV)	ACEi/ARB (%)	Beta blocker (%)	MRA (%)	Diuretic (%)	Mortality	HF hospitalization
Abraham, 2016	CHAMPION	550 (270/280)	18	61.6 ± 13	72.5	78% with EF < 40%[1]	59	III (0, 0, 100, 0)	76	89	43	92	x	x
Adamson, 2011	REDUCEhf	400 (202/198)	12	55 ± 15	68.5	23%	45	II–III (0, 53, 47, 0)	92	96	N/A	93	x	x
Bohm, 2016	OptiLink HF	1002 (505/497)	23	66.3 ± 10	79.7	26.7%	54	II–III (0, 19, 81, 0)	93	93	69	95	x	x
Boriani, 2017	MORE CARE	865 (437/428)	24	66.5 ± 11	76.0	27.3%	43	II–IV[2]	82	89	32	92	x	x
Bourge, 2008	COMPASS-HF	274 (134/140)	6	58 ± 14	65.0	Not reported[3]	47	III–IV (0, 0, 84, 16)	85	83	N/A	93	x	x
Domenichini, 2016	LIMIT-CHF	80 (41/39)	12	67.9 ± 11	94.0	28.3%	78	II–III	95	90	66	81	x	x
Hindricks, 2014	IN TIME	664 (333/331)	11	65.5 ± 9.3	80.7	26%	70	II–III (0, 45, 55, 0)	92	91	N/A	95	x	
Landolina, 2012	EVOLVO	200 (99/101)	16	67.5	78.5	30.5%	38	I–III (11, 72, 17, 0)	90	84	N/A	91	x	
Luthje, 2015	N/A	176 (87/89)	15	65.9 ± 12	77.3	32%	90	I–IV (11, 46, 41, 2)	N/A	N/A	N/A	N/A	x	x
Morgan, 2017	REM HF	1650 (824/826)	34	69.5 ± 10	85.8	29.9%	68	II–IV (0, 71, 29, 0.1)	91	91	52	77	x	
Van Veldhuisen, 2011	DOT-HF	335 (168/167)	15	64 ± 10	86.0	25%	56	I–IV (3, 60, 36, 1)	85	92	N/A	90	x	x

N/A represents data that was not reported/unable to be identified

RM remote monitoring, *SoC* standard of care, *ACEi* angiotensin-converting enzyme inhibitor, *ARB* angiotensin II receptor blocker, *MRA* mineralocorticoid receptor antagonist, *LVEF* left ventricular ejection fraction, *NYHA* New York Heart Association, *SD* standard deviation, *HF* heart failure

[1]78% of patients had LVEF less than 40%

[2]63% of patients were NYHA class III or IV at enrollment

[3]Mean LVEF not reported, but included both HFrEF and HFpEF

Table 2 Detailed study characteristics

Author, year	Study name	Primary outcome(s)	Secondary outcome(s)	Funding	Centers	Location	Transmission frequency	Audible or active alert	Type of alert	Treatment protocol	Type of monitoring system	Implantable device(s)	Proprietary systems
Abraham, 2016	CHAMPION	Rate of HF hospitalizations at 6 months, Freedom From a Device/System-related Complication (DSRC) at 6 months, Freedom From Pressure Sensor Failure at 6 months	Change from baseline in pulmonary artery mean pressure at 6 months, proportion of patients hospitalized for heart failure at 6 months, days alive outside of the hospital at 6 months, quality of life—Minnesota Living With Heart Failure Questionnaire (MLHFQ) at 6 months	St. Jude	Multicenter	USA	Daily		Clinician	Hemodynamic-guided care strategy (optivolemic—no change, hypervolemic—increase in diuretics and reevaluation in 2–3 days, hypovolemic—decrease diuretic/liberalization of oral fluid/salt restriction)	Wireless pulmonary artery pressure sensor	Wireless PA pressure sensor	CardioMEMS
Adamson, 2011	REDUCEhf	HF events (HF hospitalizations, or ED/unplanned clinic visits with IV therapy)	All-cause mortality or HF hospitalizations, CV events, all events, intracardiac pressure, NYHA class, 6MWT	Medtronic	Multicenter	USA	Weekly		Clinician	Variable (clinician-directed)	RV pressure/estimated PA diastolic pressure measurement using implantable hemodynamic monitoring-ICD	ICD	Chronicle

Table 2 (continued)

Author, year	Study name	Primary outcome(s)	Secondary outcome(s)	Funding	Centers	Location	Transmission frequency	Audible or active alert	Type of alert	Treatment protocol	Type of monitoring system	Implantable device(s)	Proprietary systems
Bohm, 2016	OptiLink HF	Composite of all-cause mortality and CV hospitalization	All-cause mortality, CV mortality, composite of all-cause mortality and HF hospitalizations, CV hospitalizations, HF hospitalizations, all-cause hospitalizations	Medtronic	Multicenter	Germany	Variable (based off fluid index threshold crossing—programmed at investigators discretion)	x	Clinician	Variable (clinician-directed)	Thoracic impedance measurements (OptiVol) with automated threshold-based clinician alerts	ICD or CRT-D	OptiVol, CareLink
Boriani, 2017	MORE CARE	Composite of all-cause mortality and CV and device-related hospitalization	CV hospitalizations or CV ED visits, HF hospitalizations, device-related hospitalizations, outpatient visits	Medtronic	Multicenter	Europe/Israel	Variable (based off fluid index threshold crossing—programmed at investigators discretion)	x	Clinician	Variable (clinician-directed)	Thoracic impedance measurements (OptiVol), atrial tachyarrhythmias with automated threshold-based clinician alerts	CRT-D	OptiVol, CareLink

Table 2 (continued)

Author, year	Study name	Primary outcome(s)	Secondary outcome(s)	Funding	Centers	Location	Transmission frequency	Audible or active alert	Type of alert	Treatment protocol	Type of monitoring system	Implantable device(s)	Proprietary systems
Bourge, 2008	COMPASS-HF	HF hospitalization (or requiring IV therapy)	Composite of all-cause hospitalization, emergency department, and urgent care visits; hospital-free days at 6 months; clinical worsening based on NYHA class or death; MLWHF; 6MWT	Medtronic	Multicenter	USA	Weekly (at least weekly)		Clinician	Variable (clinician-directed)	RV pressure/estimated PA diastolic pressure measurement using implantable hemodynamic monitoring-ICD or CRT-D (Chronicle)	Implantable right ventricular pressure monitoring system	Chronicle
Domenichini, 2016	LIMIT-CHF	HF hospitalization	Composite of all-cause hospitalization, emergency department, and unscheduled clinic visits; NYHA class; MLWHF; 6MWT	Medtronic, St. Jude	Single	UK	Variable (based off fluid index threshold specific to ICD- or CRT-D-based monitor)	x	Patient	Diuretic dose increased by 50% for 1 week	Thoracic impedance measurements (OptiVol or CorVue) with automated threshold-based patient alerts	ICD or CRT-D	OptiVol, CorVue, CareLink, Merlin.net PCN

Table 2 (continued)

Author, year	Study name	Primary outcome(s)	Secondary outcome(s)	Funding	Centers	Location	Transmission frequency	Audible or active alert	Type of alert	Treatment protocol	Type of monitoring system	Implantable device(s)	Proprietary systems
Hindricks, 2014	IN TIME	Composite of all-cause mortality, CV hospitalization, and worsening NYHA class	Mortality, HF hospitalizations	Biotronik	Multicenter	Europe/Australia/Israel	Daily or on detection of tachyarrhythmia		Clinician	Variable	Tachyarrhythmia monitoring and alerts with impedance-measurement capabilities	ICD or CRT-D	n/a
Landolina, 2012	EVOLVO	ED or unscheduled clinic visits for HF, arrhythmia, ICD-related event	ED visit for HF, ED visit for arrhythmia or ICD-related event, composite of ED, clinic visit or HF/arrhythmia/ICD hospitalization	Medtronic, Italian Ministry of Health	Multicenter	Italy	Daily		Clinician	Variable (clinician-directed: adjust medical therapy/bring to clinic if needed)	Thoracic impedance measurements (OptiVol) with automated threshold-based clinician alerts	ICD or CRT-D	OptiVol, CareLink

Table 2 (continued)

Author, year	Study name	Primary outcome(s)	Secondary outcome(s)	Funding	Centers	Location	Transmission frequency	Audible or active alert	Type of alert	Treatment protocol	Type of monitoring system	Implantable device(s)	Proprietary systems
Luthje, 2015	N/A	First HF hospitalization	Mortality, ventricular tachyarrhythmia requiring ICD-shock	Medtronic	Single	Germany	Variable (based off fluid index threshold crossing—programmed at 60 Ω)	x	Clinician	If positive alert and signs of clinical decompensation: hospital admission. If positive alert and no decompensation: increase diuretic dose by 50% and daily weights	Thoracic impedance measurements (OptiVol) with automated threshold-based clinician alerts	ICD or CRT-D	OptiVol, CareLink
Morgan, 2017	REM HF	Composite of all-cause mortality and CV hospitalization	All-cause mortality, CV mortality, non-CV mortality, composite of CV mortality and CV hospitalization	Medtronic, British Heart Foundation	Multicenter	UK	Weekly		Clinician	Variable; however clinicians instructed to value parameter trends rather than single value changes	Thoracic impedance, ventricular arrhythmias, activity, heart rate variability, device therapy (no threshold/alerts)	ICD or CRT-D	n/a

Table 2 (continued)

Author, year	Study name	Primary outcome(s)	Secondary outcome(s)	Funding	Centers	Location	Transmission frequency	Audible or active alert	Type of alert	Treatment protocol	Type of monitoring system	Implantable device(s)	Proprietary systems
Van Veldhuisen, 2011	DOT-HF	Composite of all-cause mortality and HF hospitalization	All-cause mortality, HF hospitalizations, unscheduled outpatient visits, OptiVol alert for clinically relevant event	Medtronic	Multicenter	Europe/Asia/Africa/Middle East	Variable (based off fluid index threshold specific to ICD- or CRT-D-based monitor)	x	Patient	Variable (clinician-directed)	Thoracic impedance measurements (OptiVol) with automated threshold-based patient alerts; HRV, arrhythmia, activity (Cardiac Compass) available for review at outpatient visits	ICD or CRT-D	OptiVol, Cardiac Compass

HF heart failure, *CV* cardiovascular, *ED* emergency department; *IV* intravenous, *NYHA* New York Heart Association, *ICD* implantable cardioverter-defibrillator, *6MWT* 6-min walk test, *CRT-D* cardiac resynchronization therapy-defibrillator, *MLHFQ* Minnesota Living With Heart Failure Questionnaire

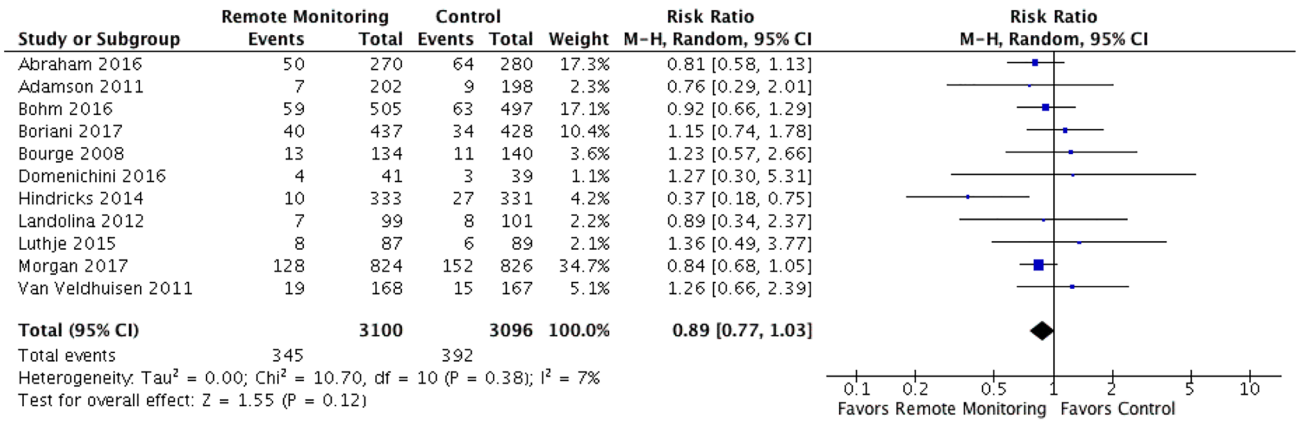

Fig. 2 All-cause mortality. Forest plot showing rate ratio and 95% confidence for each endpoint among HF patients randomized to remote monitoring versus standard of care. When comparing remote monitoring to standard of care, there was no significant reduction in mortality (RR 0.89 [95% CI 0.77–1.03]). Minimal, although statistically insignificant, heterogeneity existed among when analyzing all-cause mortality ($I^2 = 7\%$, $\text{chi}^2 = 10.7$, $p = 0.38$)

coefficient = 0.01 (95% CI − 0.01–0.04)] (Supplementary Fig. 1). Also, the meta-regression analysis found no significant relationship between the log rate ratio of remote monitoring's effect on HF hospitalization and the mean follow-up time [$\text{Tau}^2 = 0.09$, $I^2 = 79.9\%$ and $R^2 = 0.1$, regression coefficient = 0.02 (95% CI − 0.022–0.063)] (Fig. 5).

Discussion

Compared to standard of care, remote monitoring of physiologic parameters using implantable devices did not have a significant reduction in mortality or in the composite of CV or HF hospitalizations in patients with HF in the 11 RCTs included in this systematic review and meta-analysis. Sensitivity analysis of HF hospitalizations alone, which was measured in 8 of the 11 RCTs, showed that remote monitoring had no significant reduction in HF hospitalizations. However, statistically significant heterogeneity was found in the studies measuring CV or HF hospitalizations leading to a subgroup analysis that revealed a statistically significant advantage in the composite of CV or HF hospitalizations and HF hospitalizations in studies using implanted right ventricular/pulmonary pressure monitoring when compared to studies using impedance-based monitoring.

The high heterogeneity among the hospitalization outcome can be due to multiple reasons: (1) only 11 studies met inclusion and exclusion criteria, with a relatively short mean total follow-up time (21.9 months) including only 6196 patients (10,667 patient-years); (2) variability

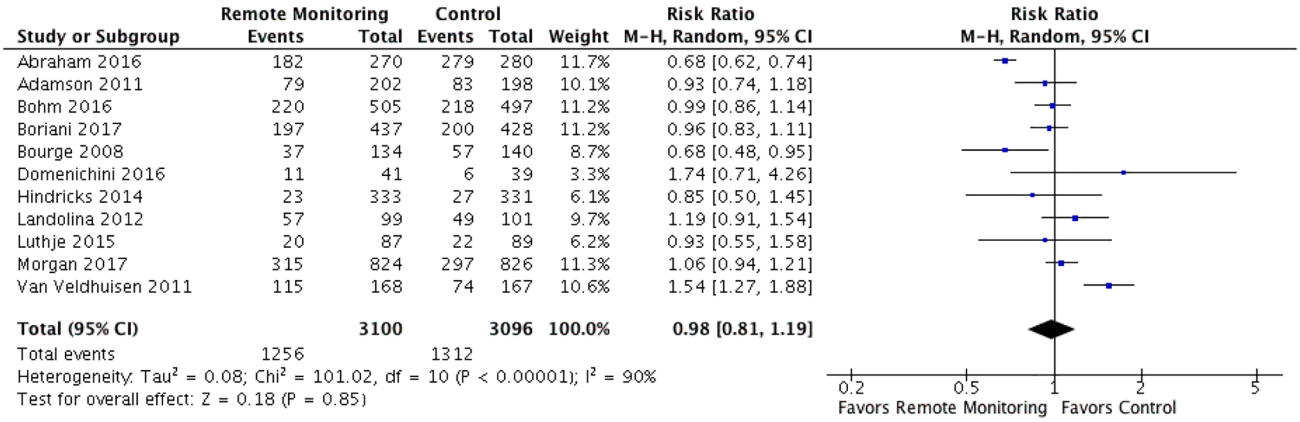

Fig. 3 CV or HF hospitalizations. Forest plot showing rate ratio and 95% confidence for each endpoint among HF patients randomized to remote monitoring versus standard of care. When comparing remote monitoring to standard of care, there was no significant reduction in the composite of CV or HF hospitalizations (RR 0.98 [95% CI 0.81–1.19]). Statistically significant heterogeneity existed among the RCTs analyzing CV or HF hospitalization ($I^2 = 90\%$, $\text{chi}^2 = 101.02$, $p < 0.0001$)

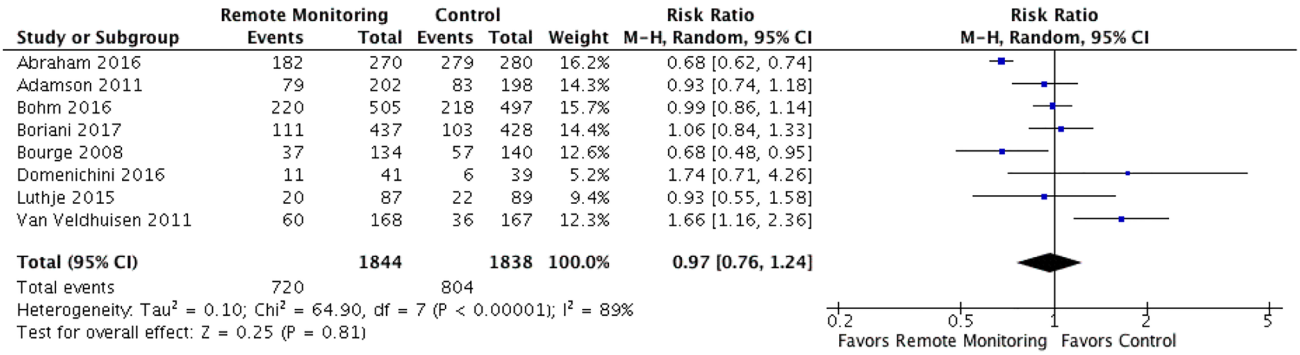

Fig. 4 HF hospitalizations. Forest plot showing rate ratio and 95% confidence for each endpoint among HF patients randomized to remote monitoring versus standard of care. Sensitivity analysis examining exclusively HF hospitalizations with data from 8 of the 11 RCTs included revealed no significant reduction in HF hospitalizations in the remote monitoring group compared to control (RR 0.97 [95% CI 0.74–1.24]). Statistically significant heterogeneity was observed among these 8 RCTs ($chi^2 = 64.9$, $p < 0.0001$, $I^2 = 89\%$)

in devices/measured parameters; and (3) variability in study protocols, including lack of a standardized treatment protocol. Multiple different devices, with proprietary data collection and transfer methods, were utilized among the RCTs, including CRT-D vs. ICD vs. pulmonary artery pressure sensor-based devices.

Any form of monitoring, but especially invasive methods as mentioned above and examined in this study, are not inexpensive; thus, it is critical to define whether these technologies are actually superior to the standard of care for outpatient follow-up [11, 12]. Value-based care is becoming increasingly prevalent in outpatient cardiology, as it has become a goal to prevent rehospitalizations for HF [3]. This meta-analysis does not support invasive methods as a more "high value" option for patients with HF. We argue that the reason why this was not captured in the data from the 11 RCTs presented is because the metrics used may lack adequate sensitivity or specificity for the *true* pathophysiology of the heart failure disease state. In addition, patient-based alerts were associated

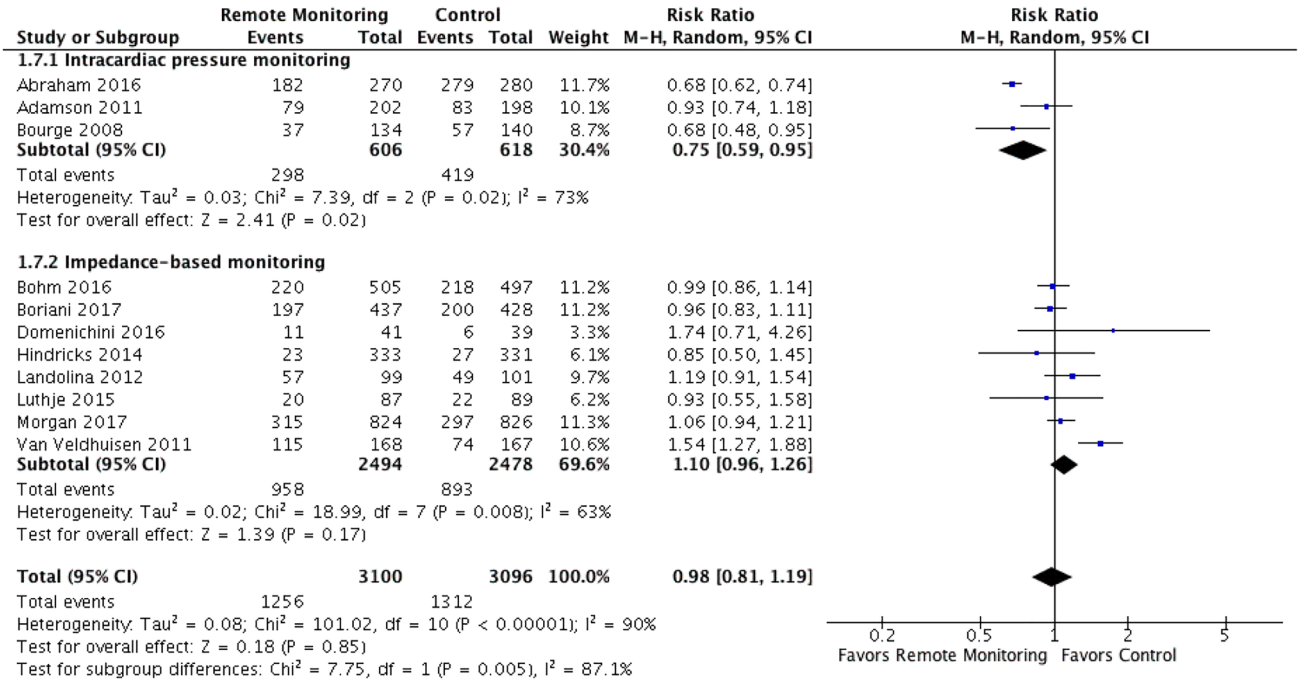

Fig. 5 Intracardiac pressure monitoring vs. thoracic impedance-based monitoring (subgroup analysis). Outcomes shown are the composite of HF or CV hospitalizations. Subgroup analysis showed that there was a statistically significant difference in the composite of CV or HF hospitalizations when comparing studies using implanted right ventricular/pulmonary pressure monitoring versus impedance-based monitoring, favoring the intracardiac pressure monitoring (RR 0.75 [95% CI 0.59–0.95] vs. RR 1.10 [95% CI 0.96–1.26]) and test for subgroup differences: $I^2 = 87.1\%$, $chi^2 = 7.75$, $p = 0.005$

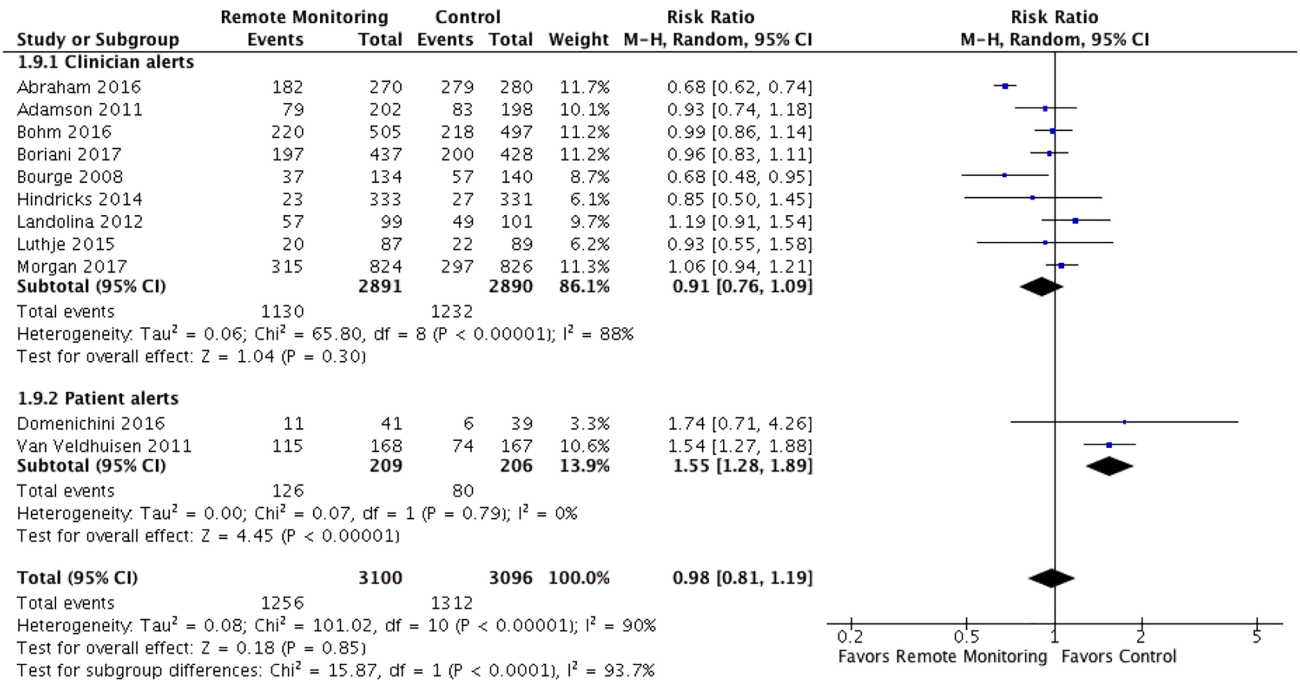

Fig. 6 Clinician vs. patient-based alerts (subgroup analysis). Outcomes shown are HF or CV hospitalizations. There was an increase in both CV or HF hospitalizations and HF hospitalizations alone when studies used devices with patient alerts (RR 1.55 [95% CI 1.28–1.89]) compared to clinician alerts (RR 0.91 [95% CI 0.76–1.09]) and test for subgroup differences: $I^2 = 93.7\%$, $\text{chi}^2 = 15.87$, $p < 0.0001$

with an increase in hospitalizations [22, 27]. This is presumably due to biasing of symptomatology, leading to a lower threshold for HF admission if a remote monitoring device designed to detect HF exacerbations is in "alert." Clinician-based alerts did not individually increase hospitalizations. Therefore, this raises concern that these alerts could lead to an unnecessary increase in hospitalization (Table 2).

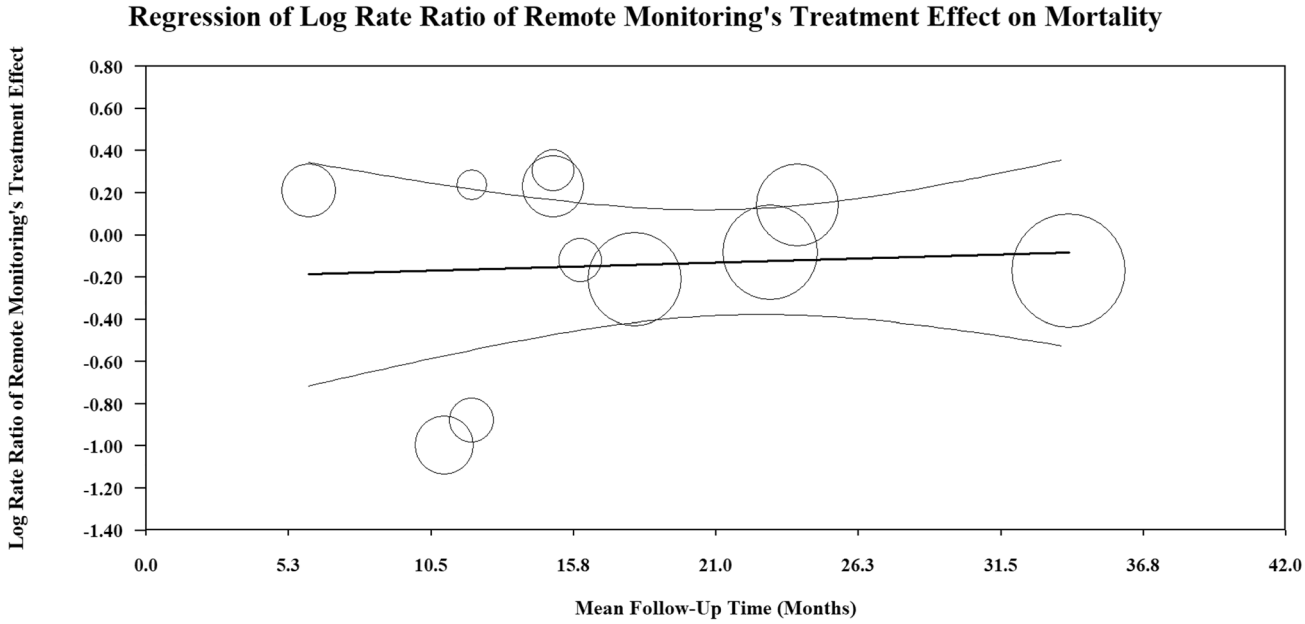

Fig. 7 This figure represents the random effect meta-regression. The log rate ratio of remote monitoring's treatment effect on mortality from each trial is plotted on the *y*-axis. The mean follow-up time in months (moderator variable) is plotted on the *x*-axis. Each circle on the graph represents an included randomized trial, and the size of the circle is proportional to the weight each study had in the regression model. The darker line in the center is the regression line and the lighter colored, outer lines represent the 95% confidence interval

While invasive remote monitoring may not have been shown to provide high value care for HF under normal circumstance, the novel coronavirus SARS-CoV2 (COVID-19) pandemic highlighted the importance of remote monitoring of various medical conditions, including heart failure [36]. Reduced in-person visits and hesitancy to seek care in the early stages of the pandemic may have paradoxically caused a decrease in HF hospitalizations; however, this merely highlighted the need for advances in telehealth and remote monitoring for HF. Experts such as Abraham et al. have postulated that remote monitoring devices, specifically invasive devices such as CardioMEMS [16, 17], should be quickly adopted by clinicians in the absence of in-person visits [36]. This would be pertinent to aid clinicians in providing remote care and prevent further HF hospitalizations.

Interestingly, the subgroup analysis shows that implantable hemodynamic pressure monitoring, whether of RV or PA pressures [17, 21, 34], did reduce hospitalizations as compared to monitors that were centered around thoracic impedance (Fig. 5). Although thoracic impedance may be a measure of pulmonary edema, it may be limited in detecting changes in patients with chronic heart failure or may be subject to changes other heart failure, such as pneumonia. Therefore, the sensitivity and specificity of this single metric may be limited. This finding is in concordance with the findings from the CHAMPION trial, which used a regimented and aggressive treatment plan based on PA pressure-based determination of volume status [17]. This included stratifying subjects as optivolemic, hypervolemic, or hypovolemic. If volume status was optimal, no changes were made. Whereas for a designation of hypervolemia or hypovolemia, clinicians were encouraged to make immediate changes to diuretics, fluid/salt restrictions, and neurohumoral/vasodilator therapy, with close (2–3 day) follow-up often included repeating laboratory testing. This monitoring strategy proved to be effective in reducing hospitalizations.

Only one of the 11 studies had a statistically significant mortality benefit, the IN-TIME trial (RR 0.37; 95% CI 0.18–0.75) [23]. Notably, this study utilized a multiparameter monitoring system and is the only RCT to use such a system, although others have been studied in non-randomized prospective observational trials including PARTNERS-HF, MultiSENSE, and MANAGE-HF (NCT03237858) [18, 28, 37, 38]. Given that these studies are not RCTs (PARTNERS-HF and MultiSENSE) or ongoing (MANAGE-HF), they were excluded from this analysis.

In addition, ongoing multisensory remote monitoring studies could potentially replicate the results from these implantable device studies, with the use of wearable devices measuring the same or surrogate parameters. This includes the Multisensor Monitoring in Congestive Heart Failure (MUSIC) study and the Nanosense cohort study (NCT03719079), which incorporates the third heart sound (S3) among other metrics measured by a wearable device [39, 40]. This would expand the number of patients that could potentially be monitored beyond those who have an indication for an ICD or CRT-D, suggesting advanced heart failure. Overall, these techniques are promising moving forward and may prove to show more benefit that intrathoracic impedance-based or intracardiac/PA pressure-based monitoring systems, with potentially less complications or side effects [11].

The results of this meta-analysis are consistent with other recent meta-analyses. Yun et al. focused on telemonitoring for HF, but not specifically using implantable devices, yet there was an all-cause mortality and HF-related mortality benefit, driven mainly by smaller clinical trials [9]. Adamson et al. showed that five clinical trials that did use hemodynamic data (intracardiac/PA pressure monitoring) had a benefit in terms of heart failure hospitalizations, which was reproduced and expanded upon in our meta-analysis [12]. A more recent meta-analysis, Alotaibi et al., of heart failure remote monitoring using implantable devices had similar conclusions to our study, however did not include the all of the RCTs due to a difference in inclusion/exclusion criteria, as well as a focus on arrhythmia-only based strategies [41].

To our knowledge, no formal meta-regression has been performed analyzing the association with follow-up time and outcomes related to HF remote monitoring. Using the mean follow-up time as the moderator on each primary endpoint, our regression analysis found no relationship between the log rate ratio of remote monitoring's effect on mortality, CV hospitalization or HF hospitalization, and mean follow-up time. Suggestions have been made that longer follow-up times would be more efficacious in detecting clinically meaningful differences in outcomes; however, this has not been proven through RCT evidence. Notably, interim results of the CHAMPION trial at 6 months showed a similar reduction in HF hospitalizations (39%) as was seen in final study analysis at 18 months (33% reduction) [16, 17]. This falls in line with our regression analysis on follow-up time and could serve to guide future studies.

Limitations

One limitation of this meta-analysis is the RCT heterogeneity observed among the hospitalization outcomes. The studies were conducted slightly differently, using a variety of remote monitoring devices/parameters. Based on the findings using hemodynamic pressure measurements, more studies investigating intracardiac or PA pressure monitoring may show that this specific measure is beneficial [13].

Another limitation of this meta-analysis was the outcome congruence and powering. Mortality was included in this analysis given that the data was reported in each study (and it is a valuable measure), yet it was not the primary

outcome of the individual RCTs and these studies were not powered to detect differences in mortality. Larger enrollment and follow-up time would be required, yet this is not always the feasible given the nature of the patient HF severity (often NYHA classes III–IV) and including those who require implantable devices such as ICD/CRT-Ds or PA pressure monitors. In addition, not every study reported heart failure hospitalizations, with some only including cardiovascular hospitalizations (any hospitalization for heart failure, arrhythmia, myocardial infarction, etc.). Ideally, studies would report both measures (in addition to all-cause hospitalization) to determine the specific benefit of remote monitoring thereby defining reduction of types of hospitalizations, if any.

Although a large majority of the studies enrolled patients with implanted CRT-D or ICD, they each had different physiologic markers as part of their monitoring protocol. One of the 11 RCTs utilized a pulmonary artery pressure sensor [17]. Two of the 11 RCTs utilized audible patient alarms [22, 27], which adds an additional confounding factor, as these alarms notified the patients directly whenever they crossed the threshold for OptiVol fluid index of 60 (ohms). One of the 11 RCTs [26] had only initial CV hospitalizations as a primary endpoint, which would likely underreport the number of total CV hospitalizations.

Future Studies

Additional studies, especially those focused on monitoring of hemodynamic parameters, will help elucidate the role for remote monitoring. This includes the GUIDE-HF trial, a follow-up to the CHAMPION trial [17] which is poised to enroll 3600 patients in order to power for mortality [13]. A study of this magnitude would not have been feasible without initial data from CHAMPION showing a positive result. The full LAPTOP-HF trial study results will also help answer this question [42]. The study was stopped early due to device implantation adverse outcomes (during atrial septal puncture for LA pressure monitor implantation), but did have a 41% reduction in annual HF hospitalizations [43].

Conclusion

In our systematic review, meta-analysis, and meta-regression, we sought to determine whether there was evidence to suggest that implantable remote physiologic monitoring in heart failure patients results in reduced mortality and hospitalizations when compared to the standard of care. While a few individual studies showed potential benefit, our meta-analysis showed no significant difference in these outcomes between patients who underwent a remote monitoring strategy and those who had regular clinic follow-up. Given the significant morbidity and healthcare burden associated with heart failure hospitalizations, further studies should assess clinically relevant metrics that can accurately predict an exacerbation state to ideally prevent hospitalization. According to our meta-analysis, right ventricular/pulmonary pressure monitoring may reduce hospitalizations compared to impedance-based monitoring. Last, regression analysis found no relationship between mean follow-up time and primary outcomes of mortality, CV hospitalization, or HF hospitalization. In future studies, utilization of standardized remote monitoring protocols for intervention would likely allow for better assessment of the utility of heart failure remote monitoring, and possibly improve overall patient outcomes.

Appendix 1 Study descriptions

CHAMPION (Abraham, 2016) randomized 550 patients with NYHA class III HF and implanted CardioMEMS pulmonary artery pressure sensor into intervention and control groups. The intervention group ($n=270$) had their pulmonary artery pressure readings uploaded daily and used by the investigators to guide outpatient diuretic therapy. The control group ($n=280$) did not have their pressure readings made available to the study investigators. After mean follow-up of 6 months, the intervention group had 182 HF hospitalizations, compared to the control group's 279 HF hospitalizations, and 50 deaths compared to the control's 64 deaths [17].

REDUCE*hf* (Adamson, 2011) randomized 400 patients with class II–III HF with an implanted hemodynamic monitor system or an ICD capable of hemodynamic monitoring. The physiologic markers measured were RV systolic pressure, RV diastolic pressure, an estimate of pulmonary artery diastolic pressure (ePAD), maximum positive and negative changes in pressure over time, heart rate, and activity. The intervention group had weekly uploads of this data sent to their cardiologist, who adjusted outpatient medication regimens per their discretion, whereas the control group did not have their data made visible to their cardiologists, instead continuing standard of care phone calls from the heart failure nursing team. After a mean follow-up time of 12 months, the intervention group ($n=202$) had 79 HF hospitalizations and 7 deaths, compared to the control group ($n=198$) with 83 HF hospitalizations and 9 deaths [34].

OptiLink HF (Bohm, 2016) randomized 1002 patients with class II–III HF and an EF $\leq 35\%$ who had recently had an ICD with or without resynchronization capability to either intervention or control group. Both groups had intrathoracic impedance measured via the OptiVol fluid index. The intervention group ($n=505$) had alerts transmitted to the study investigators whenever a certain threshold index of intrathoracic impedance had been reached, and the physicians would then follow an intervention protocol. The

control group ($n = 507$) did not have these alerts transmitted to the physicians, and instead continued standard of care with nursing phone calls. After a mean follow-up time of 23.6 months, the intervention group had 214 initial CV hospitalizations, of which 119 were initial HF hospitalizations, with a total of 220 HF hospitalizations and 59 deaths. After a mean follow-up time of 22.3 months, the control group had 221 initial CV hospitalizations, of which 128 were initial HF hospitalizations, with a total of 218 HF hospitalizations and 63 deaths [19].

MORE-CARE (Boriani, 2017) randomized 865 HF patients with recently implanted CRT-D to either intervention or control group, where both groups' CRT-D reported automatic alerts for lung fluid accumulation (OptiVol®), atrial tachyarrhythmia (atrial tachycardia/fibrillation), and system integrity. The control group ($n = 428$) had "standard of care" defined as in-office follow-up every 4 months without any remote checks of the CRT-D alerts, whereas the intervention group ($n = 437$) had follow-up every 4 months alternating between remote checks of the CRT-D alerts and regular in-office appointments. Over the median follow-up time of 24 months, the intervention group had 197 CV hospitalizations, of which 111 were HF hospitalizations, and 40 deaths. The control group had 200 CV hospitalizations, of which 103 were HF hospitalizations, and 34 deaths [20].

COMPASS-HF (Bourge, 2008) randomized 274 patients with NYHA class III–IV HF to either intervention ($n = 134$) or control ($n = 140$) groups. Both groups then received an implanted continuous hemodynamic monitoring device (Chronicle, Medtronic Inc.). The intervention group had physiologic data from their implanted devices reviewed weekly by a clinician, whereas the control group did not have their data reviewed during the mean follow-up time of 6 months. The intervention group had 37 HF hospitalizations and 13 deaths, while the control group had 57 HF hospitalizations and 11 deaths [21].

LIMIT-CHF (Domenichini, 2016) randomized 80 patients with class I–III HF, EF ≤ 50%, and recent implantation of an ICD or CRT-D capable of measuring the proprietary intrathoracic impedance indices from Medtronic OptiVol or SJM CorVue. The intervention group ($n = 41$) had an audible alarm set to the devices' default congestion thresholds (fluid index of 60 for OptiVol, congestion trigger of 13 for CorVue), with patients instructed to call their cardiologists if the alarm went off, and increase oral loop diuretic dose by 50% for 1 week if indices were rising. The control group ($n = 39$) did not have audible alarms set up, and instead had routine in-office follow-up. Over the median follow-up time of 375 days, the intervention group had 11 HF hospitalizations and 4 deaths, while the control group had 6 HF hospitalizations and 3 deaths [22].

IN-TIME (Hindricks, 2014) randomized 664 patients with class II–III HF, EF ≤ 35%, and a recent dual chamber ICD or CRT-D to either intervention ($n = 333$) or control ($n = 331$) groups. The intervention group had their hemodynamic data sent to the study investigators at a set time daily and on detection of tachyarrhythmia, and the investigators made adjustments to outpatient medication per their discretion. The control group did not have the data reviewed and instead proceeded with standard of care. Over a mean follow-up time of 335 days, the intervention group had 23 CV hospitalizations and 10 deaths. Over a mean follow-up time of 326 days, the control group had 27 CV hospitalizations and 27 deaths [23].

EVOLVO (Landolina, 2012) randomized 200 patients with class I–III HF, EF ≤ 35%, and dual chamber ICD or CRT-D capable of intrathoracic impedance monitoring to either intervention ($n = 99$) or control ($n = 101$) groups. The intervention group had data regarding thoracic impedance, arrhythmias, and ICD shocks transmitted to the study investigators, and had 4-month follow-up alternating between in-person clinic visits and remote monitoring visits based on the transmitted data, with adjustments to medications made per physicians' discretion, whereas the control group had standard of care with regular 4-month in-person clinic visits. Over the mean follow-up time of 16 months, the intervention group had 57 CV hospitalizations and 7 deaths, whereas the control group had 49 CV hospitalizations and 8 deaths [24].

Luthje (2015) randomized 176 patients with class I–IV HF and ICD or CRT-D to either the intervention group with remote monitoring via OptiVol alerts or a control group of standard in-office visits every 3 months. The intervention group ($n = 87$) had OptiVol alert system connected to the Medtronic CareLink Network, whereas the control group ($n = 89$) did not have their devices connected to the network, and instead had regular in-office visits. Of note, OptiVol audible alerts were disabled in both groups. Both groups were followed for 15 months. The intervention group had 20 HF hospitalizations during that follow-up time, whereas the control group had 22 HF hospitalizations. Eight patients died in the intervention group, compared to 6 patients who died in the control group [25].

REM-HF (Morgan, 2017) randomized 1650 patients with NYHA class II–IV HF and implanted ICD to either intervention ($n = 824$) or control ($n = 826$) groups. The intervention protocol consisted of weekly uploads of thoracic impedance, Bi-V pacing, HR variability, arrhythmia, and AF/AT burden, with guide book-directed adjustment of medical therapy by a designated clinician, whereas the control group had standard of care phone calls and clinic visits. Over a median follow-up of 34 months, the intervention group had 315 initial CV hospitalizations and 128 deaths, while the control group had 297 initial CV hospitalizations and 152 deaths [26].

DOT-HF (Van Veldhuisen, 2011) randomized 335 patients with NYHA class II–IV HF, EF ≤ 35%, and implanted ICD

or CRT-D capable of thoracic impedance monitoring with the OptiVol system to either intervention ($n=168$) or control ($n=167$) groups. The intervention group had an audible alarm set for an OptiVol fluid congestion threshold, with patients instructed to call the study investigators when the alarms went off, at which point interventions were performed per clinicians' discretion. The control group did not have any audible alarms set for a specific threshold. Over a mean follow-up time of 15 months, the intervention group had 115 CV hospitalizations, of which 60 were HF hospitalizations, as well as 19 deaths. The control group had 74 CV hospitalizations, of which 36 were HF hospitalizations, and 15 deaths [27].

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10741-021-10150-5.

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Author contribution AH designed the research study; AH and SM performed the systematic review and analyzed the data for the meta-analysis; MN analyzed the data for the meta-regression; AH and SM wrote the paper; MN, AD, and JB edited the paper and contributed to the discussion.

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Availability of data and material Primary data can be requested from the corresponding author.

Declarations

Conflict of interest John Boehmer: Boston Scientific—consultant, speaker, research grants; Nanowear, Inc.—consulting and research grant; Medtronic—consulting; Abbott—research grant. All other authors: none.

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AHA/ACC/HFSA CLINICAL PRACTICE GUIDELINE

2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

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AIM: The "2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure" replaces the "2013 ACCF/AHA Guideline for the Management of Heart Failure" and the "2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure." The 2022 guideline is intended to provide patient-centric recommendations for clinicians to prevent, diagnose, and manage patients with heart failure.

METHODS: A comprehensive literature search was conducted from May 2020 to December 2020, encompassing studies, reviews, and other evidence conducted on human subjects that were published in English from MEDLINE (PubMed), EMBASE, the Cochrane Collaboration, the Agency for Healthcare Research and Quality, and other relevant databases. Additional relevant clinical trials and research studies, published through September 2021, were also considered. This guideline was harmonized with other American Heart Association/American College of Cardiology guidelines published through December 2021.

STRUCTURE: Heart failure remains a leading cause of morbidity and mortality globally. The 2022 heart failure guideline provides recommendations based on contemporary evidence for the treatment of these patients. The recommendations present an evidence-based approach to managing patients with heart failure, with the intent to improve quality of care and align with patients' interests. Many recommendations from the earlier heart failure guidelines have been updated with new evidence, and new recommendations have been created when supported by published data. Value statements are provided for certain treatments with high-quality published economic analyses.

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*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry may apply; see Appendix 1 for detailed information. †ACC/AHA Representative. ‡ACC/AHA Joint Committee on Clinical Practice Guidelines Liaison. §ACC/AHA Task Force on Performance Measures Representative. ‖HFSA Representative.

ACC/AHA Joint Committee on Clinical Practice Guidelines Members, see page e986.

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Facet Joint Injections 2024 Review

Plain Language Summary:

Coverage question: Should OHP cover shots in the spine joints (facet joints) with numbing or steroids medicine for back pain?

Should OHP cover this treatment? No. Studies showed that these shots didn't work better than shots with no active ingredients. The research found that these shots didn't really help reduce pain or improve how well people could move.

STAFF NOTE: The draft recommendation as part of this issue summary has changed from the version published for advance public comment on December 7, 2023.

Coverage Question: Should facet joint injections with anesthetics, steroids or a combination be covered for back pain?

Question source: OHA Medical Management Committee, Shorin Nemeth DO Legacy Interventional Pain Physician

Background:

Facet joints are the area on the side of the vertebral bones. The facet joints can cause axial spinal pain and referred pain in the extremities. Facet joint interventions may be used in pain management for chronic cervical/thoracic and back pain arising from the paravertebral facet joints. The facet block procedure is an injection of a local anesthetic, with or without a steroid medication, either into the facet joint (intra-articular) or outside the joint space around the nerve supply to the joint (the medial branch nerve) known as medial branch block (MBB). Imaging guidance (fluoroscopy or CT per code descriptor) is used to assure accurate placement of the needle for the injection.

Facet joint injections are frequency used as a diagnostic test to determine if radiofrequency ablation of the facet joint nerve would be effective. Radiofrequency ablation (RFA) of the facet joint nerves were reviewed in 2021 as part of a coverage guidance and found to not be effective based on a 2021 AHRQ review.

Facet joint injections were last reviewed as part of a coverage guidance in 2015. OHA MMC has had several requests for facet joint injections recently. Dr. Nemeth also reached out to HERC staff requesting re-consideration of neuraxial injections as a way to reduce opioid use and give pain specialists more tools to help patients with back pain.

Previous HSC/HERC reviews:

As part of the 2015 coverage guidance on percutaneous interventions for low back pain, radiofrequency denervation, facet joint corticosteroid injections and therapeutic facet joint injections were not recommended for coverage.

The prior reviews focused on two systematic reviews on interventional therapies for low back pain from 2010 and 2009, and a Washington HTA report from 2011 (updated 2013 and 2014).

Facet Joint Injections 2024 Review

Current Prioritized List/Coverage status:

The following codes are on line 654 654 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
CPT 69940 Injection of upper or middle spine facet joint using imaging guidance, single level
CPT 64491 second level
CPT 64492 third and any additional level

The following codes are on line 523 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
CPT 64493 Injection of lower or sacral spine facet joint using imaging guidance, single level
CPT 64494 second level
CPT 64495 third and any additional level

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS
Line 654

The following Interventions are prioritized on Line 654 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
64490-64492	Facet joint injections cervical and thoracic	Insufficient evidence of benefit	March, 2015 Coverage guidance

Evidence:

1) **AHRQ 2016,** technology assessment, pain management injection therapies for low back pain
    a. Facet joint injections
        i. Pain and function:
            1. low strength of evidence
            2. Two trials found no clear differences between an intra-articular facet joint injection with corticosteroid vs. saline in pain or function at 1 to 3 months
        ii. Pain, function and opioid use
            1. Two trials found no differences between medial branch corticosteroid injection vs. medial branch local anesthetic injection in pain, function, or opioid use through 12 to 24 months
            2. low strength of evidence
    b. findings of our review that have implications for clinical and policy decision making included limited evidence of no effectiveness of epidural corticosteroid injections for spinal stenosis or nonradicular low back pain, or for facet joint corticosteroid injections for presumed facet joint pain. Guidelines are inconsistent with regard to use of facet joint corticosteroid injections, but recent trials have not provided additional evidence to support effectiveness.

2) **Washington HTA 2016**, updated spinal injections review https://www.hca.wa.gov/assets/program/spinal_injections-rr_final_report_021216[1].pdf
    a. Intra-articular steroid injection vs. intra-articular control injection
        i. 3 RCTs
        ii. No difference between groups for short and intermediate term pain or function, low quality of evidence
3) **Suputtitada 2023**, systematic review and meta-analysis of intra-articular facet joint injection
    a. N=3 RCTs (247 patients)
        i. Bupivacaine with methylprednisolone vs saline
        ii. Methylprednisolone vs saline
        iii. Lidocaine vs saline
        iv. All three trials used fluoroscopy guidance
    b. The active substances and normal saline had similar therapeutic effects on pain within 1 h, after 1–1.5 months, and after 3–6 months, with MD and 95% CI of 2.43 and −11.61 to 16.50, −0.63 and −7.97 to 6.72, and 1.90 and −16.03 to 19.83, respectively, as well as on the quality of life after 1 and 6 months
    c. Conclusions: The short- and long-term clinical effects of intra-articular facet joint injections of normal saline are comparable to those of other active substances in patients with LBP.

Expert guidelines:

1) **Cohen 2020**, consensus practice guidelines for lumbar facet joint pain
    a. Are facet blocks 'diagnostic', 'prognostic' or both? Intra-articular (IA) facet joint injections meet criteria for diagnostic interventions for facet-mediated pain but are less predictive than medial branch block (MBB) for response to medial branch radiofrequency ablation and are characterized by a high technical failure rate. As diagnostic tools, MBBs suffer from limitations related to aberrant lumbar facet joint innervation. Compared with saline controls, both IA and medial branch injections with lidocaine provide better predictive information for medial branch RFA; grade B recommendation, low level of certainty
    b. Are intra-articular facet or medial branch blocks with steroids therapeutic? We recommend against the routine use of therapeutic facet injections with steroids. grade D, moderate level of certainty.
    c. How many prognostic blocks should one perform before radiofrequency ablation? The committee recommends a single block. We found moderate evidence that dual blocks result in a higher subsequent success rate for medial branch RF, but that the use of a zero-block paradigm results in the highest overall number of patients with a positive response to the RFA. This has led some, including this committee, to a clinical compromise of accepting the results of a single MBB for identifying denervation candidates, with some data suggesting that higher RF treatment response rates occur in those reporting a higher degree of relief with a single block. In an era of personalized medicine, the committee believes that known variables should be used to tailor care to the needs of the individual patient and to the goals of the practice environment; grade C recommendation, low-to-moderate level of certainty.
2) **Manchikanti 2020**, American Society of Interventional Pain Physician guidelines for facet joint interventions
    a. Are the available therapeutic facet joint interventional therapies in managing chronic spinal pain effective?

i. Therapeutic lumbar facet joint nerve blocks were assessed in 2 high-quality RCTs and one moderate-quality RCT, including 293 patients either with local anesthetic alone or local anesthetic with steroid in 92 patients and conventional radiofrequency neurotomy in 50 patients. All 3 studies showed positive effectiveness of long-term and short-term relief. The improvement was seen in 69% of the patients with local anesthetic with steroids by Civelek et al, whereas it was seen in 75% and 85% of the patients in the studies by Manchikanti et al. Only the systematic review by Manchikanti et al assessed the evidence for therapeutic facet joint nerve blocks. They showed Level II evidence for lumbar facet joint nerve blocks for short-term and long-term relief.
ii. Thus, the evidence for therapeutic lumbar facet joint nerve blocks is Level II for short-term and long-term improvement with moderate strength of recommendation, when performed after the appropriate selection of the patients positive with controlled comparative local anesthetic blocks with 80% criterion standard of pain relief.

Other payer policies:

1) UHC 2023
    a. The following are proven and medically necessary:
        i. An initial diagnostic Facet Joint Injection/Medial Branch Block to determine facet joint origin when all of the following criteria are met:
            1. Pain is exacerbated by facet loading maneuvers on physical examination (e.g., hyperextension, rotation); and
            2. Clinically significant improvement has not occurred (the pain remains at a 3 or more on a 1-10 pain scale) after a minimum of four weeks of conservative care (including but not limited to pharmacotherapy, exercise, or physical therapy); and
            3. Clinical findings and imaging studies suggest no other cause of the pain (e.g., spinal stenosis with neurogenic claudication, disc herniation with radicular pain, infection, tumor, fracture, pain related to prior surgery); and o The spinal motion segment is not fused; and
            4. A radiofrequency joint denervation/ablation procedure is being considered
        ii. A second Facet Joint Injection/Medial Branch Block performed to confirm the validity of the clinical response to the initial Facet Joint Injection, when all of the following criteria are met:
            1. Administered at the same level and side as the initial block; and
            2. The initial diagnostic Facet Joint Injection produced a positive response as demonstrated when all the following criteria are met:
                a. For at least the expected minimum duration of the effect of the local anesthetic; and
                b. Functional improvement that is specific to the individual with demonstrable improvement in the physical functions previously limited by the facetogenic pain and
            3. A radiofrequency joint denervation/ablation procedure is being considered
    b. Facet Joint Injections/Medial Branch Blocks are unproven and not medically necessary due to insufficient evidence of efficacy: If radiofrequency ablation procedure not

considered as treatment option at the requested level(s) For treating spinal pain, after diagnostic injections have been completed After two Facet Injections/Medial Branch Blocks at the same level and same side (this is considered therapeutic rather than diagnostic) Therapeutic Facet Joint Injections and/or Facet Nerve Block (i.e., Medial Branch Block) for treating chronic spinal pain For a second Facet Joint Injection/Medial Branch Block if the initial injection did not confirm the joint as the source of pain In the presence of untreated Radiculopathy at the same level as the intended diagnostic injection (with the exception of Radiculopathy caused by a facet joint synovial cyst) If injection of volume of local anesthetics exceeds 0.5ml for Medial Branch Blocks When performed under ultrasound guidance

c. Therapeutic Facet Joint/Medial Branch Block Injections at the cervical, thoracic and lumbar levels of the spine are unproven and not medically necessary due to insufficient evidence of efficacy and safety.

2) Aetna 2023
   a. *Facet joint injections*
      i. An initial facet injection (intra-articular and medial branch block) from C2-3 to L5-S1 is considered medically necessary for the *diagnosis* of facet pain in persons with severe chronic neck and back pain when the following criteria are met:
         1. Member has symptoms suggestive of facet joint syndrome (symptoms of facet joint syndrome include absence of radiculopathy, pain that is aggravated by extension, rotation or lateral bending of the spine and is not typically associated with any neurological deficits); *and*
         2. Facet mediated pain is confirmed by provocative testing on physical examination (to confirm that pain is exacerbated by extension and rotation); *and*
         3. Imaging studies suggest no other obvious cause of pain (such as fracture, tumor, infection, or significant extraspinal lesion)*; and*
         4. Pain limits daily activities; *and*
         5. Pain has lasted more than 3 months; *and*
         6. Pain has persisted despite six or more weeks of conservative treatment (including, systemic medications, and/or physical therapy); *and*
         7. Radiofrequency facet neurolysis is being considered.
   b. Aetna considers *diagnostic* facet joint injections *not* medically necessary where radiofrequency facet neurolysis is not being considered.

HERC staff summary:

The most recent AHRQ and Washington HTA reports as well as a 2023 systematic review found that anesthetic and steroid facet joint injections did not produce any improvement in pain or function in the short or intermediate term compared to placebo injections. Major insurers only cover facet joint injections when radiofrequency ablation is being considered, as a diagnostic test to determine if RFA will be effective. A recent coverage guidance found that RFA of the facet joint nerve does not have evidence of effectiveness and this procedure is not covered currently for OHP. Expert guidelines are varied on whether they recommend facet joint injections.

HERC staff recommends making no change in the current non-coverage of facet joint injections.

Facet Joint Injections 2024 Review

HERC staff recommendations:

1) Remove lumbar facet joint injections from line 523 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS and add to line along with their cervical counterparts.
    a. CPT 64493 Injection of lower or sacral spine facet joint using imaging guidance, single level
    b. CPT 64494 second level
    c. CPT 64495 third and any additional level
2) Add lumbar facet joint injections to line 654 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
3) Update the entry in GN173 for facet joint injections

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS
Line 654

The following Interventions are prioritized on Line 654 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
64490-~~64492~~ 64495	Facet joint injections ~~cervical and thoracic~~	Insufficient evidence of benefit	~~March, 2015~~ January 2024 Coverage guidance

Pain Management Injection Therapies for Low Back Pain

Technology Assessment Report

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Pain Management Injection Therapies for Low Back Pain

Structured Abstract

Objectives. Low back pain is common and injections with corticosteroids are a frequently used treatment option. This report reviews the current evidence on effectiveness and harms of epidural, facet joint, and sacroiliac corticosteroid injections for low back pain conditions.

Data Sources. A prior systematic review (searches through July 2008), electronic databases (Ovid MEDLINE, Scopus, and the Cochrane Libraries from January 2008 through October 2014), reference lists, and clinical trials registries.

Review Methods. Using predefined criteria, we selected randomized trials of patients with lumbosacral radiculopathy, spinal stenosis, nonradicular back pain, or chronic postsurgical back pain that compared effectiveness or harms of epidural, facet joint, or sacroiliac corticosteroid injections versus placebo or other interventions. We also included randomized trials that compared different injection techniques and large (sample sizes >1000) observational studies of back injections that reported harms. The quality of included studies was assessed, data were extracted, and results were summarized qualitatively and using meta-analysis on outcomes stratified by immediate- (1 week to ≤2 weeks), short- (2 weeks to ≤3 months), intermediate- (3 months to <1 year), and long-term (>1 year) followup.

Results. Seventy-eight randomized trials of epidural injections, 13 trials of facet joint injections, and one trial of sacroiliac injections were included. For epidural corticosteroid injections versus placebo interventions for radiculopathy, the only statistically significant effects were on mean improvement in pain at immediate-term followup (weighted mean difference [WMD] –7.55 on a 0 to 100 scale, 95% CI –11.4 to –3.74) (strength of evidence [SOE]: moderate), mean improvement in function at immediate-term followup when an outlier trial was excluded (standardized mean difference [SMD] –0.33, 95% CI –0.56 to –0.09) (SOE: low), and risk of surgery at short-term followup (relative risk [RR] 0.62, 95% CI 0.41 to 0.92) (SOE: low). The magnitude of effects on pain and function was small, did not meet predefined thresholds for minimum clinically important differences, and there were no differences on outcomes at longer-term followup. Evidence on effects of different injection techniques, patient characteristics, or comparator interventions estimates was limited and did not show clear effects. Trials of epidural corticosteroid injections for radiculopathy versus nonplacebo interventions did not clearly demonstrate effectiveness (SOE: insufficient to low).

Evidence was limited for epidural corticosteroid injections versus placebo interventions for spinal stenosis (SOE: low to moderate) or nonradicular back pain (SOE: low), but showed no differences in pain, function, or likelihood of surgery.

Studies found no clear differences between various facet joint corticosteroid injections (intra-articular, extra-articular [peri-capsular], or medial branch) and placebo interventions (SOE: low to moderate). There was insufficient evidence from one very small trial to determine effects of peri-articular sacroiliac joint corticosteroid injections injection (SOE: insufficient).

Serious harms from injections were rare in randomized trials and observational studies, but harms reporting was suboptimal (SOE: low).

Conclusions: Epidural corticosteroid injections for radiculopathy were associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits were small and not sustained, and there was no effect on long-term risk of surgery. Evidence did not suggest that effectiveness varies based on injection technique, corticosteroid, dose, or comparator. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain and that facet joint corticosteroid injections are not effective for presumed facet joint pain. There was insufficient evidence to evaluate effectiveness of sacroiliac joint corticosteroid injections.

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MDPI

Systematic Review

Intra-Articular Facet Joint Injection of Normal Saline for Chronic Low Back Pain: A Systematic Review and Meta-Analysis

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Abstract: *Objective*: This systematic review and meta-analysis compared the patient-reported outcomes of intra-articular facet joint injections of normal saline and selected active substances to identify a more effective agent for treating subacute and chronic low back pain (LBP). *Methods*: The PubMed, Embase, Scopus, Web of Science, and CENTRAL databases were searched for randomized controlled trials and observational studies published in English. A research quality assessment was performed using ROB2 and ROBINS-I. A meta-analysis was conducted using a random-effects model, and the mean differences (MD) with 95% confidence intervals (CI) in efficacy outcomes, including pain, numbness, disability, and quality of life, were assessed. Results: Of the 2467 potential studies, 3 were included (247 patients). The active substances and normal saline had similar therapeutic effects on pain within 1 h, after 1–1.5 months, and after 3–6 months, with MD and 95% CI of 2.43 and −11.61 to 16.50, −0.63 and −7.97 to 6.72, and 1.90 and −16.03 to 19.83, respectively, as well as on the quality of life after 1 and 6 months. *Conclusions*: The short- and long-term clinical effects of intra-articular facet joint injections of normal saline are comparable to those of other active substances in patients with LBP.

Keywords: facet joint injection; chronic low back pain; normal saline; meta-analysis; patient reported clinical outcomes

check for updates

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1. Introduction

Low back pain (LBP) is characterized by discomfort, stiffness, or muscular tension between the lower rib edge and buttock creases with or without sciatica (pain radiating from the buttock and downward along the course of the sciatic nerve). Chronic or occasional lower back pain (LBP) is a common musculoskeletal disorder. This is true for people of all ages and countries regardless of whether they are economically developed [1]. In 2019, LBP remained the major cause of years lived with disability (YLDs) worldwide despite a slight decline in the age-standardized prevalence, incidence, and YLDs rate from 1990 to 2019. In 2019, the highest prevalence rates were observed in the 80–84-year-old age bracket

OPEN ACCESS

Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group

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ABSTRACT

Background The past two decades have witnessed a surge in the use of lumbar facet blocks and radiofrequency ablation (RFA) to treat low back pain (LBP), yet nearly all aspects of the procedures remain controversial.

Methods After approval by the Board of Directors of the American Society of Regional Anesthesia and Pain Medicine, letters were sent to a dozen pain societies, as well as representatives from the US Departments of Veterans Affairs and Defense. A steering committee was convened to select preliminary questions, which were revised by the full committee. Questions were assigned to 4–5 person modules, who worked with the Subcommittee Lead and Committee Chair on preliminary versions, which were sent to the full committee. We used a modified Delphi method, whereby the questions were sent to the committee en bloc and comments were returned in a non-blinded fashion to the Chair, who incorporated the comments and sent out revised versions until consensus was reached.

Results 17 questions were selected for guideline development, with 100% consensus achieved by committee members on all topics. All societies except for one approved every recommendation, with one society dissenting on two questions (number of blocks and cut-off for a positive block before RFA), but approving the document. Specific questions that were addressed included the value of history and physical examination in selecting patients for blocks, the value of imaging in patient selection, whether conservative treatment should be used before injections, whether imaging is necessary for block performance, the diagnostic and prognostic value of medial branch blocks (MBB) and intra-articular (IA) injections, the effects of sedation and injectate volume on validity, whether facet blocks have therapeutic value, what the ideal cut-off value is for a prognostic block, how many blocks should be performed before RFA, how electrodes should be oriented, the evidence for larger lesions, whether stimulation should be used before RFA, ways to mitigate complications, if different standards should be applied to clinical practice and clinical trials and the evidence for repeating RFA (see table 12 for summary).

Conclusions Lumbar medial branch RFA may provide benefit to well-selected individuals, with MBB being more predictive than IA injections. More stringent selection criteria are likely to improve denervation outcomes, but at the expense of more false-negatives. Clinical trials should be tailored based on objectives, and selection criteria for some may be more stringent than what is ideal in clinical practice.

INTRODUCTION

There are few conditions in interventional pain medicine as controversial as lumbar facet joint pain. Everything from incidence, to diagnostic criteria, patient selection for interventions and the effectiveness of treatment is a source of contention and scientific debate. Regarding prevalence, the cited frequency of lumbar facet joint pain ranges from as low as 4.8% in the multicenter National Low Back Pain Survey evaluating final diagnoses of 2374 patients with low back pain (LBP) referred to an orthopedic or neurosurgical spine surgeon, to over 50% in systematic reviews on prevalence studies using varying criteria for diagnostic blocks performed by interventional pain physicians.[1–4] The wide disparity in reported prevalence raises questions regarding the accuracy of diagnostic testing in the absence of any non-interventional diagnostic reference standard. The poor correlation between facet joint pathology on imaging and LBP further fuels debate.[5] For diagnostic criteria, research and review articles abound on the ideal cut-off for designating a block as positive, and the optimal number of blocks that should be performed before lumbar facet radiofrequency ablation (RFA) treatment, with no consensus emerging.[6–11]

Lumbar facet interventions comprise the second most common procedure performed in interventional pain practices, with millions per year being performed in the USA alone.[12] For lumbar RFA, a recent review of the Marketscan commercial claims and encounters databases from 2007 to 2016 demonstrated a 130.6% overall increase in utilization (9.7% annually).[13] Along with increasing utilization, there was also a reciprocal increase in cost,

Facet Joint Interventions Guidelines

Comprehensive Evidence-Based Guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines

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Background: Chronic axial spinal pain is one of the major causes of significant disability and health care costs, with facet joints as one of the proven causes of pain.

Objective: To provide evidence-based guidance in performing diagnostic and therapeutic facet joint interventions.

Methods: The methodology utilized included the development of objectives and key questions with utilization of trustworthy standards. The literature pertaining to all aspects of facet joint interventions, was reviewed, with a best evidence synthesis of available literature and utilizing grading for recommendations.

Summary of Evidence and Recommendations:

Non-interventional diagnosis:

- The **level of evidence is II** in selecting patients for facet joint nerve blocks at least 3 months after onset and failure of conservative management, **with strong strength of recommendation** for physical examination and clinical assessment.
- The **level of evidence is IV** for accurate diagnosis of facet joint pain with physical examination based on symptoms and signs, **with weak strength of recommendation**.

Imaging:

- The **level of evidence is I with strong strength of recommendation**, for mandatory fluoroscopic or computed tomography (CT) guidance for all facet joint interventions.
- The **level of evidence is III with weak strength of recommendation** for single photon emission computed tomography (SPECT) .
- The **level of evidence is V with weak strength of recommendation** for scintography, magnetic resonance imaging (MRI), and computed tomography (CT) .

Interventional Diagnosis:

Lumbar Spine:

- The **level of evidence is I to II with moderate to strong strength of recommendation** for lumbar diagnostic facet joint nerve blocks.
- Ten relevant diagnostic accuracy studies with 4 of 10 studies utilizing controlled comparative local anesthetics with concordant pain relief criterion standard of ≥ 80% were included.
- The prevalence rates ranged from 27% to 40% with false-positive rates of 27% to 47%, with ≥ 80% pain relief.

Cervical Spine:
- The **level of evidence is II with moderate strength of recommendation**.
- Ten relevant diagnostic accuracy studies, 9 of the 10 studies with either controlled comparative local anesthetic blocks or placebo controls with concordant pain relief with a criterion standard of ≥ 80% were included.
- The prevalence and false-positive rates ranged from 29% to 60% and of 27% to 63%, with high variability.

Thoracic Spine:
- The **level of evidence is II with moderate strength of recommendation**.
- Three relevant diagnostic accuracy studies, with controlled comparative local anesthetic blocks, with concordant pain relief, with a criterion standard of ≥ 80% were included.
- The prevalence varied from 34% to 48%, whereas false-positive rates varied from 42% to 58%.

Therapeutic Facet Joint Interventions:
Lumbar Spine:
- The **level of evidence is II with moderate strength of recommendation** for lumbar radiofrequency ablation with inclusion of 11 relevant randomized controlled trials (RCTs) with 2 negative studies and 4 studies with long-term improvement.
- The **level of evidence is II with moderate strength of recommendation** for therapeutic lumbar facet joint nerve blocks with inclusion of 3 relevant randomized controlled trials, with long-term improvement.
- The **level of evidence is IV with weak strength of recommendation** for lumbar facet joint intraarticular injections with inclusion of 9 relevant randomized controlled trials, with majority of them showing lack of effectiveness without the use of local anesthetic.

Cervical Spine:
- The **level of evidence is II with moderate strength of recommendation** for cervical radiofrequency ablation with inclusion of one randomized controlled trial with positive results and 2 observational studies with long-term improvement.
- The **level of evidence is II with moderate strength of recommendation** for therapeutic cervical facet joint nerve blocks with inclusion of one relevant randomized controlled trial and 3 observational studies, with long-term improvement.
- The **level of evidence is V with weak strength of recommendation** for cervical intraarticular facet joint injections with inclusion of 3 relevant randomized controlled trials, with 2 observational studies, the majority showing lack of effectiveness, whereas one study with 6-month follow-up, showed lack of long-term improvement.

Thoracic Spine:
- The **level of evidence is III with weak to moderate strength of recommendation** with emerging evidence for thoracic radiofrequency ablation with inclusion of one relevant randomized controlled trial and 3 observational studies.
- The **level of evidence is II with moderate strength of recommendation** for thoracic therapeutic facet joint nerve blocks with inclusion of 2 randomized controlled trials and 2 observational studies with long-term improvement.
- The **level of evidence is III with weak to moderate strength of recommendation** for thoracic intraarticular facet joint injections with inclusion of one randomized controlled trial with 6 month follow-up, with emerging evidence.

Antithrombotic Therapy:
- Facet joint interventions are considered as moderate to low risk procedures; consequently, antithrombotic therapy may be continued based on overall general status.

Sedation:
- The **level of evidence is II with moderate strength of recommendation** to avoid opioid analgesics during the diagnosis with interventional techniques.
- The **level of evidence is II with moderate strength of recommendation** that moderate sedation may be utilized for patient comfort and to control anxiety for therapeutic facet joint interventions.

Limitations: The limitations of these guidelines include a paucity of high-quality studies in the majority of aspects of diagnosis and therapy.

Conclusions: These facet joint interventions guidelines were prepared with a comprehensive review of the literature with methodologic quality assessment with **determination of level of evidence and strength of recommendation**s

Key words: Chronic spinal pain, interventional techniques, diagnostic blocks, therapeutic interventions, facet joint nerve blocks, intraarticular injections, radiofrequency neurolysis

Disclaimer: These guidelines are based on the best available evidence and do not constitute inflexible treatment recommendations. Due to the changing body of evidence, this document is not intended to be a "standard of care."

Benign Paroxysmal Positional Vertigo

Plain Language Summary:

Coverage question: Should OHP cover a condition causing dizziness or a feeling that the world is spinning?

Should OHP cover this treatment? Yes, treatment of benign paroxysmal positioning vertigo (BVVP), a condition that causes dizziness and unsteady feelings when changing head positions, should be covered for some patients. Studies show physical therapy treatment is effective.

STAFF NOTE: The draft recommendation as part of this issue summary has changed from the version published for advance public comment on December 7, 2023.

Coverage Question: Should vertigo be reprioritized? Should benign paroxysmal positional vertigo (BPPV) be reprioritized?

Question source: Lindsay Lederer, physical therapist

Background: Vertigo can be described as a dizzy or spinning sensation. Some people perceive self-motion whereas others perceive motion of the environment. Individuals may experience vertigo as an illusion of motion, vague dizziness, imbalance, disorientation, transient spinning or a sense of swaying or tilting. Vertigo may be caused by any number of conditions and is a symptom rather than a diagnosis.

Vertigo is the predominant symptom of vestibular dysfunction and can be associated with health conditions such as, but not limited to, Meniere's disease and benign paroxysmal positional vertigo (BPPV). Benign paroxysmal positioning vertigo (BPPV) is believed to be a mechanical disorder of the inner ear as a consequence of degenerated material lodging in the posterior canal of the ear.

Particle repositioning maneuvers (Canalith repositioning procedures) are used to manage episodes of BPPV. Canalith refers to collections of calcium in the inner ear. The most used particle repositioning maneuver is the Epley maneuver, but other maneuvers exist such as the Brandt-Daroff exercises and the Semont maneuver.

Based on public input and on the initial evidence review, HERC staff elected to limit this review to BPPV, as it has the best evidence of effectiveness for treatments and the most public support for coverage.

From Ms. Lederer

> Canalith repositioning (95992), is *not* covered for disorders of vestibular function (H81) line 512, for which it is a recommended intervention per the American Academy of Otolaryngology and Head and Neck Surgery (AHO-HNS) and endorsed by the American Academy of Family Physicians (AAFP). Physical Therapists are extensively educated and trained to address peripheral vertigo impairments leading to decreased risk of falls and persistent disability.
>
> Peripheral vertigo (H81 ICD-10) affects people of all ages and is common in those over the age of 20. According to the National Hospital Ambulatory Medical Care Survey: 2021, vertigo and lightheadedness represented 1.2 million emergency department visits in the US. Eighty percent

of vertigo is peripheral and benign paroxysmal positional vertigo is the most common cause of peripheral vertigo. (Lopez, et al., 2019). Vertigo can lead to falls, and perceived disability (Sulway & Whitney, 2019). The economic cost of vertigo includes loss of employment, reduced ability to maintain workload and lost working days. (Benecke, et al., 2013).

The Canalith Repositioning Procedure or CRP, also known as the Epley maneuver is a technique designed to move patients through a series of head positions to directly free adhered otoconia out of the involved semicircular canal back into the vestibule.

Previous HSC/HERC reviews:

Vertiginous conditions were last reviewed in November 2019. At that time, the staff summary concluded: "Most of the concerns about non-pairing relate to the prioritization of vertiginous syndromes on Line 512, below the funding line. There is evidence of the efficacy of vestibular rehabilitation for a variety of vertiginous conditions. A few codes are missing from line 512." Canalith repositioning (CPT 95992) was added to line 292 (now line 290) with an entry in GN106 stating that "Treatment of falls prevention with exercise interventions is included on Line 292" under the section on USPSTF recommendation coverage.

Fall prevention programs were reviewed in depth in October 2021. At that time, HCPCS S9451 (Exercise classes, non-physician provider, per session) was added to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS and GN106 was modified to include the paragraph "Supervised evidence-based exercise programs for fall prevention for persons age 65 and older who are at increased risk of falls are included on line 3 using CPT 98961 or 98962 or HCPCS S9451. HCPCS S9451 is only included on Line 3 for the provision of supervised exercise therapy for fall prevention. Programs should be culturally tailored/culturally appropriate when feasible."

Current Prioritized List/Coverage status:

ICD-10-CM H81 family (vertigo, other disorders of vestibular function) is on line 505 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM. This included ICD-10-CM H81.1 (Benign paroxysmal vertigo).
ICD-10-CM Z91.81 (History of falling) is on lines 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS and 290 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS

CPT 95992 (Repositioning exercises of head for treatment of dizziness, each day) is on lines 290 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS and 505 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM

CPT 97112 (Therapy procedure to re-educate brain-to-nerve-to-muscle function, each 15 minutes) is on 60+ lines including 290 and 505

HCPCS S9451 (Exercise classes, non-physician provider, per session) is on lines 3 and 399 CONDITIONS OF THE BACK AND SPINE

HCPCS S9476 (Vestibular rehabilitation program, non-physician provider, per diem) is on line 505

Benign Paroxysmal Positional Vertigo

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2022.
   1) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations/
      a) Treatment of falls prevention with exercise interventions is included on Line 290.
   2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
   1) http://brightfutures.aap.org. Periodicity schedule available at https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf
      a) Bright Futures is the periodicity schedule for screening for EPSDT for the Oregon Health Plan.
   2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.

C) Health Resources **and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines (revised** January 2022). Available at https://www.hrsa.gov/womens-guidelines as of July 28, 2022.

D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf
   1) COVID-19 vaccines are intended to be included on this line even if the specific administration code(s) do not yet appear on the line when the vaccine has both 1) FDA approval or FDA emergency use authorization (EUA) and 2) ACIP recommendation.
   2) Other ACIP recommended vaccines not on the routine vaccine schedule are included on Line 3 when administered according to recommendations specified in the Morbidity and Mortality Weekly Review (MMWR) as required by federal law: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html (retrieved 8/8/2023).

Colorectal cancer screening is included on Line 3 for average-risk adults aged 45 to 75, using one of the following screening programs:

A) Colonoscopy every 10 years
B) Flexible sigmoidoscopy every 5 years
C) Fecal immunochemical test (FIT) every year
D) Guaiac-based fecal occult blood test (gFOBT) every year

CT colonography (CPT 74263), FIT-DNA (CPT 81528) and mSEPT9 (HCPCS G0327) are included on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS.

Benign Paroxysmal Positional Vertigo

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered after informed decision making between patients and clinicians which includes consideration of the patient's overall health, prior screening history, and preferences.

Supervised evidence-based exercise programs for fall prevention for persons aged 65 or older OR younger patients who are at increased risk of falls are included on Line 3 using CPT 98961 or 98962 or HCPCS S9451. HCPCS S9451 is only included on Line 3 for the provision of supervised exercise therapy for fall prevention. Programs should be culturally tailored/culturally appropriate when feasible.

Note: CPT 96110 (Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument) can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.

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

Evidence:

1) **McDonnell 2015**, vestibular rehabilitation for unilateral peripheral vestibular dysfunction
    a) N=39 RCTs (2441 patients)
        i) Comparisons: control/sham interventions, medical interventions
    b) Individual and pooled analyses of the primary outcome, frequency of dizziness, showed a statistically significant effect in favor of vestibular rehabilitation over control or no intervention (odds ratio (OR) 2.67, 95% confidence interval (CI) 1.85 to 3.86; four studies, 565 participants). Secondary outcomes measures related to levels of activity or participation measured, for example, with the Dizziness Handicap Inventory, which also showed a strong trend towards significant differences between the groups (standardized mean difference (SMD) -0.83, 95% CI -1.02 to -0.64). The exception to this was when movement-based vestibular rehabilitation was compared to physical maneuvers for benign paroxysmal positional vertigo (BPPV), where the latter was shown to be superior in cure rate in the short term (OR 0.19, 95% CI 0.07 to 0.49). There were no reported adverse effects
    c) Conclusions: There is moderate to strong evidence that vestibular rehabilitation is a safe, effective management for unilateral peripheral vestibular dysfunction, based on a number of high-quality randomized controlled trials. There is moderate evidence that vestibular rehabilitation resolves symptoms and improves functioning in the medium term. However, there is evidence that for the specific diagnostic group of BPPV, physical (repositioning) maneuvers are more effective in the short term than exercise-based vestibular rehabilitation; although a combination of the two is effective for longer-term functional recovery. There is insufficient evidence to discriminate between differing forms of vestibular rehabilitation
2) **Hilton 2014**, Cochrane review of canalith repositioning maneuvers for benign paroxysmal positional vertigo
    a) N=11 RCTs (745 patients)
        i) Five studies compared the efficacy of the Epley man oeuvre against a sham maneuver, three against other particle repositioning maneuvers (Semont, Brandt-Daroff and Gans) and three against a control (no treatment, medication only,

postural restriction). Patients were treated in hospital otolaryngology departments in eight studies and family practices in two studies.

b) Complete resolution of vertigo occurred significantly more often in the Epley treatment group when compared to a sham manoeuvre or control (odds ratio (OR) 4.42, 95% confidence interval (CI) 2.62 to 7.44; five studies, 273 participants); the proportion of patients resolving increased from 21% to 56%.

c) Adverse effects were infrequently reported. There were no serious adverse effects of treatment

d) Conclusions: There is evidence that the Epley maneuver is a safe, effective treatment for posterior canal BPPV, based on the results of 11, mostly small, randomized controlled trials with relatively short follow-up. There is a high recurrence rate of BPPV after treatment (36%)

Expert guidelines:

1) **American Academy of Otolaryngology-Head and Neck Surgery 2017**: clinical practice guideline, benign paroxysmal positional vertigo
   a) Clinicians should treat, or refer to a clinician who can treat, patients with posterior canal BPPV with a canalith repositioning procedure (CRP)
      i) Grade A evidence, Strong recommendation based on systematic reviews of RCTs and a preponderance of benefit over harm.
      ii) No comparison studies have been published from which to make recommendations regarding self-treatment versus clinician-administered treatment of BPPV.
   b) The clinician may offer vestibular rehabilitation (VR), either self-administered or with a clinician, in the treatment of BPPV
      i) Option, Grade B evidence based on limited RCTs
      ii) VR is not a single specific protocol, but it refers to a broad designation of therapies that include CRP itself, as well as habituation exercises, exercises for gaze stabilization, balance retraining and facilitation of sensory and motor integration, gait retraining, fall prevention, relaxation training, conditioning exercises, functional and occupational skills retraining, and patient and family education
      iii) given the substantial evidence that movement/ habituation-based VR is significantly less effective than CRP as an initial treatment for BPPV, VR should be considered an option in the treatment of BPPV rather than a recommended first-line treatment modality for BPPV. VR is, however, indicated for patients with BPPV who have persistent disability following CRP, refuse CRP, or are not candidates for CRP. VR is particularly indicated in patients with additional impairments where further therapy is needed to resolved more nonspecific dizziness and those patients with heightened fall risk (eg, elderly)
   c) Clinicians should evaluate, or refer to a clinician who can evaluate, patients with persistent symptoms for unresolved BPPV and/or underlying peripheral vestibular or central nervous system disorders.
      i) Recommendation
      ii) Evidence quality: Grade A for treatment of observation failure and Grade B for CRP failure based on RCT and systematic review examining treatment responses and failure rates
   d) Clinicians should not routinely treat BPPV with vestibular suppressant medications such as antihistamines and/or benzodiazepines

i) Recommendation against
ii) Grade C based on observational and cross-sectional studies, medium level of confidence in the evidence
iii) vestibular suppressant medications have the potential for significant harm. All of these medications may produce drowsiness, cognitive deficits, and interference with driving or operating machinery, and increased risk of falls
iv) There is no evidence in the literature to suggest that any of these vestibular suppressant medications are effective as a definitive, primary treatment for BPPV

2) **American Academy of Neurology 2009**, canalith repositioning procedure (CRP)
   a) Based on findings from systematic reviews of the literature, the American Academy of Neurology concluded that CRP is "an established effective and safe therapy that should be offered to patients of all ages with posterior semicircular canal BPPV (Level A recommendation)."

Other payer policies:

1) Aetna 2023
   a) M*aneuvers for Benign Paroxysmal Positioning Vertigo (BPPV)*
      i) Positional nystagmus test (Barany or Dix-Hallpike maneuver) for the diagnosis of BPPV
      ii) Use of the Epley maneuver (also known as canalith repositioning procedure) or the Semont maneuver for the treatment of BPPV when *both* of the following selection criteria are satisfied:
         (a) Diagnosis of BPPV has been confirmed by a positive Hallpike test, *and*
         (b) Member had symptoms of BPPV for at least 4 months.
   b) V*estibular Rehabilitation*
      i) For chronic vertigo / persistent postural perceptual dizziness (PPPD) when *all* of the following criteria are met:
         (a) Symptoms (e.g., vertigo and imbalance) have existed for more than 6 months; *and*
         (b) The member has confirmed diagnosis of a vestibular disorder or has undergone ablative vestibular surgery; *and*
         (c) The member has failed medical management (e.g., use of vestibular suppressant medications to reduce symptoms).
2) Capital BCBS 2023
   a) Vestibular Rehabilitation Therapy for patients with vertigo, disequilibrium, and balance deficits may be considered medically necessary when all of the following criteria are met:
      i) The member has been diagnosed with a vestibular disorder or has undergone vestibular surgery (ablative); and
      ii) The member has failed medical management to reduce symptoms (i.e., canalith repositioning, medication).

Benign Paroxysmal Positional Vertigo

HERC staff summary:

Vertigo is a symptom caused by a broad variety of conditions. The current prioritization of vertiginous conditions (in the unfunded region) reflects the evidence of effectiveness or need for treatment of the large majority of conditions on that line.

Benign paroxysmal positioning vertigo (BPPV) may require one or more physical therapy visits for performance of the Epley maneuver or for fall prevention. There is good evidence that the Epley maneuver or other canalith repositioning techniques is beneficial and moderate to strong evidence that vestibular rehabilitation is beneficial for this condition. Expert groups recommend these interventions and major insurers cover this therapy for patients who have the condition for between 4 and 6 months. Expert groups do not recommend the use of medications to treat BPPV.

Five public comments were received, all from providers. All recommend coverage of PT/canalith repositioning procedures and all disagreed with the staff proposal to cover after a 4 month period of conservative therapy. Staff have clarified in the proposed guideline that up to 2 visits of PT or ENT care for canalith repositioning is available without any conservative therapy. Staff further clarified with the commenters that the concern with the 4 month period of conservative therapy is for both canalith repositioning and vestibular rehabilitation.

HERC staff initially recommended adding coverage for vestibular rehabilitation for patients with BPPV who have not had symptom resolution after 4 months (consistent with private payer policies) and who are at high risk of falls (consistent with current coverage of fall risk in GN106). Based on public comments, VBBS/HERC can discuss whether to remove the requirement for 4 months of conservative care prior to vestibular rehabilitation.

Additionally, the preventive services guideline has two entries about fall prevention that need clarification. It appears that the fall prevention services have all been added to line 3 and the entry about line 290 is no longer needed.

HERC staff recommendations:

1) Add ICD-10-CM H81.1 family (Benign paroxysmal vertigo) to line 290 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
    a. Will pair with CPT 95992 (Repositioning exercises of head for treatment of dizziness, each day) and CPT 97112 (Therapy procedure to re-educate brain-to-nerve-to-muscle function, each 15 minutes)
2) Add HCPCS S9476 (Vestibular rehabilitation program, non-physician provider, per diem) to line 290
3) Add a new guideline to lines 290 and 505 as shown below
    a. Discuss whether the highlighted language should be removed.
4) Modify GN106 as shown below

GUIDELINE NOTE XXX TREATMENT OF BENIGN PAROXYSMAL POSITIONING VERTIGO

Lines 290,505

Canalith repositioning maneuvers (CPT 95992) is included on line 290 for treatment of benign paroxysmal positioning vertigo (BPPV) for up to 2 visits per year for education by a physical therapist or an otolaryngologist, with no requirement for conservative therapy or a waiting period prior to these visits.

Benign Paroxysmal Positional Vertigo

Vestibular rehabilitation (CPT 97112 and HCPCS S9476) is included on line 290 only when ALL of the following criteria are met:

1) The patient has benign paroxysmal positioning vertigo (BPPV); AND
2) The patient has symptoms (for example, vertigo and imbalance) for more than 4 months; AND
3) The patient is aged 65 or older OR the patient is under age 65 and is at increased risk of falls.

Otherwise, vestibular rehabilitation is included on line 505.

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

E) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2022.
   1) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations/
      a) ~~Treatment of falls prevention with exercise interventions is included on Line 292.~~
   2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

F) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
   1) http://brightfutures.aap.org. Periodicity schedule available at https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf
      a) Bright Futures is the periodicity schedule for screening for EPSDT for the Oregon Health Plan.
   2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.

G) Health Resources **and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines (revised** January 2022). Available at https://www.hrsa.gov/womens-guidelines as of July 28, 2022.

H) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf
   1) COVID-19 vaccines are intended to be included on this line even if the specific administration code(s) do not yet appear on the line when the vaccine has both 1) FDA approval or FDA emergency use authorization (EUA) and 2) ACIP recommendation.
   2) Other ACIP recommended vaccines not on the routine vaccine schedule are included on Line 3 when administered according to recommendations specified in the Morbidity and Mortality Weekly Review (MMWR) as required by federal law: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html (retrieved 8/8/2023).

Colorectal cancer screening is included on Line 3 for average-risk adults aged 45 to 75, using one of the following screening programs:

Benign Paroxysmal Positional Vertigo

B) Colonoscopy every 10 years
C) Flexible sigmoidoscopy every 5 years
D) Fecal immunochemical test (FIT) every year
E) Guaiac-based fecal occult blood test (gFOBT) every year

CT colonography (CPT 74263), FIT-DNA (CPT 81528) and mSEPT9 (HCPCS G0327) are included on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS.

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered after informed decision making between patients and clinicians which includes consideration of the patient's overall health, prior screening history, and preferences.

Supervised evidence-based exercise programs for fall prevention for persons aged 65 or older OR younger patients who are at increased risk of falls are included on Line 3 using CPT 98961 or 98962 or HCPCS S9451. HCPCS S9451 is only included on Line 3 for the provision of supervised exercise therapy for fall prevention. Programs should be culturally tailored/culturally appropriate when feasible.

Note: CPT 96110 (Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument) can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.

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

Benign Paroxysmal Positional Vertigo

Disposition of Public Comments

Table of Contents

Discussion Table

IDs/#s	Summary of Issue	HERC Staff Response
All	Support coverage of canalith repositioning therapy. Disagree with staff recommendation to cover after 4 months of conservative therapy.	HERC staff have modified the proposed guideline to clarify that canalith repositioning PT or ENT visits do not require any waiting period or conservative therapy. The 4-month waiting period applies to vestibular rehabilitation only, consistent with other payers. HERC staff have added an option that would not require 4 months of conservative therapy prior to vestibular rehabilitation for discussion by VBBS.

Commenters

Identification	Stakeholder
A	Eric T. Carpenter, Doctor of Physical Therapy – OHP provider *[Submitted December 18, 2023]*
B	Matthew D Proctor MD – OHP provider *[Submitted December 17, 2023]*
C	Lindsay Lederer, Director, Physical Medicine and Rehabilitation Adventist Health *[Submitted December 15, 2023]*
D	Andrew Roof, MPT, OCS – OHP provider *[Submitted December 20, 2023]*
E	Anna Saltonstall, PT, DPT – OHP provider *[Submitted December 20, 2023]*

Benign Paroxysmal Positional Vertigo

Disposition of Public Comments

Public Comments

ID/#	Comment	Disposition
A	As a physical therapist with a focus on vestibular disorders I was amazed to see that BPPV is either not an approved condition for which a Canalith Repositioning Maneuver is deemed appropriate for or is only deemed indicated after 4 months of suffering with the condition. It has been well established that a simple canalith repositioning maneuver is an effective treatment immediately after onset of the condition and can provide relief with an efficacy of around 80%. Furthermore, to wait for 4 months seems cruel to a patient with often debilitating symptoms and most studies find that BPPV only spontaneously resolves in 1/3 to 1/2 of patients by 1 year. Denying and/or delaying access to care for patients with BPPV seems both arbitrary and cruel.	Thank you for your comments. The proposal for a 4 month waiting period is similar to private payer policies. The 4 month period of conservative therapy is only required prior to vestibular rehabilitation. One PT or ENT visit for canalith repositioning is covered without a waiting period. HERC staff have added an option without the 4 month conservative care requirement prior to vestibular rehabilitation in the proposed guideline, allowing care for patients over age 65 or at high risk of falls to access vestibular rehabilitation in a more timely fashion. The submitted article (Alvarez-Morujo 2019) provides data on the natural history of BPPV that indicates that approximately 50% of patients had spontaneous resolution of BPPV symptoms, but required up to 7 months for this resolution. “Spontaneous resolution of BPPV occurs in 18% of patients during the first month after the appearance of the first symptoms of the disease and in 51% after the first year, but it is unusual for spontaneous resolution to occur after this point.”

Benign Paroxysmal Positional Vertigo

Disposition of Public Comments

ID/#	Comment	Disposition
B	The canalolith repositioning (Epley) manuever is highly effective for treating this debilitating and common condition; providing immediate relief, often with only a single visit (85-90% of the time). While there are home remedies/maneuvers, studies (and my personal experience as an otolaryngologist) suggest that procedures performed by physical therapists work better and the results are more durable (less likely to recur). While it is true that over time the symptoms can improve on their own, this can take months and the patients are often miserable while they wait. Often they are managed by vestibular suppressants which, while they take the edge off, actually decrease the body's ability to adjust/recover. The 4 month waiting period thus seems unkind at best. Since it is an easy diagnosis to make and there is a quick and reliable "fix", I would suggest eliminating the time requirement.	*Thank you for your comments*. The submitted article is already included in the meeting materials. See the response above for commenter A
C	I'm wondering why we would consider waiting for 4 months to utilize this intervention that has promise to work so quickly for BPPV diagnoses? As we have experienced and as per the American Academy of Otolaryngology/Head Neck Surgery Clinical Indicators, most patients see improvement or resolution with 1 treatment. Some will require two or more or need to move on to vestibular rehabilitation. In response to your recommendation, I would like to suggest limiting the number of approved procedures vs a waiting period of 4 months for patient suffering from BPPV.	Thank you for your comment. See the response for commenter A above
D1	I heartily endorse approval of payment for canalith repositioning maneuvers for BPPV. However, there should be no need for symptoms to be present for four months. The Epley maneuver can be highly efficacious immediately after symptoms start. There is no logical reason for patients to wait four months to receive treatment for this highly impactful, yet easy to treat, disorder. Please	Thank you for your comment. See the response for commenter A above

Disposition of Public Comments

ID/#	Comment	Disposition
	change policy to allow OHA patients to access this treatment immediately with no requirements of a four month duration of symptoms.	
D2	As far as vestibular rehab goes, it is sometimes part of optimal treatment for patients, usually over 65, who already have some degree of balance deficit or fall risk, AND THEN develop BPPV. The canalith repositioning clears the BPPV up, but often the patients are left with some residual dysequilibrium for days or weeks. If we can re-train the vestibular system ASAP, we can decrease risk of falls and improve QOL. In summary, I see no rationale for requiring 4 months of symptoms before permitting vestibular rehab. That policy just prolongs suffering from a treatable condition.	Thank you for your comment. See the response for commenter A above.
E	The testimony submitted by Lindsay Lederer is accurate, evidence based and follows best practice guidelines. Physical therapy is the standard treatment for BPPV and is highly effective.	Thank you for your comment. The proposal will allow PT for treatment of BPPV.

References Provided by Commenters

ID	References
A	Alvarez-Morujo et al. Probable benign paroxysmal positional vertigo, spontaneously resolved: Incidence in medical practice, patients' characteristics and the natural course. J Otol. 2019 Sep; 14(3): 111–116.
B	Bhattacharyya et al 2017. Clinical Practice Guideline: Benign Paryoxysmal Positional Vertigo (Update). Otolaryngology-Head and Neck Surgery 2017, Vol 156 (35) S1-S47
C	None submitted
D	None submitted
E	None submitted

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Vestibular rehabilitation for unilateral peripheral vestibular dysfunction (Review)

McDonnell MN, Hillier SL

McDonnell MN, Hillier SL.
Vestibular rehabilitation for unilateral peripheral vestibular dysfunction.
Cochrane Database of Systematic Reviews 2015, Issue 1. Art. No.: CD005397.
DOI: 10.1002/14651858.CD005397.pub4.

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[Intervention Review]

Vestibular rehabilitation for unilateral peripheral vestibular dysfunction

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ABSTRACT

Background

This is an update of a Cochrane review first published in *The Cochrane Library* in Issue 4, 2007 and previously updated in 2011.

Unilateral peripheral vestibular dysfunction (UPVD) can occur as a result of disease, trauma or postoperatively. The dysfunction is characterised by complaints of dizziness, visual or gaze disturbances and balance impairment. Current management includes medication, physical manoeuvres and exercise regimes, the latter known collectively as vestibular rehabilitation.

Objectives

To assess the effectiveness of vestibular rehabilitation in the adult, community-dwelling population of people with symptomatic unilateral peripheral vestibular dysfunction.

Search methods

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; ISRCTN and additional sources for published and unpublished trials. The most recent search was 18 January 2014.

Selection criteria

Randomised controlled trials of adults living in the community, diagnosed with symptomatic unilateral peripheral vestibular dysfunction. We sought comparisons of vestibular rehabilitation versus control (e.g. placebo), other treatment (non-vestibular rehabilitation, e.g. pharmacological) or another form of vestibular rehabilitation. Our primary outcome measure was change in the specified symptomatology (for example, proportion with dizziness resolved, frequency or severity of dizziness). Secondary outcomes were measures of function, quality of life and/or measure(s) of physiological status, where reproducibility has been confirmed and shown to be relevant or related to health status (for example, posturography), and adverse effects

Data collection and analysis

We used the standard methodological procedures expected by The Cochrane Collaboration.

Main results

We included 39 studies involving 2441 participants with unilateral peripheral vestibular disorders in the review. Trials addressed the effectiveness of vestibular rehabilitation against control/sham interventions, medical interventions or other forms of vestibular rehabilitation. Non-blinding of outcome assessors and selective reporting were threats that may have biased the results in 25% of studies, but otherwise there was a low risk of selection or attrition bias.

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Individual and pooled analyses of the primary outcome, frequency of dizziness, showed a statistically significant effect in favour of vestibular rehabilitation over control or no intervention (odds ratio (OR) 2.67, 95% confidence interval (CI) 1.85 to 3.86; four studies, 565 participants). Secondary outcomes measures related to levels of activity or participation measured, for example, with the Dizziness Handicap Inventory, which also showed a strong trend towards significant differences between the groups (standardised mean difference (SMD) -0.83, 95% CI -1.02 to -0.64). The exception to this was when movement-based vestibular rehabilitation was compared to physical manoeuvres for benign paroxysmal positional vertigo (BPPV), where the latter was shown to be superior in cure rate in the short term (OR 0.19, 95% CI 0.07 to 0.49). There were no reported adverse effects.

Authors' conclusions

There is moderate to strong evidence that vestibular rehabilitation is a safe, effective management for unilateral peripheral vestibular dysfunction, based on a number of high-quality randomised controlled trials. There is moderate evidence that vestibular rehabilitation resolves symptoms and improves functioning in the medium term. However, there is evidence that for the specific diagnostic group of BPPV, physical (repositioning) manoeuvres are more effective in the short term than exercise-based vestibular rehabilitation; although a combination of the two is effective for longer-term functional recovery. There is insufficient evidence to discriminate between differing forms of vestibular rehabilitation.

PLAIN LANGUAGE SUMMARY

Vestibular rehabilitation to improve dizziness, balance and mobility in patients with unilateral peripheral vestibular dysfunction

Background

People with vestibular problems often experience dizziness and trouble with vision, balance or mobility. The vestibular disorders that are called unilateral and peripheral (UPVD) are those that affect one side of the vestibular system (unilateral) and only the portion of the system that is outside of the brain (peripheral - part of the inner ear). Examples of these disorders include benign paroxysmal positional vertigo (BPPV), vestibular neuritis, labyrinthitis, one-sided Ménière's disease or vestibular problems following surgical procedures such as labyrinthectomy or removal of an acoustic neuroma. Vestibular rehabilitation for these disorders is becoming increasingly used and involves various movement-based regimes. Components of vestibular rehabilitation may involve learning to bring on the symptoms to 'desensitise' the vestibular system, learning to co-ordinate eye and head movements, improving balance and walking skills, and learning about the condition and how to cope or become more active.

Study characteristics

We found 39 randomised controlled trials (involving 2441 participants) that investigated the use of vestibular rehabilitation in this group of disorders. All studies used a form of vestibular rehabilitation and involved adults who lived in the community with symptomatic, confirmed UPVD. The studies were varied in that they compared vestibular rehabilitation with other forms of management (for example, medication, usual care or passive manoeuvres), with control or placebo interventions or with other forms of vestibular rehabilitation. Another source of variation between studies was the use of different outcome measures (for example, reports of dizziness, improvements in balance, vision or walking, or ability to participate in daily life).

Key results

Due to the variation between studies, only limited pooling (combining) of data was possible. The results of four studies could be combined, which demonstrated that vestibular rehabilitation was more effective than control or sham interventions in improving subjective reports of dizziness, and in improving participation in life roles. Two studies gave a combined result in favour of vestibular rehabilitation for improving walking. Other single studies all found in favour of vestibular rehabilitation for improvements in areas such as balance, vision and activities of daily living. The exception to these findings was for the specific group of people with BPPV, where comparisons of vestibular rehabilitation with specific physical repositioning manoeuvres showed that these manoeuvres were more effective in dizziness symptom reduction, particularly in the short term. However, other studies demonstrated that combining the manoeuvres with vestibular rehabilitation was effective in improving functional recovery in the longer term. There were no reports of adverse effects following any vestibular rehabilitation. In the studies with a follow-up assessment (3 to 12 months) positive effects were maintained. There was no evidence that one form of vestibular rehabilitation is superior to another. There is a growing and consistent body of evidence to support the use of vestibular rehabilitation for people with dizziness and functional loss as a result of UPVD.

Quality of the evidence

The studies were generally of moderate to high quality but were varied in their methods. This evidence is up to date to 18 January 2014.

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The Epley (canalith repositioning) manoeuvre for benign paroxysmal positional vertigo (Review)

Hilton MP, Pinder DK

Hilton MP, Pinder DK.
The Epley (canalith repositioning) manoeuvre for benign paroxysmal positional vertigo.
Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD003162.
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[Intervention Review]

The Epley (canalith repositioning) manoeuvre for benign paroxysmal positional vertigo

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ABSTRACT

Background

This is an update of a Cochrane Review first published in *The Cochrane Library* in Issue 1, 2002 and previously updated in 2004 and 2007.

Benign paroxysmal positional vertigo (BPPV) is a syndrome characterised by short-lived episodes of vertigo in association with rapid changes in head position. It is a common cause of vertigo presenting to primary care and specialist otolaryngology clinics. Current treatment approaches include rehabilitative exercises and physical manoeuvres, including the Epley manoeuvre.

Objectives

To assess the effectiveness of the Epley manoeuvre for posterior canal BPPV.

Search methods

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; CENTRAL; PubMed; EMBASE; CINAHL; Web of Science; Cambridge Scientific Abstracts; ICTRP and additional sources for published and unpublished trials. The date of the most recent search was 23 January 2014.

Selection criteria

Randomised controlled trials of the Epley manoeuvre versus placebo, no treatment or other active treatment for adults diagnosed with posterior canal BPPV (including a positive Dix-Hallpike test). The primary outcome of interest was complete resolution of vertigo symptoms. Secondary outcomes were conversion of a 'positive' Dix-Hallpike test to a 'negative' Dix-Hallpike test and adverse effects of treatment.

Data collection and analysis

We used the standard methodological procedures expected by The Cochrane Collaboration.

Main results

We included 11 trials in the review with a total of 745 patients.

Five studies compared the efficacy of the Epley manoeuvre against a sham manoeuvre, three against other particle repositioning manoeuvres (Semont, Brandt-Daroff and Gans) and three against a control (no treatment, medication only, postural restriction). Patients were treated in hospital otolaryngology departments in eight studies and family practices in two studies. All patients were adults aged 18 to 90 years old, with a sex ratio of 1:1.5 male to female.

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There was a low risk of overall bias in the studies included. All studies were randomised with six applying sealed envelope or external allocation techniques. Eight of the trials blinded the assessors to the participants' treatment group and data on all outcomes for all participants were reported in eight of the 11 studies.

Complete resolution of vertigo

Complete resolution of vertigo occurred significantly more often in the Epley treatment group when compared to a sham manoeuvre or control (odds ratio (OR) 4.42, 95% confidence interval (CI) 2.62 to 7.44; five studies, 273 participants); the proportion of patients resolving increased from 21% to 56%. None of the trials comparing Epley versus other particle repositioning manoeuvres reported vertigo resolution as an outcome.

Conversion of Dix-Hallpike positional test result from positive to negative

Conversion from a positive to a negative Dix-Hallpike test significantly favoured the Epley treatment group when compared to a sham manoeuvre or control (OR 9.62, 95% CI 6.0 to 15.42; eight studies, 507 participants). There was no difference when comparing the Epley with the Semont manoeuvre (two studies, 117 participants) or the Epley with the Gans manoeuvre (one study, 58 participants). In one study a single Epley treatment was more effective than a week of three times daily Brandt-Daroff exercises (OR 12.38, 95% CI 4.32 to 35.47; 81 participants).

Adverse effects

Adverse effects were infrequently reported. There were no *serious* adverse effects of treatment. Rates of nausea during the repositioning manoeuvre varied from 16.7% to 32%. Some patients were unable to tolerate the manoeuvres because of cervical spine problems.

Authors' conclusions

There is evidence that the Epley manoeuvre is a safe, effective treatment for posterior canal BPPV, based on the results of 11, mostly small, randomised controlled trials with relatively short follow-up. There is a high recurrence rate of BPPV after treatment (36%). Outcomes for Epley manoeuvre treatment are comparable to treatment with Semont and Gans manoeuvres, but superior to Brandt-Daroff exercises.

PLAIN LANGUAGE SUMMARY

The Epley manoeuvre for benign paroxysmal positional vertigo (BPPV)

Background

Benign paroxysmal positional vertigo (BPPV) is caused by a rapid change in head movement. The person feels they or their surroundings are moving or rotating. Common causes are head trauma or ear infection. BPPV can be caused by debris in the semicircular canal of the ear, which continues to move after the head has stopped moving. This causes a sensation of ongoing movement that conflicts with other sensory information. The Epley manoeuvre is a treatment that is performed by a doctor (or other health personnel with appropriate training, e.g. audiological scientist, physiotherapist) and involves a series of four movements of the head and body from sitting to lying, rolling over and back to sitting. It is understood to work by moving the canal debris out of the semicircular canal. This linked video demonstrates how the Epley manoeuvre is performed.

Study characteristics

We included 11 studies in the review, with a total of 745 participants. Five studies (334 patients) compared the efficacy of the Epley manoeuvre against a sham manoeuvre, three against other particle repositioning manoeuvres (Semont, Brandt-Daroff and Gans) and three with a control (no treatment, medication only, postural restriction). Patients were treated in hospital otolaryngology (ear, nose and throat) departments in eight studies and family practices in two studies. All patients were adults aged 18 to 90 years old, with a sex ratio of 1:1.5 male to female.

Key results

For resolution of vertigo the Epley manoeuvre was significantly more effective than a sham manoeuvre or control. None of the trials that compared Epley versus other particle repositioning manoeuvres reported vertigo resolution as an outcome.

When studies looked at the conversion from a positive to a negative Dix-Hallpike test (a test to diagnose BPPV) in the patients, the results significantly favoured the Epley treatment group when compared to a sham manoeuvre or control. There was no difference when Epley was compared with the Semont or Gans manoeuvre. In one study a single Epley treatment was more effective than a week of three times daily Brandt-Daroff exercises.

Adverse effects were not often reported. There were no serious adverse effects of treatment. Rates of nausea during the repositioning manoeuvre varied from 16.7% to 32%. Some patients were unable to tolerate the manoeuvres because of cervical spine (neck) problems.

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AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

Clinical Practice Guideline

Otolaryngology–Head and Neck Surgery
2017, Vol. 156(3S) S1–S47
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Clinical Practice Guideline: Benign Paroxysmal Positional Vertigo (Update)

Neil Bhattacharyya, MD[1], Samuel P. Gubbels, MD[2], Seth R. Schwartz, MD, MPH[3], Jonathan A. Edlow, MD[4], Hussam El-Kashlan, MD[5], Terry Fife, MD[6], Janene M. Holmberg, PT, DPT, NCS[7], Kathryn Mahoney[8], Deena B. Hollingsworth, MSN, FNP-BC[9], Richard Roberts, PhD[10], Michael D. Seidman, MD[11], Robert W. Prasaad Steiner, MD, PhD[12], Betty Tsai Do, MD[13], Courtney C. J. Voelker, MD, PhD[14], Richard W. Waguespack, MD[15], and Maureen D. Corrigan[16]

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. This update of a 2008 guideline from the American Academy of Otolaryngology—Head and Neck Surgery Foundation provides evidence-based recommendations to benign paroxysmal positional vertigo (BPPV), defined as a disorder of the inner ear characterized by repeated episodes of positional vertigo. Changes from the prior guideline include a consumer advocate added to the update group; new evidence from 2 clinical practice guidelines, 20 systematic reviews, and 27 randomized controlled trials; enhanced emphasis on patient education and shared decision making; a new algorithm to clarify action statement relationships; and new and expanded recommendations for the diagnosis and management of BPPV.

Purpose. The primary purposes of this guideline are to improve the quality of care and outcomes for BPPV by improving the accurate and efficient diagnosis of BPPV, reducing the inappropriate use of vestibular suppressant medications, decreasing the inappropriate use of ancillary testing such as radiographic imaging, and increasing the use of appropriate therapeutic repositioning maneuvers. The guideline is intended for all clinicians who are likely to diagnose and manage patients with BPPV, and it applies to any setting in which BPPV would be identified, monitored, or managed. The target patient for the guideline is aged ≥18 years with a suspected or potential diagnosis of BPPV. The primary outcome considered in this guideline is the resolution of the symptoms associated with BPPV. Secondary outcomes considered include an increased rate of accurate diagnoses of BPPV, a more efficient return to regular activities and work, decreased use of inappropriate medications and unnecessary diagnostic tests, reduction in recurrence of BPPV, and reduction in adverse events associated with undiagnosed or untreated BPPV. Other outcomes considered include minimizing costs in the diagnosis and treatment of BPPV, minimizing potentially unnecessary return physician visits, and maximizing the health-related quality of life of individuals afflicted with BPPV.

Action Statements. The update group made *strong recommendations* that clinicians should (1) diagnose posterior semicircular canal BPPV when vertigo associated with torsional, upbeating nystagmus is provoked by the Dix-Hallpike maneuver, performed by bringing the patient from an upright to supine position with the head turned 45° to one side and neck extended 20° with the affected ear down, and (2) treat, or refer to a clinician who can treat, patients with posterior canal BPPV with a canalith repositioning procedure. The update group made a *strong recommendation against* postprocedural postural restrictions after canalith repositioning procedure for posterior canal BPPV. The update group made *recommendations* that the clinician should (1) perform, or refer to a clinician who can perform, a supine roll test to assess for lateral semicircular canal BPPV if the patient has a history compatible with BPPV and the Dix-Hallpike test exhibits horizontal or no nystagmus; (2) differentiate, or refer to a clinician who can differentiate, BPPV from other causes of imbalance, dizziness, and vertigo; (3) assess patients with BPPV for factors that modify management, including impaired mobility or balance, central nervous system disorders, a lack of home support, and/or increased risk for falling; (4) reassess patients within 1 month after an initial period of observation or treatment to document resolution or persistence of symptoms; (5) evaluate, or refer to a clinician who can evaluate, patients with persistent symptoms for unresolved BPPV and/or underlying peripheral vestibular or central nervous system disorders; and (6) educate patients regarding the impact of BPPV on their safety, the potential for disease recurrence, and the importance of follow-up. The update group made *recommendations against* (1) radiographic imaging for a patient who meets diagnostic criteria for BPPV in

the absence of additional signs and/or symptoms inconsistent with BPPV that warrant imaging, (2) vestibular testing for a patient who meets diagnostic criteria for BPPV in the absence of additional vestibular signs and/or symptoms inconsistent with BPPV that warrant testing, and (3) routinely treating BPPV with vestibular suppressant medications such as antihistamines and/or benzodiazepines. The guideline update group provided the *options* that clinicians may offer (1) observation with follow-up as initial management for patients with BPPV and (2) vestibular rehabilitation, either self-administered or with a clinician, in the treatment of BPPV.

Keywords

benign paroxysmal positional vertigo, BPPV

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Differences from Prior Guideline

This clinical practice guideline is as an update and replacement for an earlier guideline published in 2008 by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF).[1] An update was necessitated by new primary studies and systematic reviews that might suggest a need for modifying clinically important recommendations. Changes in content and methodology from the prior guideline include the following:

- Addition of a patient advocate to the guideline development group
- New evidence from 2 clinical practice guidelines, 20 systematic reviews, and 27 randomized controlled trials (RCTs)
- Emphasis on patient education and shared decision making
- Expanded action statement profiles to explicitly state quality improvement opportunities, confidence in the evidence, intentional vagueness, and differences of opinion
- Enhanced external review process to include public comment and journal peer review
- New algorithm to clarify decision making and action statement relationships
- New recommendation regarding canalith repositioning postprocedural restrictions
- Expansion of the recommendations regarding radiographic and vestibular testing
- Removal of the "no recommendation" for audiometric testing
- Addition of a diagnostic and treatment visual algorithm

Introduction

A primary complaint of dizziness accounts for 5.6 million clinic visits in the United States per year, and between 17% and 42% of patients with vertigo ultimately receive a diagnosis of benign paroxysmal positional vertigo (BPPV).[2-4] BPPV is a form of positional vertigo.

- *Vertigo* is defined as an illusory sensation of motion of either the self or the surroundings in the absence of true motion.
- Positional vertigo is defined as a spinning sensation produced by changes in head position relative to gravity.
- BPPV is defined as a disorder of the inner ear characterized by repeated episodes of positional vertigo (**Table 1**).

Traditionally, the terms "benign" and "paroxysmal" have been used to characterize this particular form of positional vertigo. In this context, the descriptor *benign* historically implies that BPPV was a form of positional vertigo not due to any serious central nervous system (CNS) disorder and that there was an overall favorable prognosis for recovery.[5] This favorable prognosis is based in part on the fact that BPPV can recover spontaneously in approximately 20% of patients by 1 month of follow-up and up to 50% at 3 months.[6,7] However, the clinical and quality-of-life impacts of undiagnosed and untreated BPPV may be far from "benign," as patients with BPPV are at increased risk for falls and impairment in the performance of daily activities.[8]

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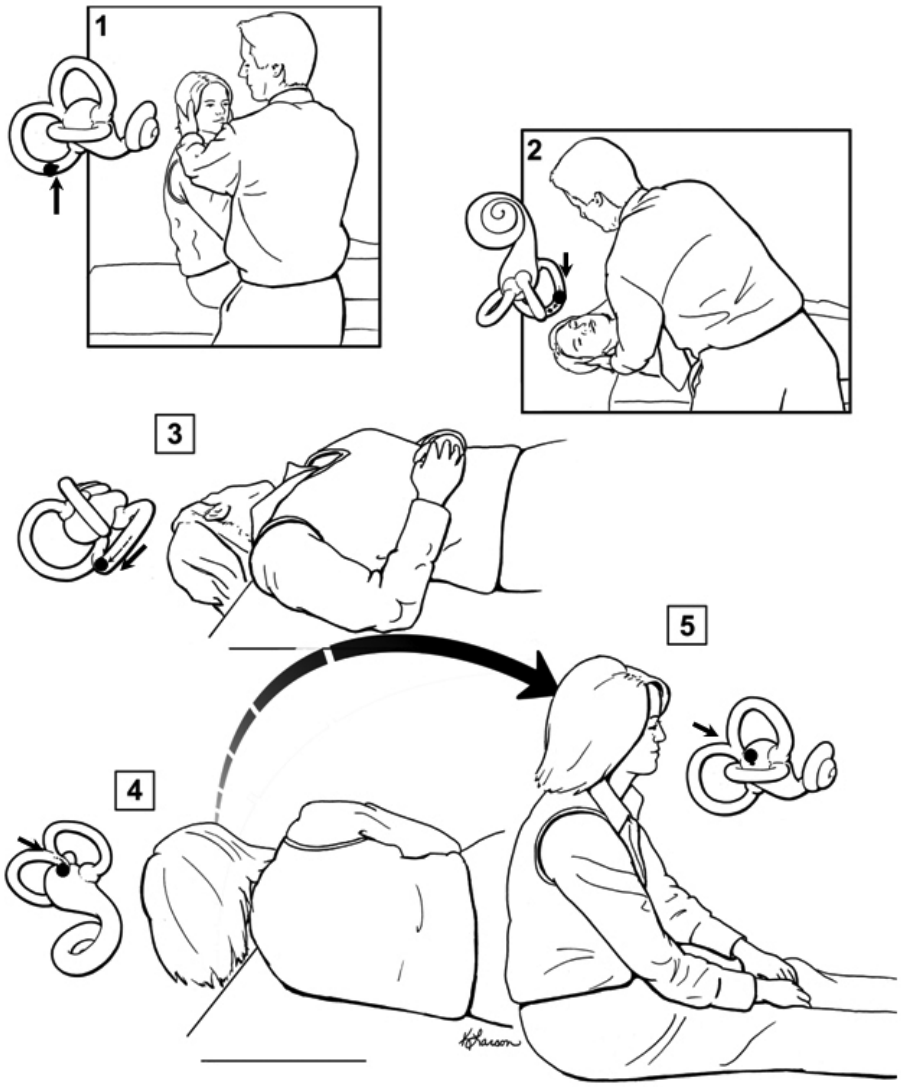
Figure. Canalith repositioning procedure for right-sided benign paroxysmal positional vertigo.



Steps 1 and 2 are identical to the Dix–Hallpike maneuver. The patient is held in the right head hanging position (Step 2) for 20 to 30 seconds, and then in Step 3 the head is turned 90 degrees toward the unaffected side. Step 3 is held for 20 to 30 seconds before turning the head another 90 degrees (Step 4) so the head is nearly in the face-down position. Step 4 is held for 20 to 30 seconds, and then the patient is brought to the sitting up position. The movement of the canalith material within the labyrinth is depicted with each step, showing how canaliths are moved from the semicircular canal to the vestibule. Although it is advisable for the examiner to guide the patient through these steps, it is the patient's head position that is the key to a successful treatment. (Figure from Fife, et al. Neurology 2008;70:2067-74)

To view a video demonstration visit: *http://www.neurology.org/cgi/content/full/70/22/2067/DC2*

THE VALUE OF THE CANALITH REPOSITIONING MANEUVER

Evidence of Effectiveness

Systematic reviews and Meta-analyses of Randomized Controlled Trials CRP has a very high level of evidence of effectiveness. CRP has been tested in numerous randomized placebo (i.e., sham procedures) controlled trials. Trial quality has been rigorously scrutinized on separate occasions by the Cochrane Collaboration,[2] the American Academy of Neurology Quality Standards Subcommittee,[9] a multidisciplinary guideline development panel chosen by the American Academy of Otolaryngology – Head and Neck Surgery Foundation,[10] and other independent groups.[11,12] The summary results of all the valid randomized controlled trials indicates that CRP has a large effect size in treating patients with BPPV. In these studies, 61-80% of patients treated with CRP had resolution of BPPV compared with only 10-20% of patients in the control groups.[9] These effect sizes translate in to a "number needed to treat" (NNT) of 1.43 to 2.44. The NNT is a statistical measure that indicates the number of patients that had to have treatment to achieve the beneficial outcome in one patient. Thus, approximately 2 patients with BPPV require treatment with CRP to eliminate the symptoms in 1 patient; this is among the largest effects achievable in clinical medicine particularly since the outcome considered was elimination of symptoms as opposed to only an improvement in symptoms. For comparison, the NNT to achieve 50% pain relief using pregabalin in fibromyalgia patients is 7.1 to 21.0.[13]

Importantly, reviews have also determined that CRP is not associated with adverse events.[2,9,10]

Guideline Statements

Recent formal guideline statements have been published in support of CRP for the treatment of BPPV.[9,10] Based on findings from systematic reviews of the literature, the American Academy of Neurology concluded that CRP is "an established effective and safe therapy that should be offered to patients of all ages with posterior semicircular canal BPPV (Level A recommendation)."[9]

In addition, the American Academy of Otolaryngology – Head and Neck Surgery Foundation, made a recommendation that "clinicians should treat patients with posterior canal BPPV with a particle repositioning maneuver."[10]

Benefit of CRP on Functional Outcomes

Though the disorder is labeled as "benign" it does have a substantial impact on the patient's life and also healthcare utilization. Patients with BPPV report that the symptoms are very disturbing and often alarming, leading to an interruption in daily activities and lost days at work.[4, 6] Most patients with BPPV present to a health care provider and many present to the emergency room.[4, 7] Older people with BPPV have a high incidence of falls, depression , and impaired daily activities.[14]

Impact of CRP on Healthcare Utilization

Patients with BPPV often seek help from various arms of the health care system.[4, 6, 7] Large proportions of these patients will undergo many unnecessary tests, including imaging studies.[4, 7, 15] There is evidence to believe that at the current time most patients with BPPV do not receive CRP treatment.[4, 6, 7, 16] The reason for the apparent underutilization of CRP, while uncertain, may include a lack of time, awareness or coverage of the procedure.

CRP AS AN OFFICE-BASED THERAPEUTIC PROCEDURE

CRP is unique as a procedure because it typically does not require any special tools or equipment, and is non-invasive. The procedure requires only an examination table, of the type typical for a physician examination room. Following an accurate diagnosis, established by the history and examination, the physician determines the location of the canaliths and then guides the patient through the positions.

There are other office based therapeutic procedures that also do not require special tools or equipment, and are non-invasive. These are performed after a clinical evaluation and diagnosis. For instance, a closed reduction of a dislocated shoulder or elbow require an analogous effort, namely that of a cognitive diagnostic process followed by a distinct therapeutic maneuver. The diagnostic and therapeutic units have long been recognized and codified as separate and distinct procedures, but performed on the same date by the same provider.

APPROPRIATE PATIENT SELECTION FOR CRP

A key aspect to the effective use of CRT is patient selection. BPPV is by far the most common cause of attacks of positional vertigo. However, in rare cases patients with positional vertigo attacks can have a structural brain abnormality (e.g., Chiari malformation, or mass lesion). Patients with structural brain lesions can typically be identified by other abnormalities on the examination or a pattern of nystagmus that is not consistent with BPPV. Some patients with dizziness caused by a migraine equivalent (i.e., so-called "vestibular migraine") can have prominent positional components to their symptoms, but again these patients typically do not have the key nystagmus patterns of BPPV.

CRP is also not effective in patients with other causes of dizziness or vertigo such as vestibular neuritis, Meniere's disease, orthostatic hypotension, or panic attacks.

Therefore, proper and effective use of the CRP requires appropriate patient selection, clear identification of the affected side, proper positioning of the patient's head during the procedure, and waiting the appropriate intervals in-between the steps of the procedure.

Indications:

1. Recurrent episodes of positionally triggered dizziness characteristic of BPPV.
2. Positive finding of symptoms and characteristic nystagmus with positional testing (e.g., the Dix-Hallpike test).

Limitations:

1. Use of CRP in patients not having BBPV (incorrect diagnosis).
2. Incorrect performance of the individual components of CRP.