Health Evidence Review Commission's Value-based Benefits Subcommittee

March 10, 2022

8:00 AM - 1:00 PM

Virtual Meeting

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Section 1.0

Call to Order

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE
3/10/2022
8:00am - 1:00pm
Online Meeting
All times are approximate

Note: public testimony on specific agenda topics will be taken at the time that agenda item is discussed

I. Call to Order, Roll Call, Orientation Statement

II. Approval of Minutes – Kevin Olson **8:00 AM**

III. Staff report – Ariel Smits **8:05 AM**
- **A.** Errata
- **B.** Pneumococcal vaccine codes
- **C.** Below the line review

IV. Straightforward/Consent agenda – Ariel Smits **8:15 AM**
- **A.** Consent table
- **B.** Straightforward guideline note changes
- **C.** Covid coding changes March 2022
- **D.** Newborn home visits
- **E.** Significant ligament and tendon injuries coding corrections
- **F.** Intravascular lithotripsy 2022 coding update
- **G.** Pica in adults
- **H.** Topics not discussed in past 5 years with no changes recommended
    - A. Fusion for mid-foot arthritis

V. New discussion items **8:30 AM**
- **A.** Chemodenervation (botulinum toxin) guideline update
- **B.** Enteropathic arthropathies
- **C.** Erythropoietin in chronic kidney disease
- **D.** Pelvic congestion syndrome

VI. Coverage guidance **9:00 AM**
- **A.** High-Frequency Chest Wall Oscillation Devices

VII. Break **10:00 AM**

VIII. New discussion items continued **10:10 AM**
- **A.** Platelet rich plasma
- **B.** Breast reconstruction after lumpectomy
- **C.** Breast MRI guidelines

- **D.** Actinic keratoses
- **E.** Radiofrequency ablation and cryotherapy for select renal cell cancers
- **F.** Clarification of the lower urinary tract symptoms (LUTS) guideline
- **G.** Sensory integration therapy
- **H.** Congenital foot deformity code review
- **I.** Gait analysis and surface electromyography

IX. Previously discussed items **12:00 AM**

- **A.** Polydactyly clarification

X. 2024 Biennial Review **12:15 AM**

- **A.** Agenesis of lung
- **B.** Dorsal rhizotomy for spastic diplegic cerebral palsy

XI. Public comment **12:55 PM**

XII. Adjournment – Kevin Olson **1:00 PM**

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on November 18, 2021

For specific coding recommendations and guideline wording, please see the text of the 11/18/2021 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 1/1/22 Prioritized List unless otherwise noted)

- Add multiple new procedure codes for COVID-19 vaccines to the funded preventive services line
- Move the procedure code for expanded carrier genetic screening from an unfunded line and added to the Diagnostic Procedures File
- Add the procedure code for whole genome sequencing to the Diagnostic Procedures File
- Add the 2022 CPT, CDT, and HCPCS codes to various lines and files
- Move porcelain crowns from an unfunded to a funded line
- Make various coding changes to allow coverage of orthodontia for handicapping malocclusion, with an expected implementation date of 1/1/23.
- Add the procedure code for dental screening to the funded preventive services line
- Move the diagnosis code for nightmare disorder to a funded line from an unfunded line
- Add several procedure codes for substance use disorder treatment to the funded SUD line
- Move the diagnosis code for selective mutism to a funded line from an unfunded line. For the 1/1/24 Prioritized List, delete the previous selective mutism line
- Effective 1/1/24, delete the unfunded duplicate angioedema line
- Move the procedure code for cyanoacrylate vein ablation from an unfunded line to a funded line
- Make various straightforward coding changes

RECOMMENDED GUIDELINE CHANGES (changes to the 1/1/22 Prioritized List unless otherwise noted)

- Edit the prenatal and non-prenatal genetic testing guidelines to specify when expanded carrier screening is covered and when whole genome sequencing is covered
- Add a new guideline regarding decoronation or submergence of an erupted tooth
- Edit the dental medicament guideline to allow use of a wider variety of products
- Edit the orthodontia guideline to allow coverage of orthodontia for handicapping malocclusion, with an expected implementation date of 1/1/23.
- Make multiple changes to the guideline for services with lack of effectiveness for 2022 CPT codes
- Make changes to several guidelines to include 2022 CPT codes
- Add a new guideline regarding peroral endoscopic myotomy
- Edit the statement of intent regarding the intended use of the Prioritized List to add effects on childhood growth and development as a possible reason for allowing coverage of a procedure in the unfunded region or that does not pair with a diagnosis, or allow use of medications or other Ancillary services
- Update the references to NCCN in 2 guidelines
- Make several straightforward guideline note changes

VALUE-BASED BENEFITS SUBCOMMITTEE
Online Meeting
November 18, 2021
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-chair; Kathryn Schabel, MD (arrived 8:30 AM); Brian Duty, MD; Adriane Irwin, PharmD; Regina Dehen, ND, LAc; Cris Pinzon, MPH, BSN, BS, RN (arrived 9 AM, left 11AM)

Members Absent: Mike Collins

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

Also Attending: Kaz Rafia, DMD, Diane Quiring and Sarah Wetherson (Oregon Health Authority); Gary Allen, DMD; Alyssa Franzen; Andrea Vannata; Ashley Arthur; Ashley Svenson; Chris Tanaka (DEXCOM); Christian Moller-Andersen (A Smile for Kids); Devki Nagar (Myriad); Alissa Doth (Medtronic); Elena Rivera; Haywood Brown, MD; Jeanne McLaws; Jen Lewis-Goff (Oregon Dental Association); John Fox, MD (Illumina); Matthew Jones; Karen Heller; Laura; Laura McKeane (AllCare CCO); Manu Chaudhry, DDS; Michelle Brandama; Mike Flanigan; Peggy Flanigan; msinnottl; Paulina Almaraz; Renee Doan (YCCO); Ruth Miles (Salem Health); Samantha Coover; Shelagh Baird; Susan Hahn; Taryn Couture; Taylor Kane (Remember The Girls); Alyssa Thiebaul; Tonya Clark; Van Bivens; Yael Weinstein.

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

  The meeting was called to order at 8:00 am and roll was called. A quorum of members was present at the meeting. Minutes from the 10/7/2021 VbBS meeting were reviewed and approved.

  Gingerich reviewed upcoming membership changes. Dr. Gary Allen's term will end December 31, 2021 and an oral surgeon, Dr. Stacy Geisler, will be replacing him. Dr. Allen was thanked for his service. There are other member changes that will be announced at HERC. Gingerich also reviewed the errata document.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) Add CPT 20680 (Removal of implant; deep (eg, buried wire, pin, screw, metal band, nail, rod or plate)) to line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
  2) Modify GN 101 as shown in Appendix A
  3) Modify GN 37 as shown in Appendix A

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

- **Topic: COVID-19 Coding Updates**

  Discussion: There was no discussion about the COVID-19 coding updates.

  Recommended Actions:
  1) The following CPT codes were added to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS:

0004A	Pfizer-Biontech Covid-19 Vaccine Administration – Booster
91307	Pfizer COVID-19 vaccine pediatric (age 5-11) dosage
0071A	Pfizer COVID-19 vaccine pediatric dosage 1ST dose
0072A	Pfizer COVID-19 vaccine pediatric dosage 2ND dose
91305	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) tris-sucrose formulation
0051A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation - First dose
0052A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation - Second dose
0053A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation – third dose
0054A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation – Booster
91306	Moderna Covid-19 Vaccine (Low Dose) –Booster dose
0064A	Moderna Covid-19 Vaccine (Low Dose) Administration – Booster dose
0034A	Janssen Covid-19 Vaccine (Low Dose) Administration - Booster dose

MOTION: To recommend the code changes as presented. CARRIES 5-0. *(Absent: Schabel, Pinzon)*

- **Topic: GAP Report—Expanded Carrier Screening**

  Discussion: Smits reviewed the summary document.

  Public testimony

  1) Peggy Flanigan, parent: Ms. Flanigan testified she is a carrier of the fragile X gene and was unaware of her carrier status when her daughter was born in the 1980s. Her daughter is also a carrier. There are effects for female carriers as well as for boys affected by fragile X. She wanted to bring awareness to screening for rare genetic disorders. She testified that discovering her carrier status influenced her decision to not have additional children.
  2) Taylor Kane, Executive Director of Remember the Girls: Ms. Kane testified she is a carrier of a rare genetic disorder. Knowledge of her carrier status has empowered her in terms of reproductive planning. She wanted to stress that learning of one's carrier status is not overwhelming, rather it is empowering.
  3) Ashley Svenson, genetic counselor with Myriad Genetics (manufacturer): Ms. Svenson expressed support for the proposed changes which align with ACMG's recommendation. Ms. Svenson said these changes will help to eliminate racial bias in testing.
  4) Yael Weinstein, genetic counselor in Springfield, Oregon: Ms. Weinstein testified that expanded carrier screening is the only approach that allows adequate screening for patients. Not using the expanded carrier screening approach gives the patient a false-negative result. In her experience, she educates couples on their results. She can offer consults by phone. In many cases, she sees patients who have only a partial carrier screening and then needs to do additional testing. Her clinic uses a panel of 176 genes. Many screens use 14-20 conditions. In her opinion, Oregon has the resources to offer and counsel for expanded carrier screening. 80% of children born with genetic conditions have no family history. She also noted that the labs have genetic counselors available to assist patients/families. She will send information on the specific panels she uses in her practice to HERC staff to distribute to members.
  5) Samantha Coover, parent: Ms. Coover testified she has a son with fragile X syndrome but she was never offered prenatal screening. Expanded carrier screening could have helped her by allowing her to get early interventions in place for her child from infancy.
  6) Mike Flanigan, parent: Mr. Flanigan testified that expanded carrier screening will reach so many more patients. Genetic counseling is now more available than ever due to telehealth and other advances developed during the pandemic.
  7) Haywood Brown, OB/GYN and Medical Director for ACCESS (carrier screening advocacy group): Dr. Brown testified that an expansion in screening is a very powerful tool. He agreed with the GAP recommendation and felt it is more equitable coverage.

The subcommittee members discussed that there is increased access to genetic counseling with telehealth. Hodges expressed concerns about large panels being marketed to providers that give results that are very difficult to interpret. She also expressed concern for the cost ($7,000 in some cases). She expressed concerns about families that decide to not have children due to a mutation that the medical community does not understand. She also expressed concern about how to operationalize the proposed guideline as it will be difficult for reviewers to determine if the panel being ordered meets the guideline criteria. Pinzon noted that genetic counselors should be involved in this testing, especially for larger panels. Olson noted that the guideline offers a path to coverage rather than a mandate for coverage. Pinzon suggested revisiting this topic and analyzing utilization of this technology in a year or so.

There was a suggestion to add reference to the 2021 ACMG guideline to the prenatal and non-prenatal guidelines which was accepted. HERC staff will consider additional edits to the guideline to specify which tables in the guideline should be included as a possible consent agenda item in the future.

Recommended Actions:

1) Remove CPT 81443 from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Remove the entry for CPT 81443 from Guideline Note 173 as shown in Appendix A
2) Advise HSD to add CPT 81443 to the Diagnostic Procedures File
3) Modify Diagnostic Guideline D1 and Diagnostic Guideline D17 as shown in Appendix A

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

- **Topic: GAP Report—Whole Genome Sequencing**

Discussion: Smits reviewed the summary document.

Public testimony

1) John Fox, pediatrician, former medical director of a Michigan state health plan in Michigan, and current employee of Illumina (manufacturer): Dr. Fox testified that there is a large unmet need in both the inpatient and outpatient setting. He said that whole exome is similar in cost to whole genome sequencing. Michigan found clinical utility in WGS as it changes management in 95% of patients as well as changes reproductive decisions. Without WGS, microarray testing is generally done first, which adds cost. Michigan decided to add coverage for WGS as it is overall less expensive. In his health plan, the cost of WGS was $5,100 versus $4,900 for whole exome sequencing.

Hodges noted that her CCO is approving this test by exception in complex cases. There was discussion about GAP wanting limited coverage as the medical community is just starting to understand the correct utilization for WGS.

Recommended Actions:

1) Remove CPT 81425-81427 (Genome sequence analysis) from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Delete the entry on CPT 81425-81427 from GN173 as shown in Appendix A
3) Advise HSD to add CPT 81425-81427 to DIAGNOSTIC PROCEDURES file
4) Modify Diagnostic Guideline D1 as shown in Appendix A

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

- **Topic: GAP Report—NCCN Reference Update**

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

Recommended Actions:

1) Modify Guideline Note 3 as shown in Appendix A
2) Modify Diagnostic Guideline D25 as shown in Appendix A

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

- **Topic: OHAP Report—Straightforward Items**

Discussion: There was no discussion about CDT code placement, porcelain crowns, or non-restorative caries treatment.

Recommended Actions:

1) Add a new guideline as shown in Appendix B
2) 2022 CDT code placement as shown in Appendix C
3) Add CDT D2740 (Crown - porcelain/ceramic) to line 469 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: ADVANCED RESTORATIVE (I.E., BASIC CROWNS)
    a. Remove CDT D2740 from line 592 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: ADVANCED RESTORATIVE-ELECTIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS
4) Modify GN91 as shown in Appendix A

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

- **Topic: OHAP Report—Handicapping Malocclusion**

Discussion: Smits reviewed the summary document. Allen echoed the concerns regarding implementation and cost but noted that these are beyond the HERC's purview. The index scoring requires a referral to an orthodontist for determination. The benefit would need to be coordinated between CCOs and DCOs for patients who need craniofacial surgery.

Public testimony

a) Christian Moller-Anderson, Executive Director for Smile for Kids (orthodontics non-profit): Mr. Moller-Anderson testified that state Medicaid programs are required to cover dental treatment, including handicapping malocclusion. There is a massive barrier to health for low income populations with non-coverage, which goes against OHA's triple aim. Without equitable access to orthodontic care, low income kids have deleterious health outcomes.
b) Manu Chaudhry, dentist and President of Capital Dental Care: Dr. Chaudhry testified that he initially supported moving this forward at the OHAP meeting. However, he has since revised his position on this issue. Dental disease that is caused by handicapping malocclusion is worsened when treatment is applied and there is a lack of pristine hygiene post-treatment. He recommended against adding this as a benefit currently and felt cost could be better spent to address and prevent inequities in oral health.

Allen asked Chaudhry about his experience with handicapping malocclusion under the California model, which Chaudhry helped to implement treatment during his time as a dental director in

California. Chaudhry noted that kids had high rates of no-shows and extended treatment, which resulted in extensive dental disease/tooth decay from the braces. Chaudhry also stated that orthodontists in Oregon may not take Medicaid and that the scoring systems are extremely subjective. Allen noted that there is an inadequate network of orthodontists and an inadequate infrastructure to administer this benefit. His recommendation is to implement this as a biennial review item which would start January 1, 2024.

Kaz Rafia, the OHA Dental Director, was invited to address the subcommittee regarding the challenges of implementation. Dr. Rafia noted that all other states have implemented this and their experiences can be useful for Oregon to find what works well and what does not. Handicapping malocclusion does not have adequate evidence that it increases dental decay. His recommendation is to move forward but he did not have a preference for implementation date.

Pinzon noted the psychological component to handicapping malocclusion that has not been addressed. Hodges noted that oral surgeons do not contract with CCOs in many cases, so there is a need for individual contracts when patients need them.

Recommended Actions (effective January 1, 2023:

1) Rename line 256 DEFORMITIES OF HEAD AND HANDICAPPING MALOCCLUSION Treatment CRANIOTOMY/CRANIECTOMY; ORTHODONTIA
2) Modify GN 169 as shown in Appendix A
3) Add the following ICD-10 codes to line 256

ICD-10 Code	Code description
K00.1	Supernumerary teeth
K00.2	Abnormalities of size and form of teeth
K00.5	Hereditary disturbances in tooth structure, not elsewhere classified
K00.6	Disturbances in tooth eruption
K00.9	Disorder of tooth development, unspecified
M26.211	Malocclusion, Angle's class I
M26.212	Malocclusion, Angle's class II
M26.213	Malocclusion, Angle's class II
M26.219	Malocclusion, Angle's class, unspecified
M26.220	Open anterior occlusal relationship
M26.221	Open posterior occlusal relationship
M26.23	Excessive horizontal overlap
M26.24	Reverse articulation
M26.25	Anomalies of interarch distance
M26.29	Other anomalies of dental arch relationship
M26.31	Crowding of fully erupted teeth
M26.33	Horizontal displacement of fully erupted tooth or teeth
M26.34	Vertical displacement of fully erupted tooth or teeth
M26.35	Rotation of fully erupted tooth or teeth
M26.36	Insufficient interocclusal distance of fully erupted teeth (ridge)
M26.37	Excessive interocclusal distance of fully erupted teeth
M26.4	Malocclusion, unspecified
M26.70	Unspecified alveolar anomaly
Z46.4	Encounter for fitting and adjustment of orthodontic device

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

- **Topic: OHAP Report—Dental Screening**

Discussion: Smits reviewed the summary document. Rafia noted that this service is essential to the primary care practice. Pinzon noted that as a nurse she routinely looks at the mouth and appreciates adding this code. Hodges noted that this code was used by some CCOs to encourage implementation and utilization of the First Tooth program and strongly recommended adding the code to line 3. Allen noted that this issue is neither controversial nor costly. He noted that CDT D0191 can be used by non-dental professionals using First Tooth and similar programs. He noted that this code could be used for mass screenings, which would be problematic. The DCOs wanted guardrails around use to prevent use in mass screenings. Hodges noted that this code is part of dental metrics.

Recommended Actions:

1) Add CDT D0190 (Screening of a patient) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

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

- **Topic: BHAP report**

Discussion: There was minimal discussion regarding any of the BHAP report items.

Recommended Actions:

1) Add ICD-10-CM F51.5 (Nightmare disorder) to Line 173 POSTTRAUMATIC STRESS DISORDER
    a. Remove ICD-10 F51.5 from line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA
2) Advise HSD to add H0022 (Alcohol and/or drug intervention service (planned facilitation)) to the DIAGNOSTIC PROCEDURE file
3) Advise HSD to add HCPCS H0043 (Supported housing, per diem) to the Excluded File
4) Add HCPCS H2032 (Activity therapy, per 15 min) to line 4 SUBSTANCE USE DISORDER
5) Add HCPCS H2036 (Alcohol and/or other drug treatment program, per diem) to line 4 SUBSTANCE USE DISORDER
6) For implementation January 1, 2022:
    a. Add ICD-10-CM F94.0 (Selective mutism) to Line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED
        i. Remove F94.0 from line 474 SELECTIVE MUTISM
    b. Strike through line 474 SELECTIVE MUTISM
7) For implementation January 1, 2024:
    a. Delete line 474 SELECTIVE MUTISM

MOTION: To recommend the code and line changes as presented. CARRIES 6-0. *(Absent: Pinzon)*

- **Topic: 2022 CPT and HCPCS code review**

Discussion: There was no discussion about any of the 2022 CPT or HCPCS code placements, except:

1) Peroral endoscopic myotomy (CPT 43497): Hodges requested a more specific guideline note, similar to the commercial guidelines reviewed. The subcommittee agreed to adopt the wording from the PacificSource policy as modified by HERC staff.

2) Rapid culture (CPT 87154): The group discussed briefly the possible utility of this test in reducing antibiotic use and resistance. The subcommittee elected to follow the staff recommendation of placement on line 662/GN173.

3) New vaccine codes (CPT 90626, 90627, 90671, 90677, 90758, 90759): Hodges expressed concern that these tests would not be visible to health plans and providers if placed on the Excluded file. Staff noted that these vaccines do not have evidence of ineffectiveness which would warrant placement on either line 502 or 662; however, they do not have ACIP approval and therefore cannot be covered. The best placement was determined to be the Excluded File. NOTE: The intent of the VBBS is that these codes be added to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS when/if they receive ACIP approval (other than the Ebola vaccine code which is a travel vaccine).

Recommended Actions:

1) Place the 2022 CPT codes as shown in Appendix C
2) Modify GN148 as shown in Appendix A
3) Modify GN173 as shown in Appendix A

4) Add HCPCS G0424 (Pulmonary rehab) to line 399 INFLUENZA, NOVEL RESPIRATORY VIRUSES
5) Adopt a new guideline as shown in appendix B
6) Modify Diagnostic Guideline D1 as shown in Appendix A
7) Modify Diagnostic Guideline D17 as shown in Appendix A
8) Place HCPCS C1832 (Autograft suspension, including cell processing and application, and all system components), C1833 (Monitor, cardiac, including intracardiac lead and all system components (implantable)) and G0465 (Autologous platelet rich plasma (prp) for diabetic chronic wounds/ulcers, using an fda-cleared device (includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment)) on line CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

NOTE: after the November 18, 2021 meeting, ACIP recommendations for coverage of PCV15 and PCV20 (CPT 90671 and 90677) were identified and per VBBS/HERC intent, these codes were added to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS for 1/1/22.

MOTION: To recommend the code placements, code changes, and guideline note changes as presented. CARRIES 6-0. *(Absent: Pinzon)*

- **Topic: Deletion of Duplicate Angioedema Line**

Discussion: There was no discussion about this topic.

Recommended Actions:

1) For the January 1, 2022 Prioritized List:
    a. Strike through line 487 ANGIOEDEMA
    b. Rename line 192 ~~HEREDITARY~~ ANGIOEDEMA
    c. Delete ICD-10-CM D81.810 (Biotinidase deficiency) from line 192 HEREDITARY ANGIOEDEMA
2) For the January 1, 2024 Prioritized List:
    a. Delete line 487

MOTION: To recommend the code and line title changes as presented. CARRIES 6-0. *(Absent: Pinzon)*

- **Topic: Platelet Rich Plasma**

Discussion: Tabled to the January 2022 VBBS meeting

- **Topic: Radiofrequency Ablation and Cryotherapy for Select Renal Cell Cancers**

Discussion: Tabled to the January 2022 VBBS meeting

- **Topic: Pelvic Congestion Syndrome**

Discussion: Tabled to the January 2022 VBBS meeting

- **Topic: Cyanoacrylate vein ablation**

  Discussion: Smits reviewed the summary document. There was a question about relative cost compared to other treatments. Hodges replied that this treatment is equivalent or less costly than current covered treatments for varicose veins.

  Public testimony

  1) Alissa Doth, representing Medtronic (manufacturer): Ms. Doth presented a slide set and agreed with staff recommendations. Her slide set included multiple private payers that are currently covering cyanoacrylate ablation. She also noted that in addition to the positive NICE review, there is a positive BCBS TEC review as well.

  Recommended Actions:

  1) Add CPT 36482-36483 (Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate)) to lines 379 CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS and 639 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION
  2) Delete CPT 36482-36483 from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
  3) Modify GN173 as shown in Appendix A

  MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0. *(Absent: Pinzon)*

- **Topic: Breast Reconstruction after Lumpectomy**

  Discussion: Tabled to the January 2022 VBBS meeting

- **Topic: Breast MRI Guidelines**

  Discussion: Tabled to the January 2022 VBBS meeting

- **Topic: Modify Statement of Intent 4 to add childhood growth and development**

  Discussion: Smits reviewed the summary document. Olson asked whether the guideline modifications would apply to a normal child when lack of treatment might result in harms to growth. Gingerich responded that it would apply but noted treatments were subject to medical necessity review. Gingerich gave the example of a non-sedating antihistamine for allergic rhinitis as now having a pathway to coverage if a sedating antihistamine impairs school function.

  Recommended Actions:

  1) Modify Statement of Intent 4 as shown in Appendix A

  MOTION: To recommend the guideline note changes as presented. CARRIES 6-0. *(Absent: Pinzon)*

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**
  - Platelet rich plasma
  - Radiofrequency ablation and cryotherapy for select renal cell cancers
  - Pelvic congestion syndrome
  - Breast reconstruction after lumpectomy
  - Breast MRI guidelines

- **Next meeting:**

  January 20, 2021; location and format TBD

- **Adjournment:**

  The meeting adjourned at 1:00 PM.

Appendix A

Revised Guideline Notes

STATEMENT OF INTENT 4: ROLE OF THE PRIORITIZED LIST IN COVERAGE

The Commission makes its prioritization decisions based on the best available published evidence about treatments for each condition. The Prioritized List prioritizes health services according to their importance for the population served and the legislature determines where to place the funding line on the Prioritized List.

The Commission recognizes that a condition and treatment pairing above the funding line does not necessarily mean that the service will be covered by the Oregon Health Plan (OHP). There may be other restrictions that apply, such as the service not being medically necessary or appropriate for an individual member. Likewise, the absence of a treatment and condition pairing above the funding line is not meant to be an absolute exclusion from coverage. Coverage may still be authorized under applicable federal and state laws, and Oregon's Medicaid State Plan and Waiver for an individual member. For example, OAR 410-141-~~0480~~ 3820 (Oregon Health Plan Benefit Package of Covered Services) includes services such as, but not limited to, the following:

- Diagnostic services, subject to the List's diagnostic guideline notes when applicable;
- Ancillary services (such as hospitalization, durable medical equipment, certain medications and anesthesia) provided for conditions appearing above the funding line, subject to the List's ancillary guideline notes when applicable; and
- Services paired with (or ancillary to) an unfunded condition which is causing or exacerbating a funded condition, the treatments for the funded condition are not working or contraindicated, and treatment of the unfunded condition would improve the outcome of treating the funded condition (the "Comorbidity Rule" OAR 410-141-3820 (10))
- Services paired with (or ancillary to) an unfunded condition (or otherwise not consistent with the funded region of the List) which, based on the child's individual circumstances, adversely affects the child's ability to grow, develop, or participate in school only when providing the unfunded service would improve the child's ability to grow, develop or participate in school.

In addition, Oregon's 1115(a) Waiver includes coverage for services such as, but not limited to:

- Services on unfunded lines for children from birth through age 1
- Services provided for a condition appearing in the funded region of the List in conjunction with federal requirements for Early and Periodic Screening, Diagnosis and Treatment (EPSDT) and Oregon's waiver

As a result, the Prioritized List must be used in conjunction with applicable OHP provisions found in federal and state laws, the State Plan and Waiver in coverage determination.

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, ~~and~~ 81229 and 81349, Cytogenomic constitutional microarray analysis: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
   2) CPT 81243, 81244, 81171,81172 Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
   3) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.

E) Related to preconception testing/carrier screening:
   1) The following tests are covered for a pregnant patient or patient contemplating pregnancy as well as the male reproductive partner:
      i. Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:
         1. Screening for cystic fibrosis carrier status (CPT 81220-81224)
         2. Screening for fragile X status (CPT 81243, 81244, 81171. 81172)
         3. Screening for spinal muscular atrophy (CPT 81329)
         4. 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.
         5. Screening for hemoglobinopathies (CPT 83020, 83021)
      i. 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:

1. the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater, AND
2. the included genes have well-defined phenotype, AND
3. 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
4. the included genes result in conditions have an onset early in life, AND
5. 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 HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN INTERVENTIONS

2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:

a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal

b) Diagnostic testing for cystic fibrosis (CF)

i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81221, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.

~~c) Carrier testing for cystic fibrosis~~

~~i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220-81224) is covered once in a lifetime.~~

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

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

f) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for

adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

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

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

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

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

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

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

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

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

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

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

Appendix A

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

r) CPT 81425-81427, whole genome sequencing: testing is only covered when:

i) ~~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

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

B) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.

C) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening

D) Validated questionnaire to assess genetic risk in all pregnant women

E) ~~Screening for hemoglobinopathies (CPT 83020, 83021)~~

F) Screening for aneuploidy with any of six screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, contingency, and cell free fetal DNA testing] (CPT 76813, 76814, 81508, ~~-~~81510, 81511, 81420, 81507, 81512, 82105, 82677,84163)

G) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)

H) CVS or amniocentesis (CPT 59000, 59015, 76945,76946, 82106, 88235, 88261-88264, 88267, 88269, 88280, 88283, 88285, 88289,88291) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.

I) Array CGH (CPT 81228, 81229, 81349) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in (H) above.

J) FISH testing (CPT 88271, 88272, 88274, 88275, 81171, 81172) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)

K) ~~Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)~~

L) ~~Screening for fragile X status (CPT 81243, 81244, 81171. 81172) once in a lifetime~~

M) ~~Screening for spinal muscular atrophy (CPT 81329) once in a lifetime~~

N) ~~Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255) once in a lifetime. 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.~~

Appendix A

O) Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:
   a. Screening for cystic fibrosis carrier status (CPT 81220-81224)
   ~~b.~~ Screening for fragile X status (CPT 81243, 81244, 81171. 81172)
   c. Screening for spinal muscular atrophy (CPT 81329)
   d. 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.
   e. Screening for hemoglobinopathies (CPT 83020, 83021)

B) Expanded carrier screening (CPT 81443): ~~for those genetic conditions identified above~~ A genetic counseling/geneticist consultation must be offered prior to ordering test and after results are reported. Expanded carrier testing is ONLY covered when all of the following are met:
   a. the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater per ACMG 2021 guidelines, AND
   b. the included genes have well-defined phenotype, AND
   c. 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
   d. the included genes result in conditions have an onset early in life, AND
   e. 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.

The following genetic screening tests are not covered:

A) Serum triple screen
B) ~~Expanded carrier screening which includes results for conditions not explicitly recommended for coverage~~

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

DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING

Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history, services are provided according to the Comprehensive Cancer Network Guidelines.

A) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V1.2021 (5/11/21) ~~V1.2020 (7/21/20).~~ 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 V1.2022 (8/11/21) ~~V1.2021 (9/8/20)~~ 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 V1.2022 (8/11/21)) ~~V1.2021 (9/8/20)~~ 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. V1.2022 (8/11/21) ~~V1.2021 (9/8/20)~~ or Genetic/Familial High-Risk Assessment: Colorectal V1.2021 (5/11/21) ~~V1.2020 (7/21/20).~~ 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.
   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 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 V1.2022 (8/11/21) ~~Breast Cancer Risk Reduction. V.1.2020 (12/4/19).~~ www.nccn.org. Prior to surgery, women without a personal history of breast cancer must have a genetics consultation as defined in section A2 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.

Appendix A

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-oophrectomy.

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

Lines 346,529

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

1) 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 529.

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

For all other indications, spine surgery is included on Line 529.

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

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529. Diagnostic anesthetic injections for selective nerve root blocks are included on Line 529 for lumbar or sacral symptoms.

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

GUIDELINE NOTE 91, CARIES ARRESTING MEDICAMENT APPLICATION

Line 343

CDT D1354, when used to represent ~~is limited to~~ silver diamine fluoride applications for the treatment (rather than prevention) of caries, is limited to ~~with~~ a maximum of two applications per year.

D1354 is also included on this line to

1) arrest or reverse noncavitated carious lesions on occlusal surfaces using sealants plus 5% fluoride varnish (application every 3-6 months) or sealants alone (application every 3-6 months), 1.23% fluoride gel (application every 3-6 months), resin infiltration plus 5% fluoride varnish (application every 3-6 months), or 0.2% fluoride mouthrinse (once per week).
2) arrest or reverse noncavitated carious lesions on approximal surfaces using 5% fluoride varnish (application every 3-6 months), resin infiltration alone, resin infiltration plus 5% fluoride varnish (application every 3-6 months), or sealants alone.
3) arrest or reverse noncavitated carious lesions on facial or lingual surfaces using 1.23% fluoride gel (application every 3-6 months) or 5% fluoride varnish (application every 3-6 months).

GUIDELINE NOTE 101, ARTIFICIAL DISC REPLACEMENT

Lines 346,529

Artificial disc replacement (CPT 22856-22865) is included on Line 346 as an alternative to fusion for patients who meet criteria for spinal fusion procedures as defined in Guideline Note 37 only when all of the following criteria are met:

Lumbar artificial disc replacement

A) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
B) Patients must be 60 years or under;
C) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
   - Failure of at least six months of conservative treatment
   - Skeletally mature patient
   - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Appendix A

Cervical artificial disc replacement

D) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
   - Skeletally mature patient
   - Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

Otherwise, artificial disc replacement is included on Line 529.
Artificial disc replacement combined with fusion in a single procedure (hybrid procedure) is not covered.
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 148, BIOMARKER TESTS OF CANCER TISSUE

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

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

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

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

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

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

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

Appendix A

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

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

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on Line 157. BRAF (CPT 81210) and Oncotype DX are not included on this line. Microsatellite instability (MSI) is included on the Line 662.

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

For prostate cancer, Oncotype DX Genomic Prostate Score, Prolaris Score Assay (CPT 81541), and Decipher Prostate RP (CPT 81542) are included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

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

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

Effective January 1, 2023

GUIDELINE NOTE 169, ORTHODONTICS ~~AND CRANIOFACIAL SURGERY~~ FOR CRANIOFACIAL ANOMALIES AND HANDICAPPING MALOCCLUSION

Line 256

Orthodontic treatment is included on this line for persons under the age of 21 with

1) Cleft lip and palate, cleft palate or cleft lip with alveolar process involvement, OR
2) Other craniofacial anomalies resulting in significant malocclusion expected to result in difficulty with mastication, speech, or other oral function, OR
3) Deep impinging overbite when lower incisors are destroying the soft tissue of the palate, tissue laceration and/or clinical attachment must be present, OR
4) Crossbite of individual anterior teeth when clinical attachment loss and recession of the gingival margin are present, OR
5) Severe traumatic deviation, OR
6) Overjet greater than 9mm with incompetent lips or mandibular protrusion (reverse overjet) greater than 3.5mm with masticatory and speech difficulties; OR
7) Severe malocclusions with a Handicapping Labiolingual Deviation Index California Modification score of 26 or higher.

~~Orthodontics and craniofacial surgery are included on this line only for pairing with craniofacial anomaly diagnoses when there is significant malocclusion expected to result in difficulty with mastication,~~

~~speech, or other oral function.~~ Advanced dental imaging is included on this line only when required for surgical planning for repair of craniofacial anomalies.

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
C1832	Autograft suspension, including cell processing and application, and all system components	Insufficient evidence of effectiveness	November, 2021
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	Insufficient evidence of effectiveness	November, 2021
G0460 G0465	Autologous platelet rich plasma for diabetic or non-diabetic chronic wounds/ulcers including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	Insufficient evidence of effectiveness	May, 2021
33267, 33268, 33269 33340	Exclusion of left atrial appendage Percutaneous transcatheter closure of the left atrial appendage with endocardial implant	Insufficient evidence of effectiveness	~~November, 2016~~ November 2021
33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s)	Insufficient evidence of effectiveness	November 2021
~~36482 36483~~	~~Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate)~~	~~Unproven treatment~~	~~November, 2017~~
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic	Insufficient evidence of effectiveness	November 2021
53451, 53452, 53454	Periurethral transperineal adjustable balloon continence device	Insufficient evidence of effectiveness	November 2021

Appendix A

Procedure Code	Intervention Description	Rationale	Last Review
61736, 61737	Laser interstitial thermal therapy (LITT) of lesion, intracranial	Insufficient evidence of effectiveness	November 2021
64581, 64583	Implantation, revision or replacement of hypoglossal nerve neurostimulator array	Insufficient evidence of effectiveness	November 2021
64628-64629	Thermal destruction of intraosseous basivertebral nerve	Insufficient evidence of effectiveness	November 2021
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each	Insufficient evidence of effectiveness	November 2021
76376-76377 99319	3D rendering of imaging studies	No additional proven benefit beyond the standard study, therefore not reimbursed separately	~~November 2019~~ November 2021
77089-77092	Trabecular bone score	Insufficient evidence of effectiveness	November 2021
~~81425-81427~~	~~Genome sequence analysis~~	~~Insufficient evidence of effectiveness~~	~~November, 2014~~
~~81443~~	~~Expanded carrier screening~~	~~Insufficient evidence of effectiveness~~	~~November, 2018~~
81560	Transplantation medicine (allograft rejection, pediatric liver and small bowel), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score	Insufficient evidence of effectiveness	November 2021
83529	Interleukin-6 (IL-6)	Insufficient evidence of effectiveness	November 2021
87154	Culture, typing; identification of blood pathogen and resistance typing, when performed, by nucleic acid (DNA or RNA) probe, multiplexed amplified probe technique including multiplex reverse transcription, when performed, per culture or isolate, 6 or more targets	Insufficient evidence of effectiveness	November 2021
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon	Insufficient evidence of effectiveness	November 2021

Appendix B

New Guideline Notes

GUIDELINE NOTE XXX DECORONATION OR SUBMERGENCE OF AN ERUPTED TOOTH

Lines 384, 411, 444, 456, 507, 538

Decoronation or submergence of an erupted tooth (CDT D3921) is only included on these lines for teeth that would otherwise qualify for endodontic services included on these lines but for which endodontics cannot be performed due to high-risk circumstances (e.g. certain medications or radiation related osteonecrosis).

GUIDELINE NOTE XXX PERORAL ENDOSCOPIC MYOTOMY (POEM)

Line 378

Peroral endoscopic myotomy (POEM; CPT 43497) is included on this line only when ALL the following criteria are met:

1) A diagnosis of esophageal achalasia type III (spastic) is established by the following:
    a. Twenty percent (20%) or more of swallows have premature spastic contractions as indicated by esophageal manometry; AND
    b. Non-relaxing lower esophageal sphincter pressure (LES) indicated by a barium esophagogram with fluoroscopy and esophageal manometry; AND
2) Failure of a previous treatment for achalasia (e.g. Botox, pneumatic dilation); AND
3) None of the following contraindications are present:
    a. Severe pulmonary disease; or
    b. Esophageal irradiation; or
    c. Esophageal malignancy; or
    d. Bleeding disorder, including coagulopathy; or
    e. Recent esophageal surgery; and endoscopic intervention

2022 CDT CODE REVIEW
APPENDIX C

CDT code	Code Description	Suggested Placements
D3911	intraorifice barrier	**384** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT ANTERIOR TOOTH) Treatment: BASIC ENDODONTICS (I.E., ROOT CANAL THERAPY) **411** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT BICUSPID/PREMOLAR TOOTH) Treatment: BASIC ENDODONTICS (I.E., ROOT CANAL THERAPY) **444** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT MOLAR TOOTH) Treatment: BASIC ENDODONTICS (I.E., ROOT CANAL THERAPY) **456** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT ANTERIOR TOOTH) Treatment: ADVANCED ENDODONTICS (E.G., RETREATMENT OF PREVIOUS ROOT CANAL THERAPY) **507** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT BICUSPID/PREMOLAR TOOTH) Treatment: ADVANCED ENDODONTICS (E.G., RETREATMENT OF PREVIOUS ROOT CANAL THERAPY) **538** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT MOLAR TOOTH) Treatment: ADVANCED ENDODONTICS (E.G., RETREATMENT OF PREVIOUS ROOT CANAL THERAPY)
D3921	decoronation or submergence of an erupted tooth	384, 411, 444, 456, 507, 538 See proposed new guideline below
D4322	splint – intra-coronal; natural teeth or prosthetic crowns	**492** DENTAL CONDITIONS (E.G., PERIODONTAL DISEASE) Treatment: ADVANCED PERIODONTICS (E.G., SURGICAL PROCEDURES AND SPLINTING)
D4323	splint – extra-coronal; natural teeth or prosthetic crowns	**492** DENTAL CONDITIONS (E.G., PERIODONTAL DISEASE) Treatment: ADVANCED PERIODONTICS (E.G., SURGICAL PROCEDURES AND SPLINTING)
D5227	immediate maxillary partial denture - flexible base (including any clasps, rests and teeth)	**646** DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment: ELECTIVE DENTAL SERVICES
D5228	immediate mandibular partial denture - flexible base (including any clasps, rests and teeth)	**646** DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment: ELECTIVE DENTAL SERVICES

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APPENDIX C

CDT code	Code Description	Suggested Placements
D5725	rebase hybrid prosthesis	**619** DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment: IMPLANTS (I.E., IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)
D5765	soft liner for complete or partial removable denture – indirect	**454** DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS (E.G., FULL AND PARTIAL DENTURES, RELINES)
D6198	remove interim implant component	**619** DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment: IMPLANTS (I.E., IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)
D7298	removal of temporary anchorage device [screw retained plate], requiring flap	**42** CLEFT PALATE WITH AIRWAY OBSTRUCTION **256** DEFORMITIES OF HEAD **300** CLEFT PALATE AND/OR CLEFT LIP **618** DENTAL CONDITIONS (E.G., MALOCCLUSION) Treatment: ORTHODONTIA
D7299	removal of temporary anchorage device, requiring flap	**42,256,300,618**
D7300	removal of temporary anchorage device without flap	**42,256,300,618**
D9912	pre-visit patient screening	**Diagnostic Procedure File**
D9947	custom sleep apnea appliance fabrication and placement	**202** SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
D9948	adjustment of custom sleep apnea appliance	**202** SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
D9949	repair of custom sleep apnea appliance	**202** SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER

CPT Codes
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Code	Code Description	Recommended Placement
00100	Anesthesia for procedures on salivary glands, including biopsy	ANCILLARY PROCEDURES
01937	Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic	ANCILLARY PROCEDURES
01938	Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral	ANCILLARY PROCEDURES
01939	Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic	ANCILLARY PROCEDURES
01940	Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral	ANCILLARY PROCEDURES
01941	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic	ANCILLARY PROCEDURES
01942	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral	ANCILLARY PROCEDURES
33267	Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33268	Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33269	Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

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Code	Code Description	Recommended Placement
33509	Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, endoscopic	69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 98 CARDIOMYOPATHY 189 CHRONIC ISCHEMIC HEART DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
33894	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; across major side branches	44 COARCTATION OF THE AORTA
33895	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; not crossing major side branches	44 COARCTATION OF THE AORTA
33897	Percutaneous transluminal angioplasty of native or recurrent coarctation of the aorta	44 COARCTATION OF THE AORTA
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])	378 ESOPHAGEAL STRICTURE; ACHALASIA
53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon	424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
61736	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Code	Code Description	Recommended Placement
61737	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)	47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS 150 CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR UNSTABLE; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY 200 CANCER OF BONES 254 CHRONIC OSTEOMYELITIS 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS 361 SCOLIOSIS 401 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS 478 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS 558 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)	47, 150, 200, 254, 346, 361, 401, 478, 529, 558
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

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Code	Code Description	Recommended Placement
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	311 HEARING LOSS - AGE 5 OR UNDER 445 HEARING LOSS - OVER AGE OF FIVE

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Code	Code Description	Recommended Placement
69719	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	311, 445
69726	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 311, 445
69727	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	285, 311, 445
77089	Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture-risk	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
77090	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
77091	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
77092	Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture-risk only by other qualified health care professional	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:
80220	Hydroxychloroquine	DIAGNOSTIC PROCEDURES
80503	Pathology clinical consultation; for a clinical problem, with limited review of patient's history and medical records and straightforward medical decision making When using time for code selection, 5-20 minutes of total time is spent on the date of the consultation.	DIAGNOSTIC PROCEDURES
80504	Pathology clinical consultation; for a moderately complex clinical problem, with review of patient's history and medical records and moderate level of medical decision making When using time for code selection, 21-40 minutes of total time is spent on the date of the consultation.	DIAGNOSTIC PROCEDURES

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Code	Code Description	Recommended Placement
80505	Pathology clinical consultation; for a highly complex clinical problem, with comprehensive review of patient's history and medical records and high level of medical decision making When using time for code selection, 41-60 minutes of total time is spent on the date of the consultation.	DIAGNOSTIC PROCEDURES
80506	Pathology clinical consultation; prolonged service, each additional 30 minutes (List separately in addition to code for primary procedure)	DIAGNOSTIC PROCEDURES
81349	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-pass sequencing analysis	DIAGNOSTIC PROCEDURES
81523	Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis	191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
81560	Transplantation medicine (allograft rejection, pediatric liver and small bowel), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
82653	Elastase, pancreatic (EL-1), fecal; quantitative	DIAGNOSTIC PROCEDURES
83521	Immunoglobulin light chains (ie, kappa, lambda), free, each	DIAGNOSTIC PROCEDURES
83529	Interleukin-6 (IL-6)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
86015	Actin (smooth muscle) antibody (ASMA), each	DIAGNOSTIC PROCEDURES
86036	Antineutrophil cytoplasmic antibody (ANCA); screen, each antibody	DIAGNOSTIC PROCEDURES
86037	Antineutrophil cytoplasmic antibody (ANCA); titer, each antibody	DIAGNOSTIC PROCEDURES
86051	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA)	DIAGNOSTIC PROCEDURES
86052	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each	DIAGNOSTIC PROCEDURES
86053	Aquaporin-4 (neuromyelitis optica [NMO]) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each	DIAGNOSTIC PROCEDURES
86231	Endomysial antibody (EMA), each immunoglobulin (Ig) class	DIAGNOSTIC PROCEDURES

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Code	Code Description	Recommended Placement
86258	Gliadin (deamidated) (DGP) antibody, each immunoglobulin (Ig) class	DIAGNOSTIC PROCEDURES
86362	Myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody; cell-based immunofluorescence assay (CBA), each	DIAGNOSTIC PROCEDURES
86363	Myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each	DIAGNOSTIC PROCEDURES
86364	Tissue transglutaminase, each immunoglobulin (Ig) class	DIAGNOSTIC PROCEDURES
86381	Mitochondrial antibody (eg, M2), each	DIAGNOSTIC PROCEDURES
86596	Voltage-gated calcium channel antibody, each	DIAGNOSTIC PROCEDURES
87154	Culture, typing; identification of blood pathogen and resistance typing, when performed, by nucleic acid (DNA or RNA) probe, multiplexed amplified probe technique including multiplex reverse transcription, when performed, per culture or isolate, 6 or more targets	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
90626	Tick-borne encephalitis virus vaccine, inactivated; 0.25 mL dosage, for intramuscular use	EXCLUDED FILE
90627	Tick-borne encephalitis virus vaccine, inactivated; 0.5 mL dosage, for intramuscular use	EXCLUDED FILE
90671	Pneumococcal conjugate vaccine, 15 valent (PCV15), for intramuscular use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
90677	Pneumococcal conjugate vaccine, 20 valent (PCV20), for intramuscular use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
90758	Zaire ebolavirus vaccine, live, for intramuscular use	EXCLUDED FILE
90759	Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2), 10 mcg dosage, 3 dose schedule, for intramuscular use	EXCLUDED FILE
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
91303	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5 mL dosage, for intramuscular use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

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Code	Code Description	Recommended Placement
93319	3D echocardiographic imaging and postprocessing during transesophageal echocardiography, or during transthoracic echocardiography for congenital cardiac anomalies, for the assessment of cardiac structure(s) (eg, cardiac chambers and valves, left atrial appendage, interatrial septum, interventricular septum) and function, when performed (List separately in addition to code for echocardiographic imaging)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Code	Code Description	Recommended Placement
93593	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections	45 CORONARY ARTERY ANOMALY 67 VENTRICULAR SEPTAL DEFECT 70 CONGENITAL PULMONARY VALVE ANOMALIES 76 PATENT DUCTUS ARTERIOSUS; AORTIC PULMONARY FISTULA/WINDOW 84 ENDOCARDIAL CUSHION DEFECTS 85 CONGENITAL PULMONARY VALVE ATRESIA 88 DISCORDANT CARDIOVASCULAR CONNECTIONS 89 CONGENITAL MITRAL VALVE STENOSIS/INSUFFICIENCY 104 TETRALOGY 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 653 CARDIOVASCULAR CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
93594	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
93595	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653

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Code	Code Description	Recommended Placement
93596	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
93597	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
93598	Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects (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
94625	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)	9 ASTHMA 58 BRONCHIECTASIS 222 OCCUPATIONAL LUNG DISEASES 233 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS 240 CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION 283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE 399 INFLUENZA, NOVEL RESPIRATORY VIRUSES
94626	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session)	9, 58, 222, 233, 240, 283, 399
98975	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment	EXCLUDED FILE
98976	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days	EXCLUDED FILE

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Code	Code Description	Recommended Placement
98977	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days	EXCLUDED FILE
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes	EXCLUDED FILE
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)	EXCLUDED FILE
99424	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month.	All lines with E&M codes

CPT Codes
APPENDIX C

Code	Code Description	Recommended Placement
99425	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)	All lines with E&M codes
99426	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month.	All lines with E&M codes

CPT Codes
APPENDIX C

Code	Code Description	Recommended Placement
99427	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)	All lines with E&M codes
99437	Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)	All lines with E&M codes

HCPCS Codes

C1832	Autograft suspension, including cell processing and application, and all system comp	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantabl	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

CPT Codes
APPENDIX C

Code	Code Description	Recommended Placement
G0465	Autologous platelet rich plasma (prp) for diabetic chronic wounds/ulcers, using an fda-cleared device (includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Section 2.0

Staff Report

Errata
March 2022

1) On December 1, 2021, the following corrections were made:
    a. CPT 63052 (Laminectomy, facetectomy, or foraminotomy…) was added to two lines:
        i. Line 401 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS
        ii. Line 558 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY
    b. The placement changes shown in attachment A were made to align with previous intent.

2) On December 28, 2021, one correction was made to Guideline 173 INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS:
    a. CPT code 99319 was erroneously listed as an entry in Guideline 173 instead of the correct code, CPT 93319 (3D echocardiographic imaging and postprocessing…). This was corrected.

3) On January 10, 2022, one correction was made to Guideline Note 98 SIGNIFICANT INJURIES TO LIGAMENTS, TENDONS AND MENISCI:
    a. Sentence structure was revised in the first paragraph, clarifying that non-significant injuries are included on Line 608 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR.

Pneumococcal Vaccine Codes

Issue: At the November 2021 VBBS and HERC meetings, new 2022 CPT codes for new pneumococcal vaccines (PCV 15 and PCV20) were reviewed and added to the Excluded file as not yet having approval by the Advisory Committee on Immunization Practices (ACIP). The intent expressed at both of these meetings was to move these codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS when ACIP approval was granted.

After the November meeting, HERC staff became aware that ACIP had approved both vaccines for use at their October 20, 2021 meeting.

From ACIP October 2021 meeting materials
[https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/01-Pneumococcal-Poehling-508.pdf]

Previously posted on CDC website:

> ACIP approved the following recommendations by majority vote at its October 20, 2021 meeting:
>
> Adults 65 years of age or older who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.
>
> Adults ages 19 to 64 years with certain underlying medical conditions or other risk factors* who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.
>
> These recommendations have been adopted by the CDC Director and will become official once published in MMWR

After consultation with HERC leadership, HERC staff moved these codes from the Excluded file to Line 3 per the HERC intent.

Note: the recommendation above has been published in the MMWR, and is attached to this issue summary for further review if desired.

Actions:
Added to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS effective 1/1/22:

1) **90671:** Pneumococcal conjugate vaccine, 15 valent (PCV15)
2) **90677**: Pneumococcal conjugate vaccine, 20 valent (PCV20)

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 71 / No. 4
January 28, 2022

Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022

Miwako Kobayashi, MD[1]; Jennifer L. Farrar, MPH[1]; Ryan Gierke, MPH[1]; Amadea Britton, MD[1,2]; Lana Childs, MPH[3]; Andrew J. Leidner, PhD[1]; Doug Campos-Outcalt, MD[4]; Rebecca L. Morgan, PhD[5]; Sarah S. Long, MD[6]; H. Keipp Talbot, MD[7]; Katherine A. Poehling, MD[8]; Tamara Pilishvili, PhD[1]

In 2021, 20-valent pneumococcal conjugate vaccine (PCV) (PCV20) (Wyeth Pharmaceuticals LLC, a subsidiary of Pfizer Inc.) and 15-valent PCV (PCV15) (Merck Sharp & Dohme Corp.) were licensed by the Food and Drug Administration for adults aged ≥18 years, based on studies that compared antibody responses to PCV20 and PCV15 with those to 13-valent PCV (PCV13) (Wyeth Pharmaceuticals LLC, a subsidiary of Pfizer Inc.). Antibody responses to two additional serotypes included in PCV15 were compared to corresponding responses after PCV13 vaccination, and antibody responses to seven additional serotypes included in PCV20 were compared with those to the 23-valent pneumococcal polysaccharide vaccine (PPSV23) (Merck Sharp & Dohme Corp.). On October 20, 2021, the Advisory Committee on Immunization Practices (ACIP) recommended use of either PCV20 alone or PCV15 in series with PPSV23 for all adults aged ≥65 years, and for adults aged 19–64 years with certain underlying medical conditions or other risk factors* who have not previously received a PCV or whose previous vaccination history is unknown. ACIP employed the Evidence to Recommendation (EtR) framework,† using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE)§ approach to guide its deliberations regarding use of these vaccines. Before this, PCV13 and PPSV23 were recommended for use for U.S. adults

* Alcoholism; chronic heart, liver, or lung disease; chronic renal failure; cigarette smoking; cochlear implant; congenital or acquired asplenia; cerebrospinal fluid leak; diabetes mellitus; generalized malignancy; HIV; Hodgkin disease; immunodeficiency; iatrogenic immunosuppression; leukemia, lymphoma, or multiple myeloma; nephrotic syndrome; solid organ transplant; sickle cell disease; or other hemoglobinopathies.

† https://www.cdc.gov/vaccines/acip/recs/grade/downloads/acip-evidence-recs-framework.pdf

§ https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html

INSIDE

Continuing Education examination available at https://www.cdc.gov/mmwr/mmwr_continuingEducation.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

and the recommendations varied by age and risk groups. This was simplified in the new recommendations.

PPSV23 has been recommended for use in the United States since the 1980s for adults aged ≥65 years and for younger adults with underlying conditions that increase their risk for pneumococcal disease (*1*). PCV13 was first recommended for use in U.S. children in 2010, and indirect effects from its use in children reduced PCV13-type pneumococcal disease incidence in all adult groups (Figure). In 2012, ACIP recommended administration of PCV13 in series with PPSV23 for adults with immunocompromising conditions,[¶] cerebrospinal fluid leaks, or cochlear implants (*2*), and in 2014, the recommendation was extended to all adults aged ≥65 years (*3*). On the basis of review of accrued evidence, the PCV13 recommendation was changed in 2019 to shared clinical decision-making for adults aged ≥65 years without an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant. The recommended pneumococcal vaccine doses and intervals between doses differ by age and underlying conditions, making adult pneumococcal vaccine recommendations complicated.

Recent systematic reviews continue to support the effectiveness of PCV13 against invasive pneumococcal disease (IPD)[**] and pneumococcal pneumonia among adults (*4*,*5*). Whereas effectiveness of PPSV23 against IPD has been demonstrated, data on effectiveness against pneumococcal pneumonia were considered to be inconsistent (*3*); recent observational studies reported 21%–46% effectiveness against PPSV23-type pneumococcal pneumonia when PPSV23 was given <5 years before illness onset (*6*–*8*). Nevertheless, older adults and adults with chronic medical conditions[††] or immunocompromising conditions, cerebrospinal fluid leaks, or cochlear implants (certain underlying conditions) remain at increased risk for pneumococcal disease, accounting for >90% of adult IPD cases in 2019 (Active Bacterial Core surveillance, unpublished data, 2021).

During February–October 2021, ACIP reviewed the epidemiology of pneumococcal disease and considerations for use of PCV15 and PCV20 in adults. The ACIP Pneumococcal

[¶] Immunocompromising conditions are defined as chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, HIV, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies.

[**] The case definition used by CDC's Active Bacterial Core surveillance is isolation of *S. pneumoniae* from a normally sterile site or pathogen-specific nucleic acid in a specimen obtained from a normally sterile body site using a validated molecular test. https://www.cdc.gov/abcs/methodology/case-def-ascertain.html

[††] Alcoholism; chronic heart, liver, or lung disease; cigarette smoking; or diabetes mellitus.

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. MMWR Morb Mortal Wkly Rep 2022;71:[inclusive page numbers].

Vaccines Work Group (Work Group) evaluated the quality of evidence for PCV15 and PCV20 immunogenicity and safety using the GRADE approach.[§§] Using the EtR framework,[¶¶] the Work Group reviewed relevant scientific evidence regarding the benefits and harms of PCV15 and PCV20 use among adults aged ≥65 years and younger adults with certain underlying conditions. Within the EtR framework, ACIP considered the importance of the public health problem, benefits and harms, target populations' values and preferences, resource use, equity, acceptability, and feasibility for PCV15 or PCV20 use. After a systematic review of the literature, the Work Group defined critical outcomes and used GRADE to assess certainty of evidence rated on a scale of 1 (high certainty) to 4 (very low certainty) (*9*).

[§§] https://www.cdc.gov/vaccines/acip/recs/grade/pneumo-PCV20-risk-based.html; https://www.cdc.gov/vaccines/acip/recs/grade/pneumo-PCV15-PPSV23-risk-based.html; https://www.cdc.gov/vaccines/acip/recs/grade/pneumo-PCV20-age-based.html; https://www.cdc.gov/vaccines/acip/recs/grade/pneumo-PCV15-PPSV23-age-based.html

[¶¶] https://www.cdc.gov/vaccines/acip/recs/grade/pneumo-PCV20-risk-based-etr.html; https://www.cdc.gov/vaccines/acip/recs/grade/pneumo-PCV20-age-based-etr.html; https://www.cdc.gov/vaccines/acip/recs/grade/pneumo-PCV15-PPSV23-risk-based-etr.html; https://www.cdc.gov/vaccines/acip/recs/grade/pneumo-PCV15-PPSV23-age-based-etr.html

Evidence

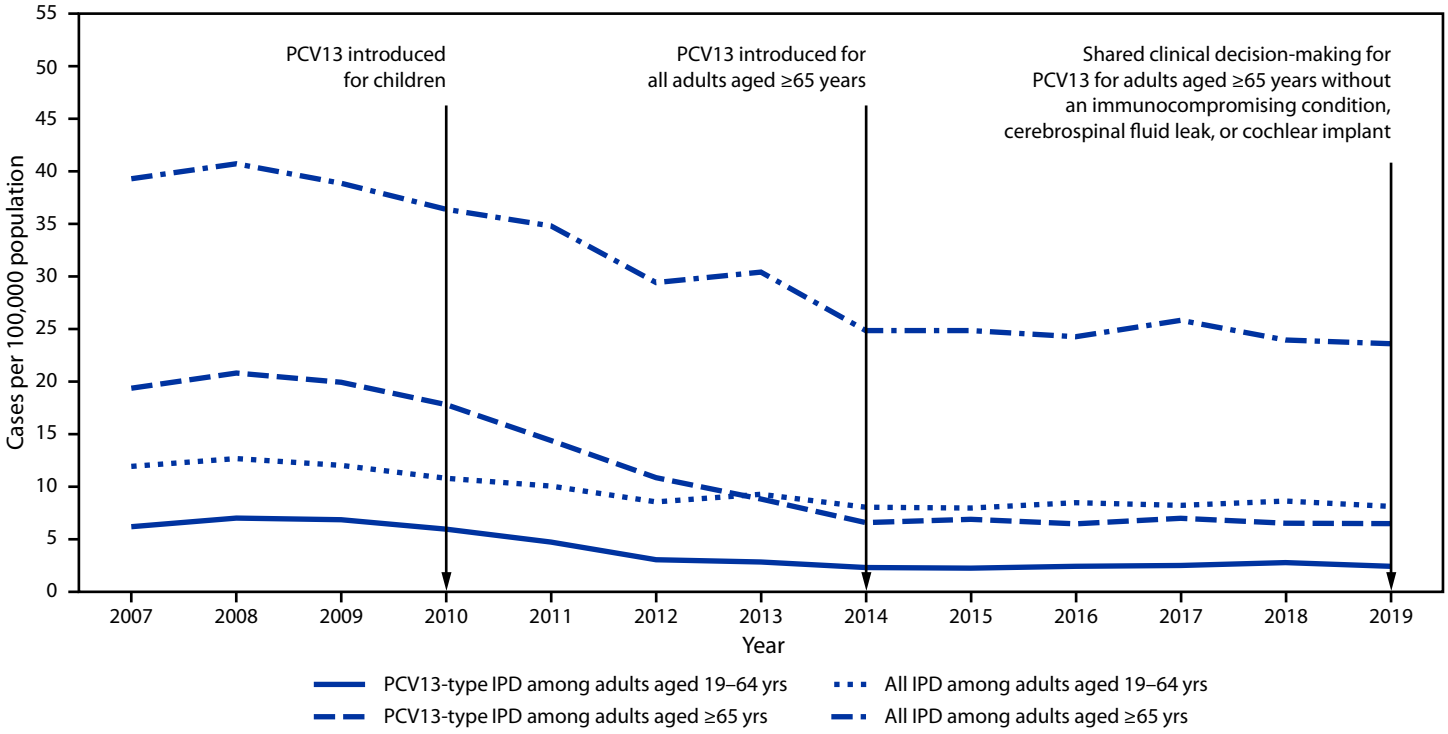
Pneumococcal disease incidence in adults. During 2018–2019, the incidence of all IPD in adults aged ≥65 years was 24 per 100,000 population (Figure), and PCV13 serotypes accounted for 27% of cases; additional serotypes unique to PCV15,[***] PCV20,[†††] and PPSV23[§§§] caused 15%, 27%, and 35% of IPD, respectively. In adults aged 19–64 years with certain underlying conditions, PCV13 serotypes accounted for 30% of IPD; serotypes unique to PCV15, PCV20, and PPSV23 caused 13%, 28%, and 43% of IPD, respectively. Estimates of pneumococcal pneumonia incidence are more variable. Annual incidence among U.S. adults aged <65 and ≥65 years hospitalized with community-acquired pneumonia was estimated at 126–422 and 847–3,365 per 100,000, respectively, during 2010–2016 (*10*). In a multisite study of adults hospitalized with community-acquired pneumonia, 4.6% of cases were caused by PCV13 serotypes, and 1.4% and 3.3% were caused by additional serotypes included in PCV15 and PCV20, respectively (*11*).

[***] Serotypes 22F and 33F, in addition to PCV13 serotypes.

[†††] Serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F, in addition to PCV13 serotypes.

[§§§] Serotypes 2, 8, 9N, 10A, 11A, 12F, 15B, 17F, 20, 22F, and 33F, in addition to PCV13 serotypes.

FIGURE. Incidence of all invasive pneumococcal disease and 13-valent pneumococcal conjugate vaccine-type* invasive pneumococcal disease among adults aged ≥19 years, by invasive pneumococcal disease type and age group — United States, 2007–2019†



Abbreviations: IPD = invasive pneumococcal disease; PCV13 = 13-valent pneumococcal conjugate vaccine.

* Includes serotype 6C, which shows cross-protection from 6A antigen in PCV13 and was grouped with PCV13 serotypes for IPD incidence.

† Active Bacterial Core surveillance, 2021.

PCV15 immunogenicity. PCV15 contains pneumococcal polysaccharide serotypes 22F and 33F in addition to the PCV13 serotypes, conjugated to CRM197 (genetically detoxified diphtheria toxin) (*9*). Phase II and III randomized controlled trials (RCTs) evaluated the immunogenicity and safety of a dose of PCV15 compared with a dose of PCV13 in healthy adults aged ≥50 years (*12–14*), adults aged 18–49 years who are Native American (a population with higher rates of IPD than the general U.S. population) (*15*) or with ≥1 risk condition for pneumococcal disease (*16*), and adults aged ≥18 years with HIV infection (*17*). Serotype-specific functional antibody responses were measured 1 month after vaccination using an opsonophagocytic activity (OPA) assay. Correlates of protection have not been established for adults. In one phase III RCT among adults aged ≥50 years, PCV15 met the noninferiority criteria[¶¶¶] compared with PCV13 for the 13 shared serotypes and had statistically significantly greater response[****] for shared serotype 3 and PCV15-unique serotypes 22F and 33F (*14*). In studies that evaluated the immunogenicity of PCV15 or PCV13 followed by PPSV23 2–12 months later (*16–18*), persons who received PCV15 had numerically similar or higher OPA geometric mean antibody titers (GMTs) for 9–13[††††] shared PCV13 serotypes and a higher percentage of seroresponders[§§§§] for 5–11 shared serotypes compared with persons who received PCV13 when measured 1 month after receipt of PPSV23.

PCV15 safety. Safety of PCV15 was assessed in seven RCTs with 5,630 participants aged ≥18 years who received 1 dose of PCV15. Most participants were immunocompetent; however, one study included 302 adults with HIV infection. Participants included those vaccinated with PPSV23 ≥1 year before receiving PCV15, those who received PCV15 followed by PPSV23, and those who received PCV15 concomitantly with a seasonal inactivated quadrivalent influenza vaccine (QIV). The most frequently reported adverse reactions were injection site pain, fatigue, and myalgia. The rates of serious adverse events (SAEs) within 6 months of vaccination were 2.5% among PCV15 recipients and 2.4% among PCV13 recipients. No SAEs or deaths were considered to be related to the study vaccines (*9*,*19*).

PCV20 immunogenicity. PCV20 contains pneumococcal polysaccharide serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F, in addition to PCV13 serotypes, conjugated to CRM197 (*20*). A phase II study among adults aged 60–64 years and two phase III RCTs among adults aged ≥18 years evaluated immunogenicity and safety of PCV20 compared with PCV13 and with PPSV23 for the seven additional serotypes included in PCV20 (*21–23*). These studies included adults with stable medical conditions, but none included adults with immunocompromising conditions. Compared with PCV13 recipients, PCV20 recipients elicited responses that met noninferiority criteria[¶¶¶¶] for all 13 serotypes in a phase III trial among adults aged ≥60 years (*21*); however, PCV20 recipients appeared to have lower GMTs and included a lower percentage of seroresponders to 12–13 of the 13 PCV13-shared serotypes (*21*,*22*). Compared with PPSV23 recipients, PCV20 recipients had numerically higher GMTs and a higher percentage of seroresponders to six of seven (excluding serotype 8) shared non-PCV13 serotypes (*21*,*23*); noninferiority criteria were met for those six serotypes (*21*).

PCV20 safety. Safety of PCV20 was assessed in six trials among immunocompetent adults aged ≥18 years that included a total of 4,552 participants who received PCV20. Participants included those who were naïve to pneumococcal vaccination and those who had previously received pneumococcal vaccination. The most frequently reported adverse reactions were injection site pain, muscle pain, fatigue, headache, and joint pain. SAEs reported within 6 months after vaccination occurred among 1.5% of PCV20 recipients and 1.8% among controls. No SAEs or deaths were considered to be related to study vaccines (*20*,*24*).

Intervals between PCV and PPSV23. Findings from eight immunogenicity studies that evaluated the immune response after a sequence of 7-valent PCV, PCV13, or PCV15 followed by PPSV23 administered at intervals of 2, 6, or 12 months or 3–4 years were reviewed (*16–18*,*25–29*). Three studies comparing intervals ranging from 2 to 6 months between administration of PCV and PPSV23 found no significant difference in immunogenicity measured after PPSV23 receipt, although reactogenicity tended to be higher with shorter intervals (*25–29*). In a study that compared antibody responses to 1 dose of PCV13 with responses to PCV13 followed by PPSV23 1 year apart, the immune responses following PPSV23 were significantly lower compared with the responses after a dose of PCV13 for eight of 12 common serotypes (*27*). In another study that compared antibody response to 1 dose of PCV13 with responses to PCV13 followed by PPSV23 approximately 4 years apart, the immune responses following PPSV23 were significantly higher for seven of 12 common serotypes (*26*).

[¶¶¶] Lower bound of the two-sided 95% CI of the OPA GMT ratio (PCV15 / PCV13) to be >0.5.

[****] For PCV15-unique serotypes 22F and 33F, defined as the lower bound of the two-sided 95% CI of the OPA GMT ratio (V114 / PCV13) to be >2.0 and the lower bound of the two-sided 95% CI of the differences (V114 – PCV13) between the percentages of participants with a fourfold rise to be >0.1. For serotype 3, defined as the lower bound of the two-sided 95% CI of the OPA GMT ratio (V114 / PCV13) to be >1.2 and the lower bound of the two-sided 95% CI of the differences (V114 – PCV13) between the percentages of participants with a fourfold rise to be >0.

[††††] Range reflects the difference in results across studies.

[§§§§] Subjects with a fourfold or larger rise in OPA GMT titer postvaccination compared with prevaccination.

[¶¶¶¶] Defined as the lower bound of the two-sided 95% CI of the ratio (PCV20 / PCV13) of opsonophagocytic geometric mean titers being >0.5.

These findings suggested that longer intervals between administration of PCV and PPSV23 might improve immunogenicity in immunocompetent adults, although a direct comparison between a 1- versus 4-year interval was not made.

Cost-effectiveness. Economic models assessed cost-effectiveness of the new policy options compared with existing recommendations (*30*). Three economic models assessed PCV20 alone for all adults aged ≥65 years; cost-effectiveness estimates ranged from cost-saving[*****] to $39,000 per quality-adjusted life-year (QALY) gained. Two economic models assessed use of PCV15 in series with PPSV23 for all adults aged ≥65 years; estimates ranged from cost-saving to $282,000 per QALY gained. The CDC model found cost savings in all scenarios for use of either PCV20 alone or PCV15 in series with PPSV23 for all adults aged ≥65 years. Cost estimates of policy options for adults aged 19–64 years with certain underlying medical conditions ranged from $11,000 to $292,000 per QALY gained for PCV20 and from $250,000 to $656,000 for PCV15 in series with PPSV23.

Summary. Use of PCV20 alone or PCV15 in series with PPSV23 is expected to reduce pneumococcal disease incidence in adults aged ≥65 years and in those aged 19–64 years with certain underlying conditions. Findings from studies suggested that the immunogenicity and safety of PCV20 alone or PCV15 in series with PPSV23 were comparable to PCV13 alone or PCV13 in series with PPSV23. Cost-effectiveness studies demonstrated that use of PCV20 alone or PCV15 in series with PPSV23 for adults at age 65 years was cost-saving. The new policy simplifies adult pneumococcal vaccine recommendations (Table 1) and is expected to improve vaccine coverage among adults and prevent more pneumococcal disease. An amendment to recommend PCV20 for all adults aged ≥50 years instead of age ≥65 years was considered but rejected (Table 2). A summary of Work Group deliberations on use of either PCV20 alone or PCV15 in series with PPSV23 for all

[*****] Lower cost and improved health outcomes compared with previous recommendations.

TABLE 1. Recommendations for use of 15-valent pneumococcal conjugate vaccine in series with 23-valent pneumococcal polysaccharide vaccine or 20-valent pneumococcal conjugate vaccine in pneumococcal conjugate vaccine-naïve adults aged ≥19 years — United States, 2022

Medical indication group	Specific underlying medical condition	Age group, yrs	
		19–64	≥65
None	None	None	1 dose of PCV20 or 1 dose of PCV15 followed by a dose of PPSV23 ≥1 years later*
Underlying medical conditions or other risk factors	Alcoholism Chronic heart disease† Chronic liver disease Chronic lung disease¶ Cigarette smoking Diabetes mellitus Cochlear implant CSF leak Congenital or acquired asplenia Sickle cell disease or other hemoglobinopathies Chronic renal failure** Congenital or acquired immunodeficiencies**,†† Generalized malignancy** HIV infection** Hodgkin disease** Iatrogenic immunosuppression**,§§ Leukemia** Lymphoma** Multiple myeloma** Nephrotic syndrome** Solid organ transplant**	1 dose of PCV20 or 1 dose of PCV15 followed by a dose of PPSV23 ≥1 years later§	1 dose of PCV20 or 1 dose of PCV15 followed by a dose of PPSV23 ≥1 years later*

Abbreviations: CSF = cerebrospinal fluid; PCV15 = 15-valent pneumococcal conjugate vaccine; PCV20 = 20-valent pneumococcal conjugate vaccine; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

* Adults with immunocompromising conditions, cochlear implant, or CSF leak might benefit from shorter intervals such as ≥8 weeks. These vaccine doses do not need to be repeated if given before age 65 years.

† Includes congestive heart failure and cardiomyopathies.

§ Adults with immunocompromising conditions, cochlear implant, or CSF leak might benefit from shorter intervals such as ≥8 weeks.

¶ Includes chronic obstructive pulmonary disease, emphysema, and asthma.

** Indicates immunocompromising conditions.

†† Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).

§§ Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy.

adults aged ≥65 years or adults aged 19–64 years with certain underlying conditions is available in the EtR tables.

New Pneumococcal Vaccine Recommendations

Adults aged ≥65 years. Adults aged ≥65 years who have not previously received PCV or whose previous vaccination history is unknown should receive 1 dose of PCV (either PCV20 or PCV15). When PCV15 is used, it should be followed by a dose of PPSV23 (Table 1).

Adults aged 19–64 years with certain underlying medical conditions or other risk factors. Adults aged 19–64 years with certain underlying medical conditions or other risk factors who have not previously received PCV or whose previous vaccination history is unknown should receive 1 dose of PCV (either PCV20 or PCV15). When PCV15 is used, it should be followed by a dose of PPSV23.

Clinical Guidance

Dosing schedule. When PCV15 is used, the recommended interval between administration of PCV15 and PPSV23 is ≥1 year. A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk for IPD caused by serotypes unique to PPSV23 in these vulnerable groups (*31*).

Adults with previous PPSV23 only. Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.

Adults with previous PCV13. The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These adults should complete the previously recommended PPSV23[†††††] series (*2*,*30*).

Coadministration with other vaccines. PCV15, PCV20, or PPSV23 can be coadministered with QIV in an adult immunization program, as concomitant administration (PCV15 or PPSV23 and QIV [Fluarix], PCV20 and adjuvanted QIV [Fluad]) has been demonstrated to be immunogenic and safe. However, slightly lower pneumococcal serotype-specific OPA GMTs or geometric mean concentrations were reported when pneumococcal vaccines were coadministered with QIV compared with when pneumococcal vaccines were given alone (*9*,*19*,*32*,*33*). Currently, no data are available on coadministration with other vaccines (e.g., tetanus, diphtheria, acellular pertussis vaccine, hepatitis B, or zoster vaccine) among adults. Evaluation of coadministration of PCV15, PCV20, or PPSV23 with COVID-19 vaccines is ongoing (*34*,*35*).

Future Research and Monitoring Priorities

CDC and ACIP will continue to assess safety of PCV15 and PCV20 vaccines, monitor the impact of implementation of new recommendations, and assess postimplementation vaccine effectiveness and update pneumococcal vaccination recommendations as appropriate.

[†††††] For adults who have received PCV13 but have not completed their recommended pneumococcal vaccine series with PPSV23, one dose of PCV20 may be used if PPSV23 is not available.

TABLE 2. Age-based policy options for use of 15-valent pneumococcal conjugate vaccine or 20-valent pneumococcal conjugate vaccine in adults presented for a vote and considerations by the Advisory Committee on Immunization Practices — United States, October 2021

Proposed policy	Considerations raised during October 2021 ACIP meeting in favor of the option	Outcome (votes in favor: against)
Adults aged ≥50 years who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.	Might reduce existing pneumococcal disease disparity in adults aged 50–64 years. Age-based recommendation is easier to implement than risk-based recommendation. Might provide more opportunities to vaccinate adults before underlying conditions develop.	Rejected (4:11)
Adults aged ≥65 years who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15). If PCV15 is used, this should be followed by a dose of PPSV23.	Potential for waning vaccine-induced immunity makes it favorable to vaccinate later in life when risk for disease is higher. Consistently cost saving in cost-effectiveness analyses. Still provides an opportunity for higher PCV coverage in adults compared with current recommendations. No evidence that lowering the age-based recommendation will reduce disparity in vaccine-preventable disease compared with risk-based recommendations.	Affirmed (15:0)

Abbreviations: ACIP = Advisory Committee on Immunization Practices; PCV = pneumococcal conjugate vaccine; PCV15 = 15-valent PCV; PCV20 = 20-valent PCV; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

Summary

What is already known about this topic?

Currently, the 13-valent pneumococcal conjugate vaccine (PCV) (PCV13) and the 23-valent pneumococcal polysaccharide vaccine (PPSV23) are recommended for U.S. adults. Recommendations vary by age and risk groups.

What is added by this report?

On October 20, 2021, the Advisory Committee on Immunization Practices recommended 15-valent PCV (PCV15) or 20-valent PCV (PCV20) for PCV–naïve adults who are either aged ≥65 years or aged 19–64 years with certain underlying conditions. When PCV15 is used, it should be followed by a dose of PPSV23, typically ≥1 year later.

What are the implications for public health practice?

Pneumococcal vaccination recommendations were simplified across age and risk group. Eligible adults may receive either PCV15 in series with PPSV23 or PCV20 alone.

Before administering PCV20, PCV15, or PPSV23, health care providers should consult relevant package inserts (*9*,*20*,*36*) regarding precautions and contraindications. Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available at https://vaers.hhs.gov/.

Acknowledgments

Members of the Advisory Committee on Immunization Practices (member roster for August 24, 2021–June 20, 2022, is available at https://www.cdc.gov/vaccines/acip/members/index.html).

ACIP Pneumococcal Vaccines Work Group

Chair: Katherine A. Poehling, Wake Forest School of Medicine; ACIP members: Sarah S. Long, Drexel University College of Medicine; H. Keipp Talbot, Vanderbilt University Medical Center. Ex officio members: Jeffrey Kelman, Centers for Medicare & Medicaid Services; Lucia Lee, Tina Mongeau, Food and Drug Administration; Thomas Weiser, Uzo Chukwuma, Indian Health Service; Kristina Lu, Mamodikoe Makhene, National Institutes of Health; Liaison representatives: Lynn Fisher, American Academy of Family Physicians; Mark Sawyer, American Academy of Pediatrics/ Committee on Infectious Diseases; Jason Goldman, American College of Physicians; David Nace, American Geriatrics Society/ The Society for Post-Acute and LTC Medicine; Emily Messerli, Association of Immunization Managers; Elissa Abrams, Oliver Baclic, Canadian National Advisory Committee on Immunization; Carol Baker, Infectious Diseases Society of America; William Schaffner, National Foundation for Infectious Diseases; Virginia Cane, National Medical Association; Consultants: Doug Campos-Outcalt, University of Arizona; Monica M. Farley, Atlanta Veterans Affairs Medical Center/Emory University; Keith Klugman, Bill & Melinda Gates Foundation; Rebecca L. Morgan, McMaster University; Arthur Reingold, University of California, Berkeley; Lorry Rubin, Cohen Children's Medical Center of Northwell Health; Cynthia Whitney, Emory University; Richard K. Zimmerman, University of Pittsburgh. Marc Fischer, Penina Haber, Pedro Moro, Sarah Schillie, CDC.

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Section 3.0

Consent Agenda-

Straightforward Items

Consent Agenda Issues—March 2022

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
M62.81	Muscle weakness (generalized)	659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	M62.81 may be a diagnosis used for PT/OT or other supportive treatments	Add M62.81 to the dysfunction lines 71,292,345,377
N96	Recurrent pregnancy loss	658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	Recurrent pregnancy loss can be a symptom of an underlying autoimmune disorder or coagulopathy. Testing for causes is a routine part of the work up of this condition.	Remove N96 from line 658 Advise HSD to add N96 to the Diagnostic Workup File
H02.73 family	Vitiligo of eyelid and periocular area	426 SEVERE INFLAMMATORY SKIN DISEASE 654 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY 656 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	Vitiligo was recently reviewed and moved to a funded line (426) when it is severe enough to meet the criteria of GN21. The only code identified in this review was L80 (Vitiligo). The H02.73 family also represents vitiligo and should be moved to the same lines as L80 and treatment allowed under GN21. Also, the current placement is on an inappropriate line that has no skin diagnoses.	Remove H02.73 family from line 654 Add H02.73 family to lines 426 and 656
K22.10	Ulcer of esophagus without bleeding	56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE 513 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA	All other GI ulcer diagnosis codes are on line 56. K22.10 appears only on 513	Remove K22.10 from line 513 Add K22.10 to line 56

Consent Agenda Issues—March 2022

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
M35.00	Sjogren syndrome, unspecified	330 SYSTEMIC SCLEROSIS; SJOGREN'S SYNDROME 510 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION	M35.00 appears mistakenly on line 510. It should move to line 330 with all other Sjogren syndrome diagnoses	Remove M35.00 from line 510 Add M35.00 to line 330
L49.7	Exfoliation due to erythematous condition involving 70-79 percent of body surface	57 SEVERE BURNS 127 MODERATE BURNS 504 ERYTHEMATOUS CONDITIONS	L49.7 appears on lines 57 and 127. The other L49 codes appear only on line 504, which is the appropriate line.	Remove L49.7 from lines 57 and 127 Add L49.7 to line 504
H70.1 Family H70.9 family	Chronic mastoiditis Unspecified mastoiditis	170 ACUTE MASTOIDITIS 476 CHRONIC OTITIS MEDIA; OPEN WOUND OF EAR DRUM	H70.1X currently appears only on line 476. The specific treatments such as mastoidectomy appear on line 170	Remove H70.1 and H70.9 families from line 476 Add H70.1 and H70.9 families to line 170
		482 LICHEN PLANUS	More severe forms of lichen planus are included on the severe inflammatory skin disease line. Line 482 title should be changed to reflect that	Change the title of line 482 to MILD/MODERATE LICHEN PLANUS
D78.02	Intraoperative hemorrhage and hematoma of the spleen complicating other procedure	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 529 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS	D78.02 is on an unfunded line. D78.01 Intraoperative hemorrhage and hematoma of the spleen during a procedure on the spleen is on line 285; these codes should both appear on line 285.	Remove D78.02 from line 529 Add D78.02 to line 285

Consent Agenda Issues—March 2022

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
B33.2 family	Viral endocarditis, myocarditis, pericarditis, cardiomyopathy	81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 615 OTHER VIRAL INFECTIONS	The B33.2 family belongs with other similar causes of endocarditis, myocarditis, etc.	Remove B33.2 family from line 615 Add B33.2 family to line 81
H16.31 family	Corneal abscess	244 CORNEAL ULCER; SUPERFICIAL INJURY OF EYE AND ADNEXA 473 KERATOCONJUNCTIVITIS	Corneal abscesses need treatment similar to corneal ulcers	Remove H16.31 family from line 473 Add H16.31 family to line 244
C9761	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable	49 CONGENITAL HYDRONEPHROSIS 180 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER 352 URINARY SYSTEM CALCULUS	C9761 is on the Ancillary file and should be on lines similar to CPT 52356 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy) which is on lines 49, 180, and 352	Add HCPCS C9761 to lines 49, 180, and 352
67515	Injection of medication or other substance into Tenon's capsule	370 AMBLYOPIA 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN	CPT 67515 is on 8 ophthalmology lines. CareOregon is requesting that 67515 be paired with amblyopia and strabismus based on ophthalmology requests. This code is used for a steroid injection that helps with post operative pain and recovery.	Add 67515 to lines 370 and 393

Consent Agenda Issues—March 2022

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
17000	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); first lesion	373 ACNE CONGLOBATA AND ACNE FULMINANS 453 SEVERE CYSTIC ACNE 522 ROSACEA; MILD/MODERATE ACNE	17000 appears on all the acne lines inappropriately, but not the code for more than the first lesion (17003 and 17004).	Remove 17000 from lines 373, 453, 522

Straightforward Guideline Changes

March 2022

The penile anomaly guideline was modified to include acquired deformities in 2021. One diagnosis (N48.82 Acquired torsion of penis) was overlooked in this review and needs to be included in the guideline and the diagnosis added to the covered line.

HERC staff recommendations

1) Add N48.82 (Acquired torsion of penis) to line 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT and leave on line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
2) Modify GN73 as shown below

GUIDELINE NOTE 73, PENILE ANOMALIES

Lines 424,433,571,658

Congenital anomalies of the penis (ICD-10-CM Q54.4, Q55.5 and Q55.6) are included on Line 434 only when they

A. Are associated with hypospadias, OR
B. Result in documented urinary retention, OR
C. Result in repeated urinary tract infections, OR
D. Result in recurrent infections such as meatitis or balanitis, OR
E. Involve 35 degrees of curvature or greater for conditions resulting in lateral or ventral curvature, OR
F. Involve 60 degrees of rotation or greater for conditions resulting in penile torsion, OR
G. Involve aplasia/congenital absence of the penis.

Otherwise, these diagnoses are included on Line 658.

Acquired anomalies of the penis (ICD-10-CM N48.82, N48.83, N48.89 or T81.9XXA) are included on Line 424 only when they are the result of a prior penile procedure AND either

A. Result in a skin bridge, OR
B. Result in a buried penis, OR
C. Are associated with hypospadias, OR
D. Result in documented urinary retention, OR
E. Result in repeated urinary tract infections, OR
F. Result in recurrent infections such as meatitis or balanitis, OR
G. Involve 35 degrees of curvature or greater for conditions resulting in lateral or ventral curvature, OR
H. Involve 60 degrees of rotation or greater for conditions resulting in penile torsion.

Otherwise, these diagnoses are included on Line 571 or Line 658.

COVID-19 Related Codes
March 2022

Issues:

1) Several new codes were added for COVID pediatric vaccines on February 3, 2022 that includes new product and administration codes assigned to the Pfizer-BioNTech COVID-19 vaccine for children 6 months to under 5 years of age. These codes will become active upon FDA EUA or approval.

HERC staff recommendations:

CPT Code	Code Description	Recommended Placement
91308	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
0081A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose	3
0081B	Second dose	3

Newborn Home Visits

Issue: OHA requested that CPT 99502 (Home visit for newborn care and assessment) be added to the Prioritized List to allow compliance with Senate Bill 526. The program is known as "Family Connects." This code is currently listed as "Never Reviewed." OHA added this code to the Diagnostic Procedures File effective 1/1/22 and requested that it be added to the Prioritized List at next publication date. CPT 99502 is most appropriate to add to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS to pair with Well Baby visit ICD-10-CM codes.

From OHA:

> Statute now requires that all health insurance providers in Oregon (both commercial and public) offer nurse home visits to all newborns. OHA is working on creating this program for Medicaid beneficiaries as a joint venture between HSD, Public Health and Local Public Health Authorities. The purpose is to do assessments to identify the need for medical interventions. Medicaid will begin reimbursing for the program 1/1/22 using CPT 99502. The federal matching funds will come from Public Health to the Health Systems Division (HSD). Providers will not contribute match funds.

On review of Senate Bill 526, "maternal health" assessments are mandated as part of these home visits. Staff identified an additional CPT code that should be considered for addition to the Prioritized List to allow a postpartum visit: CPT 99501 (Home visit for postnatal assessment and follow-up care). This code is most appropriate on line 1 PREGNANCY to pair with ICD-10 Z39.2 (Encounter for routine postpartum follow-up).

CCOs will not be responsible for paying for these during 2022 and 2023, according to OHA staff. The services will be reimbursed through the fee-for-service Medicaid program. This arrangement may be revisited for future years beyond 2023.

HERC staff recommendations:

1) Add CPT 99502 (Home visit for newborn care and assessment) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
2) Add CPT 99501 (Home visit for postnatal assessment and follow-up care) to line 1 PREGNANCY

A-Engrossed
Senate Bill 526

Ordered by the Senate March 26
Including Senate Amendments dated March 26

Sponsored by Senators STEINER HAYWARD, HANSELL, Representatives SCHOUTEN, STARK; Senators BENTZ, BURDICK, FAGAN, FREDERICK, GOLDEN, HASS, KNOPP, MANNING JR, RILEY, TAYLOR, WAGNER, Representatives BONHAM, GREENLICK, NOBLE, WILLIAMSON (Presession filed.)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

Directs Oregon Health Authority to [*study home visiting by licensed health care providers. Requires report to interim committee of Legislative Assembly related to health care.*]

[*Sunsets January 2, 2020.*]

[*Declares emergency, effective on passage.*] **design, implement and maintain voluntary statewide program to provide nurse home visiting services to families with infants up to six months of age. Specifies desired outcomes and services. Requires authority to adopt rules specifying criteria for coverage of newborn nurse home visiting service coverage by health benefit plans.**

Requires health benefit plans to cover nurse home visiting services to enrollees with newborns without cost-sharing.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

Relating to home visiting; and prescribing an effective date.

Be It Enacted by the People of the State of Oregon:

SECTION 1. (1) As used in this section, "community" means a geographic region, county, tribe or other group of individuals living in proximity as defined by the Oregon Health Authority by rule.

(2) The authority shall design, implement and maintain a voluntary statewide program to provide universal newborn nurse home visiting services to all families with newborns residing in this state to support healthy child development and strengthen families. The authority shall design the universal newborn nurse home visiting program to be flexible so as to meet the needs of the communities where the program operates.

(3) In designing the program described in subsection (2) of this section, the authority shall consult, coordinate and collaborate, as necessary, with insurers that offer health benefit plans in this state, hospitals, local public health authorities, the Early Learning Division, existing early childhood home visiting programs, community-based organizations and social service providers.

(4) The program must provide nurse home visiting services that are:

(a) Based on criteria established by the United States Department of Health and Human Services for an evidence-based early childhood home visiting service delivery model;

(b) Provided by registered nurses licensed in this state to families caring for newborns up to the age of six months, including foster and adoptive newborns;

(c) Provided in the family's home; and

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

(d) Aimed at improving outcomes in one or more of the following domains:

(A) Child health;

(B) Child development and school readiness;

(C) Family economic self-sufficiency;

(D) Maternal health;

(E) Positive parenting;

(F) Reducing child mistreatment;

(G) Reducing juvenile delinquency;

(H) Reducing family violence; or

(I) Reducing crime.

(5) The services provided in the program must:

(a) Be voluntary and carry no negative consequences for a family that declines to participate;

(b) Be offered in every community in this state;

(c) Include an evidence-based assessment of the physical, social and emotional factors affecting the family;

(d) Be offered to all families with newborns residing in the community where the program operates;

(e) Include at least one visit during a newborn's first three months of life with the opportunity for the family to choose up to three additional visits;

(f) Include a follow-up visit no later than three months after the last visit; and

(g) Provide information and referrals to address each family's identified needs.

(6) The authority shall collect and analyze data generated by the program to assess the effectiveness of the program in meeting the aims described in subsection (4)(d) of this section and shall work with other state agencies to develop protocols for sharing data, including the timely sharing of data with primary care providers of care to the families with newborns receiving the services.

(7) In collaboration with the Department of Consumer and Business Services, the authority shall adopt by rule, consistent with the provisions of this section, criteria for universal newborn nurse home visiting services that must be covered by health benefit plans in accordance with section 3 of this 2019 Act.

SECTION 2. Section 3 of this 2019 Act is added to and made a part of the Insurance Code.

SECTION 3. (1) As used in this section, "carrier," "enrollee" and "health benefit plan" have the meanings given those terms in ORS 743B.005.

(2) A health benefit plan offered in this state must reimburse the cost of universal newborn nurse home visiting services as prescribed by the Oregon Health Authority by rule under section 1 (7) of this 2019 Act.

(3) The coverage must be provided without any cost-sharing, coinsurance or deductible applicable to the services.

(4) Carriers must offer the services in their health benefit plans but enrollees are not required to receive the services as a condition of coverage and may not be penalized or in any way discouraged from declining the services.

(5) A carrier must notify an enrollee about the services whenever an enrollee adds a newborn to coverage.

(6) A carrier may use in-network providers or may contract with local public health au-

thorities to provide the services.

(7) This section does not require a carrier to reimburse the cost of the services in any specific manner. The services may be reimbursed using:

(a) A value-based payment methodology;

(b) A claim invoicing process;

(c) Capitated payments;

(d) A payment methodology that takes into account the need for a community-based entity providing the services to expand its capacity to provide the services and address health disparities; or

(e) Any other methodology agreed to by the carrier and the provider of the services.

(8) Carriers shall report to the authority, in the form and manner prescribed by the authority, data regarding claims submitted for services covered under this section to monitor the provision of the services.

SECTION 4. The Department of Consumer and Business Services may request a waiver for state innovation under 42 U.S.C. 18052 to obtain federal financial participation in the cost of services provided under section 3 of this 2019 Act.

SECTION 5. In addition to and not in lieu of any other appropriation, there is appropriated to the Oregon Health Authority, for the biennium beginning July 1, 2019, out of the General Fund, the amount of $_____, which may be expended for carrying out section 1 of this 2019 Act.

SECTION 6. This 2019 Act takes effect on the 91st day after the date on which the 2019 regular session of the Eightieth Legislative Assembly adjourns sine die.

Significant Ligament and Tendon Injuries Coding Corrections

Question: Should various diagnosis codes for ligament and tendon injuries be added to covered lines to represent complete tendon or ligament tears or other serious injuries requiring surgical treatment?

Question source: MMC, HERC staff

Issue: There is a lack of specific ICD-10-CM codes for complete tears of certain tendons and ligaments. This makes it difficult to determine when an ICD-10-CM code indicates a serious injury that requires surgical repair, or when a code indicates a minor injury. To help with this issue, Guideline Note 98 was implemented after the 2012 ICD-10 Sports Medicine review to better clarify when an injury is on a funded versus an unfunded line. Over the years, multiple ICD-10-CM codes were added to funded lines to allow treatment, based on GN98.

HERC staff have identified additional ICD-10-CM codes on lines 608 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR and 634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS that need to move to lines covered by Guideline Note 98 or need to be added to additional lines to allow surgical treatment when indicated.

There remain some ICD-10-CM codes on line 634 that involve injuries to ligaments or tendons, but these codes are so non-specific that staff recommends they remain on this line.

GUIDELINE NOTE 98, SIGNIFICANT INJURIES TO LIGAMENTS, TENDONS AND MENISCI

Lines 376,417,432,608

Significant injuries to ligaments, tendons and/or menisci are those that result in clinically demonstrable joint instability or mechanical interference with motion. Significant injuries are covered on Line 376, Line 417, or Line 432 for both medical and surgical interventions non-significant injuries are included on Line 608.

Iliotibial (IT) band syndrome (ICD10 M76.3) is included on Line 376 only for pairing with 2 physical therapy visits with a provider licensed to provide physical therapy services, anti-inflammatory medications, and primary care office visits. Otherwise, it is included on Line 608.

Significant Ligament and Tendon Injuries Coding Corrections

HERC staff recommendations:

ICD-10 Code	Code description	Current placement	Recommended placement
S86.11 family	Strain of other muscle(s) and tendon(s) of posterior muscle group at lower leg level	608 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR	376 DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT 608
S46.00 family	Unspecified injury of muscle(s) and tendon(s) of the rotator cuff of shoulder	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	417 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6 608
S46.09 family	Other injury of muscle(s) and tendon(s) of the rotator cuff of shoulder	634	376, 417, 608
S46.19 family	Other injury of muscle, fascia and tendon of long head of biceps	634	376, 417, 608
S46.29 family	Other injury of muscle, fascia and tendon of other parts of biceps	634	376, 417, 608
S46.39 family	Other injury of muscle, fascia and tendon of triceps	634	376, 417, 608
S46.89 family	Other injury of other muscles, fascia and tendons at shoulder and upper arm level	634	376, 417, 608
S46.99 family	Other injury of unspecified muscle, fascia and tendon at shoulder and upper arm level	634	376, 417, 608
S56.00 family	Unspecified injury of flexor muscle, fascia and tendon of right thumb at forearm level	634	376,608
S56.09 family	Other injury of flexor muscle, fascia and tendon of right thumb at forearm level	634	376,608
S56.19 family	Other injury of flexor muscle, fascia and tendon of index finger at forearm level	634	376,608
S56.20 family	Unspecified injury of other flexor muscle, fascia and tendon at forearm level	634	376,608

Significant Ligament and Tendon Injuries Coding Corrections

ICD-10 Code	Code description	Current placement	Recommended placement
S56.29 family	Other injury of other flexor muscle, fascia and tendon at forearm level	634	376,608
S56.39 family	Other injury of extensor or abductor muscles, fascia and tendons of thumb at forearm level	634	376,608
S56.49 family	Other injury of extensor muscle, fascia and tendon of middle finger at forearm level	634	376,608
S56.59 family	Other injury of other extensor muscle, fascia and tendon at forearm level	634	376,608
S56.89 family	Other injury of other muscles, fascia and tendons at forearm level	634	376,608
S66.00 family	Unspecified injury of long flexor muscle, fascia and tendon of thumb at wrist and hand level	634	376,608
S66.09 family	Other specified injury of long flexor muscle, fascia and tendon of thumb at wrist and hand level	634	376,608
S66.10 family	Unspecified injury of flexor muscle, fascia and tendon of index finger at wrist and hand level	634	376,608
S66.19 family	Other injury of flexor muscle, fascia and tendon of index finger at wrist and hand level	634	376,608
S66.20 family	Unspecified injury of extensor muscle, fascia and tendon of thumb at wrist and hand level	634	376,608
S66.29 family	Other specified injury of extensor muscle, fascia and tendon of thumb at wrist and hand level	634	376,608
S66.30 family	Unspecified injury of extensor muscle, fascia and tendon of other finger at wrist and hand level	634	376,608

Significant Ligament and Tendon Injuries Coding Corrections

ICD-10 Code	Code description	Current placement	Recommended placement
S66.39 family	Other injury of extensor muscle, fascia and tendon of index finger at wrist and hand level	634	376,608
S66.40 family	Unspecified injury of intrinsic muscle, fascia and tendon of thumb at wrist and hand level	634	376,608
S66.49 family	Other specified injury of intrinsic muscle, fascia and tendon of thumb at wrist and hand level	634	376,608
S66.50 family	Unspecified injury of intrinsic muscle, fascia and tendon of index finger at wrist and hand level	634	376,608
S66.59 family	Other injury of intrinsic muscle, fascia and tendon of index finger at wrist and hand level	634	376,608
S76.09 family	Other specified injury of muscle, fascia and tendon of hip	634	376,608
S76.10 family	Unspecified injury of quadriceps muscle, fascia and tendon	634	376,608
S76.20 family	Unspecified injury of adductor muscle, fascia and tendon of thigh	634	376,608
S76.29 family	Other injury of adductor muscle, fascia and tendon of right thigh	634	376 432 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT 608
S76.39 family	Other specified injury of muscle, fascia and tendon of the posterior muscle group at thigh level	634	376, 432, 608
S86.00 family	Unspecified injury of right Achilles tendon	634	376,608
S86.09	Other specified injury of Achilles tendon	634	376,608

Significant Ligament and Tendon Injuries Coding Corrections

ICD-10 Code	Code description	Current placement	Recommended placement
S86.19	Other injury of other muscle(s) and tendon(s) of posterior muscle group at lower leg level	634	376, 432, 608
S86.29	Other injury of muscle(s) and tendon(s) of anterior muscle group at lower leg level	634	376, 432, 608
S86.39	Other injury of muscle(s) and tendon(s) of peroneal muscle group at lower leg level	634	376, 432, 608
S96.00 family	Unspecified injury of muscle and tendon of long flexor muscle of toe at ankle and foot level	634	376,608
S96.09 family	Other injury of muscle and tendon of long flexor muscle of toe at ankle and foot level	634	376,608
S96.10 family	Unspecified injury of muscle and tendon of long extensor muscle of toe at ankle and foot level	634	376,608
S96.19 family	Other specified injury of muscle and tendon of long extensor muscle of toe at ankle and foot level	634	376,608
S96.20 family	Unspecified injury of intrinsic muscle and tendon at ankle and foot level	634	376,608
S96.29 family	Other specified injury of intrinsic muscle and tendon at ankle and foot level	634	376,608

Intravascular Lithotripsy for Peripheral Vascular Disease
2022 Coding Update

Issue:
In January 2021, HCPCS C9772-C9775 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy) were reviewed and found to be experimental. Recently, several similar HCPCS codes were brought to HERC staff attention as highly related but listed as Ancillary. These codes need to be added to the line 662/GN173 entry created for HCPCS C9772-C9775.

HERC staff summary from January 2021: Intravascular shockwave lithotripsy of the lower extremity arteries has only been studied in small, non-randomized trials. This technology appears to be experimental.

HCPCS codes:
C9764: Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
C9765 Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9766 Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
C9767 Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed

HERC staff recommendation
1) Add HCPCS C97640-C9767 to line 662/GN173
2) Edit 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 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
C9764-C9767 C9772-C9775	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies) ~~tibial/peroneal artery(ies),~~ with intravascular lithotripsy	Insufficient evidence of effectiveness	March 2022

Pica in Adults

Question: Should the diagnosis code for childhood pica be removed from the unfunded pica line? If so, should the line be renamed?

Question source: Dr. Ben Hoffman, OHSU pediatrician (and new HERC member)

Issue: Childhood pica (ICD-10-CM F98.3) is on both lines 149 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD and on line 631 PICA. There are types of childhood pica (e.g., ice) that don't require treatment. However, Dr. Hoffman points out that pica is common in children, particularly those with developmental disorders. Any type of pica that affects the child's growth or health would be included on the upper line (line 149). The lower line contains the diagnosis code for adult pica (ICD-10-CM F50.89). Generally, having a diagnosis on both a funded and an unfunded line without a guideline is confusing to reviewers.

HERC staff recommendations:

1) Remove ICD-10-CM F98.3 (Pica of infancy and childhood) from line 631 PICA
2) Rename line 631 PICA IN ADULTS

Foot Arthrodesis for Osteoarthritis

Question: Should arthrodesis be paired with mid-foot osteoarthritis?

Question source: Alison Little, CCO medical director

Issue: Mid-foot arthrodesis ("fusion") is a treatment for osteoarthritis of various bones of the foot. Currently, arthrodesis for treatment of arthritis of the MTP joint ("big toe"; CPT 28289-28291) and ankle arthritis (CPT 27870) are on covered lines. Arthrodesis of the metatarsals for midfoot fractures is also covered. However, arthrodesis for midfoot arthritis is on line 542 DEFORMITIES OF FOOT. Dr. Little has received requests for pairing of midfoot arthritis with arthrodesis.

Current Prioritized List status

CPT Code	Code Description	Placement
28730	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse;	132 OPEN FRACTURE/DISLOCATION OF EXTREMITIES 355 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES) 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS 542 DEFORMITIES OF FOOT
M19.071 M19.072 M19.079	Primary osteoarthritis, foot	356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE 463 OSTEOARTHRITIS AND ALLIED DISORDERS

Evidence

1) **Seybold 2016,** surgical management of midfoot arthritis
    a. Studies evaluating the outcomes of surgical treatment of post-traumatic midfoot arthritis
        i. Case series N=16 (Sangeorzan et al)
            1. 92% fusion rate. Only 69% of patients reported good to excellent results although 94% of patients were satisfied with their outcomes.
        ii. Case series N=32 (Komenda et al)
            1. At a minimum 2-year follow-up (mean, 50 mo), American Orthopaedic Foot and Ankle Society (AOFAS) midfoot scores improved significantly from 44 to 78.
        iii. Case series N=40 (Mann et al)
            1. 98% fusion rate and 93% patient satisfaction at an average of 6 years follow-up.
            2. >25% complication rate (metatarsalgia, second metatarsal stress fractures, and neuromas)
        iv. Case series N=72 (Filippi et al)
            1. All but 3 patients demonstrated evidence of radiographic union by 12 weeks postoperatively
            2. 17% reported postoperative complications (wound dehiscence, hardware breakage, tendon adhesions, neuropraxis)

v. Case series N=22 (Raikin and Schon)
    1. Significant decreases were reported in visual analog pain scale scores from 5.1 to 1.3 postoperatively. AOFAS midfoot scores improved from 35 to 78
vi. Overall complication rates as high as 30%

HERC staff summary

Midfoot arthrosis for arthritis has only been studied in case series. Pain and function generally decrease after surgery. There is a very high rate of post-operative complications.

HERC staff recommendation:

1) Make no change in the non-pairing of mid-foot arthrosis with foot arthritis

Surgical Management of Posttraumatic Midfoot Deformity and Arthritis

Jeffrey D. Seybold, MD and J. Chris Coetzee, MD

Abstract: Posttraumatic joint disruption and deformity remains one of the most common etiologies for midfoot degenerative joint disease. Patients presenting with midfoot arthritis commonly complain of increased pain with weight-bearing activity, and tenderness over the dorsum of the foot with constrictive shoe wear secondary to dorsal osteophyte formation. Nonoperative measures assist with symptom control, focusing on limiting both pain and deformity. Operative intervention is generally considered after an adequate trial of nonoperative measures. Arthrodesis procedures remain the "gold standard" for operative treatment of midfoot arthritis. Interpositional tendon arthroplasty of the fourth and fifth tarsometatarsal joints has been supported as a motion-sparing alternative to arthrodesis for patients with lateral column disease. The indications, complications, postoperative management, and techniques for posttraumatic midfoot arthritis procedures are discussed in further detail below.

Level of Evidence: Diagnostic Level 5. See Instructions for Authors for a complete description of levels of evidence.

Key Words: posttraumatic, arthritis, midfoot, lateral column, Lisfranc

(*Tech Foot & Ankle* 2016;15: 79–86)

HISTORICAL PERSPECTIVE

The naviculocuneiform (NC) joints, the tarsometatarsal (TMT) joints, and the intercuneiform joints define the borders of the midfoot. The TMT articulations are further divided into 3 columns: the first TMT joint defines the medial column, the second and third TMT joints form the middle column, and the articulation between the cuboid and the fourth and fifth metatarsals define the lateral column.[1] The medial and middle columns are stiff structures, accommodating for only 4 degrees of dorsiflexion, 1 degree of plantarflexion, and 2 degrees of supination and pronation. The lateral column is much more mobile, allowing for 10 degrees of dorsiflexion, plantarflexion, supination, and pronation.[2]

The exact incidence of midfoot arthritis is unknown, as many patients may never develop symptoms that require formal evaluation. Posttraumatic arthritis remains the most common identified etiology of midfoot arthritis—whereas Lisfranc fracture-dislocations account for only 0.2% of all fractures, the reported incidence of arthritic changes after this injury is as high as 30%.[3,4] In a Lisfranc injury, primary disruption of the weak dorsal ligaments may lead to instability of the TMT and intercuneiform joints. In more severe injuries, the stronger plantar and interosseous Lisfranc ligaments may tear, resulting in TMT joint subluxation and/or dislocation with dorsal displacement of the metatarsals. Even after early identification and anatomic reduction, the cartilage and ligament damage sustained at the time of injury may lead to abnormal joint loading, progressive and eccentric wear patterns, and subsequent degenerative joint disease.

Kuo et al[4] reported outcomes for 48 patients with Lisfranc injuries, noting a 25% incidence of posttraumatic arthritis despite operative fixation within 6 weeks of injury. The sole statistically significant factor affecting the onset of posttraumatic arthritis in this series was anatomic versus nonanatomic reduction and fixation, with onset of degenerative changes occurring in 16% versus 60% of these cohorts, respectively. Philbin et al[5] noted a significant difference in rates of posttraumatic arthritis relative to timing of fixation, with a 23% incidence of midfoot arthritis after delayed presentation or treatment of Lisfranc injuries (defined as over 6 wk from injury) versus a 9.5% incidence in patients treated within a 6-week postinjury window. Multiple authors have supported these findings, noting that the severity of injury and anatomic reduction are critical factors in limiting the development of posttraumatic degenerative changes.[6,7] Unfortunately, the incidence of missed or mistreated Lisfranc injuries, and the resulting increase in posttraumatic degenerative changes, is likely underreported.

The difficulty treating patients with missed or malreduced TMT fracture-dislocations is well-described.[1,7,8] Kuo et al[4] observed a trend toward increased rates of posttraumatic arthritis following purely ligamentous Lisfranc injuries, which may be related to the difficulty initially diagnosing the injury. As the ligamentous structures of the midfoot become attenuated, the normally rigid midfoot joints lose their support. Foot deformity progresses with forefoot abduction, midfoot pronation, medial column dorsiflexion, and lateral column shortening. Elongation of the posterior tibial tendon and contracture of the peroneal and Achilles tendons occurs with continued midfoot collapse.

INDICATIONS AND CONTRAINDICATIONS

Nonoperative treatment is always pursued with a focus on limiting pain and accommodating or limiting progressive deformity. Nonsteroidal anti-inflammatory drugs, ice, and limiting impact activity may all decrease inflammation and pain associated with midfoot degenerative disease. Rigid orthotic devices, such as a full-length carbon fiber plate, stiffen the shoe and limit motion through the midfoot with gait. Any orthotic device should provide a soft, conforming contour that supports the foot but does not attempt to correct rigid deformity. Rocker bottom modifications not only stiffen the shoe, but also decrease the bending moment arm at the midfoot and limit stress at the TMT joints during the toe-off stage of gait.[9]

Failure of nonoperative management, manifested by persistent pain and diminished quality of life, after 3 months of treatment is an indication for surgery. Severe deformity associated with impending skin breakdown necessitates more urgent operative intervention, regardless of the duration of conservative care. In general, arthrodesis procedures that include a corrective osteotomy are indicated for sagittal or transverse plane deformity at the TMT joints greater than 15 degrees or displacement

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Section 4.0

New Discussion Items

Chemodenervation Guideline Updates

Question: Should two additional lines with chemodenervation (with botulinum toxin) CPT codes be added to the chemodenervation guideline?

Question source: Max Kaiser, CCO medical director

Issue: Guideline Note 219 CHEMODENERVATION was created last year when coding specifications regarding chemodenervation (e.g. Botox treatments) were removed from lines and consolidated into a guideline. Dr. Kaiser pointed out that GN219 is missing an entry for line 500 SIALOLITHIASIS, MUCOCELE, DISTURBANCE OF SALIVARY SECRETION, OTHER AND UNSPECIFIED DISEASES OF SALIVARY GLANDS which contains CPT 64611 (Chemodenervation of parotid and submandibular salivary glands, bilateral). Additionally, the guideline is missing an entry for line 526 CHRONIC ANAL FISSURE which contains CPT 46505 (Chemodenervation of internal anal sphincter). Staff recommend adding these two additional lines to the guideline as it is confusing to CCOs to not include all relevant lines that deal with Botox and similar treatments.

HERC staff recommendation:

1) Modify GN219 as shown below to clarify placement of chemodenervation for conditions on lines 500 and 526.

GUIDELINE NOTE 219, CHEMODENERVATION

Lines 292,327,351,362,378,393,410,500,517,526

Inclusion of chemodenervation on the Prioritized List has the following limitations for the lines specified below:

Line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS

Chemodenervation with botulinum toxin injection (CPT 64642-64647) is included on this line for treatment of upper and lower limb spasticity (ICD-10-CM codes G24.02, G24.1, G35, G36.0, I69.03- I69.06 and categories G71, and G80-G83)

Line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION

Chemodenervation of the bladder (CPT 52287) is included on this line only for treatment of idiopathic detrusor over-activity or neurogenic detrusor over-activity (ICD-10-CM N32.81) in patients who have not responded to or been unable to tolerate at least two urinary incontinence antimuscarinic therapies (e.g. fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, trospium). Treatment is limited to 90 days, with additional treatment only if the patient shows documented positive response. Positive response to therapy is defined as a reduction of urinary frequency of 8 episodes per day or urinary incontinence of 2 episodes per day compared to baseline frequency.

Line 351 STRABISMUS DUE TO NEUROLOGIC DISORDER

Chemodenervation with botulinum toxin injection (CPT 67345) is included on this line for the treatment of strabismus due to other neurological disorders (ICD-10-CM H50.89).

Line 362 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM

Chemodenervation with botulinum toxin injection (CPT 64612, 64616) is included on this line only for treatment of blepharospasm (ICD-10-CM G24.5), spasmodic torticollis (ICD-10-CM G24.3), and other fragments of torsion dystonia (ICD-10-CM G24.9).

Line 378 ESOPHAGEAL STRICTURE; ACHALASIA

Chemodenervation with botulinum toxin injection (CPT 43201) is included on this line for treatment of achalasia (ICD-10 K22.0).

Line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN

Chemodenervation with botulinum toxin injection (CPT 67345) is included on this line for the treatment of strabismus due to other neurological disorders (ICD-10-CM H50.89).

Line 410 MIGRAINE HEADACHES

Chemodenervation for treatment of chronic migraine (CPT 64615) is included on this line for prophylactic treatment of adults who meet all of the following criteria:

A) have chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine

B) has not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies (e.g. beta-blocker, anticonvulsant or tricyclic antidepressant)

C) their condition has been appropriately managed for medication overuse

D) treatment is administered in consultation with a neurologist or headache specialist.

Treatment is limited to two injections given 3 months apart. Additional treatment requires documented positive response to therapy. Positive response to therapy is defined as a reduction of at least 7 headache days per month compared to baseline headache frequency.

Line 500 SIALOLITHIASIS, MUCOCELE, DISTURBANCE OF SALIVARY SECRETION, OTHER AND UNSPECIFIED DISEASES OF SALIVARY GLANDS

Chemodenervation with botulinum toxin injection (CPT 64611) is included on this line for the treatment of excessive salivation.

Line 517 DISORDERS OF SWEAT GLANDS

Chemodenervation with botulinum toxin injection (CPT 64650, 64653) is included on this line for the treatment of axillary hyperhidrosis and palmar hyperhidrosis (ICD-10-CM L74.52, R61).

Line 526 CHRONIC ANAL FISSURE

Chemodenervation with botulinum toxin injection (CPT 46505) is included on this line for the treatment of anal fissures.

Enteropathic Arthropathies

Question: Should enteropathic arthropathies (various forms of inflammatory arthritis represented by ICD-10-CM M07.6 family) be moved to a funded line?

Question source: HERC staff

Issue: HERC staff have been reviewing unfunded diagnoses on the Prioritized List to determine if any are inappropriately prioritized. Enteropathic arthropathies are only found on line 659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. All other inflammatory polyarthropathies are included on line 46 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES

Enteropathic arthropathy is a spondylarthritis which occurs in patients with inflammatory bowel diseases and other gastrointestinal diseases, such as Whipple's disease, celiac disease, and intestinal bypass surgery. Enteropathic arthropathy is treated with anti-inflammatory or immunosuppressant medications, including immunomodulatory medications. Local treatments such as joint steroid injections are also used. No previous review of this topic was identified.

All private payers surveyed considered the ICD-10-CM M07.6 code family to be inflammatory polyarthropathies and covered a wide range of treatments for this condition.

HERC staff recommendation

1) Remove ICD-10-CM M07.6 code family (enteropathic arthropathy) from line 659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY.
2) Add ICD-10-CM M07.6 family (enteropathic arthropathy) to line 46 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES

Hindawi Publishing Corporation
Clinical and Developmental Immunology
Volume 2013, Article ID 631408, 12 pages
http://dx.doi.org/10.1155/2013/631408

Review Article

Enteropathic Spondyloarthritis: From Diagnosis to Treatment

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Enteropathic arthritis (EA) is a spondyloarthritis (SpA) which occurs in patients with inflammatory bowel diseases (IBDs) and other gastrointestinal diseases. Diagnosis is generally established on the medical history and physical examination. It was, generally, made according to the European Spondyloarthropathy Study Group (ESSG) criteria. Rheumatic manifestations are the most frequent extraintestinal findings of IBD with a prevalence between 17% and 39%, and IBD is associated, less frequently, with other rheumatic disease such as rheumatoid arthritis, Sjogren syndrome, Takayasu arteritis, and fibromyalgia. Although the pathogenesis of EA has not been plainly clarified, the most popular theory supposes that joint inflammation occurs in genetically predisposed subjects with bacterial gut infections, provided an important evidence for a possible relationship between inflammation of the gut mucosa and arthritis. The management of patients with EA requires an active cooperation between the gastroenterologist and rheumatologist.

1. Introduction

Enteropathic arthritis or enteroarthritis (EA) is a spondyloarthritis (SpA) which occurs in patients with inflammatory bowel diseases (IBDs) and other gastrointestinal diseases, such as Whipple's disease (WD), celiac disease (CD), and intestinal bypass surgery [1, 2].

A relationship between bowel and joints was reported for the first time by Smith in 1922, who described in patients with rheumatoid arthritis (RA) underwent surgery for colectomy an improvement of articular symptoms [3]. Later, Bargen et al. [4], in 1929, and Hench [5], in 1935, described a peripheral arthritis involvement in patients with IBD and also reported the arthritis tendency to flare with exacerbation of the colitis and to recede with the remission of bowel symptoms. At the end of the 1950s, some authors described the occurrence of sacroiliitis in patients with UC [6] and CD [7–9]. Finally, in 1964, the American Rheumatism Association classified arthritis associated with IBD as independent clinical form [10], and, later, Wright and Moll included enteroarthritis definitively among SpA group [11]. In the group of enteropathic spondyloarthritis, more lately, the rare Whipple's disease [12, 13] and postenteritis reactive forms [14, 15] were also included.

The aim of this review is to describe clinical and pathophysiological data about EA. However, because of the significant lack of studies on this specific issue, most of results are derived from studies on IBD or other types of spondyloarthritis.

2. Classification Criteria

Diagnosis is generally established on the medical history and physical examination, because at present no "gold standard" criteria is available for the diagnosis of EA. Thus, being the SpA a group of distinct diseases with similar clinical features and a common genetic predisposition [16], the diagnosis

Erythropoietin in Chronic Renal Disease

Question: Should several changes be made to the Prioritized List to clarify coverage for erythropoietin for non-end stage renal disease?

Question source: Jennifer Smith, PharmD, pharmacy manager, Providence Health Plan

Issue: Chronic renal failure with a hemoglobin level <10 was added as an indication for erythropoiesis-stimulating agents in Guideline Note 7 in 2012. The current GN7 only applies to Line 59 END STAGE RENAL DISEASE. Line 59 only includes ICD-10-CM N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease). Earlier stages of chronic kidney disease (ICD-10-CM N18.1-N18.4 and N18.9) are on line 339 CHRONIC KIDNEY DISEASE which is not referenced in the guideline. Additionally, ICD-10-CM D63.1 (Anemia in chronic kidney disease) is only on line 574 ANEMIAS DUE TO DISEASE. According to P&T, all ICD-10 codes above the funding line (i.e., all N18 series codes) are being funded for erythropoietin currently in their PA process.

The FDA has approved erythropoietin for all stages of chronic kidney disease with a low hemoglobin level. All private insurers cover the ICD-10-CM codes noted above for erythropoietin use.

FDA Epogen labeling 7/2018:
1 INDICATIONS AND USAGE

1.1 Anemia Due to Chronic Kidney Disease

Epogen is indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.

For adult patients with CKD on dialysis:
• Initiate Epogen treatment when the hemoglobin level is less than 10 g/dL.
• If the hemoglobin level approaches or exceeds 11 g/dL, reduce or interrupt the dose of Epogen.
• The recommended starting dose for adult patients is 50 to 100 Units/kg 3 times weekly intravenously or subcutaneously. The intravenous route is recommended for patients on hemodialysis.

For adult patients with CKD not on dialysis:
• Consider initiating Epogen treatment only when the hemoglobin level is less than 10 g/dL and the following considerations apply:
  o The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion and,
  o Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal
• If the hemoglobin level exceeds 10 g/dL, reduce or interrupt the dose of Epogen, and use the lowest dose of Epogen sufficient to reduce the need for RBC transfusions.
• The recommended starting dose for adult patients is 50 to 100 Units/kg 3 times weekly intravenously or subcutaneously.

For pediatric patients with CKD:
• Initiate Epogen treatment only when the hemoglobin level is less than 10 g/dL.
• If the hemoglobin level approaches or exceeds 12 g/dL, reduce or interrupt the dose of Epogen.
• The recommended starting dose for pediatric patients (ages 1 month or older) is 50 Units/kg 3 times weekly intravenously or subcutaneously.

HERC staff recommendations:

1) Add D63.1 (Anemia in chronic kidney disease) to Line 339 CHRONIC KIDNEY DISEASE
    a. Delete D63.1 from Line 574 ANEMIAS DUE TO DISEASE
2) Add Guideline Note 7 to Line 339
    a. Will ensure that the N18 code series is regulated by this guideline
3) Modify GN7 as shown below

GUIDELINE NOTE 7, ERYTHROPOIESIS-STIMULATING AGENT (ESA) GUIDELINE

Lines 12,59,92,94,111-115,125,133,135,157,158,161,163,179,191,199,200,208,210,214,215,217, 229,234,237,238,258-262,271,276,286-288,294,295,314-316,329,339,396,397,401,419,435,559,593

A) Indicated for anemia (Hgb < 10gm/dl or Hct < 30%) induced by cancer chemotherapy given within the previous 8 weeks or in the setting of myelodysplasia.
    1) Reassessment should be made after 8 weeks of treatment. If no response, treatment should be discontinued. If response is demonstrated, ESAs should be discontinued once the hemoglobin level reaches 10, unless a lower hemoglobin level is sufficient to avoid the need for red blood cell (RBC) transfusion.

B) Indicated for anemia (Hgb < 10gm/dl or HCT < 30%) associated with HIV/AIDS.
    1) An endogenous erythropoietin level < 500 IU/L is required for treatment, and patient may not be receiving zidovudine (AZT) > 4200 mg/week.
    2) Reassessment should be made after 8 weeks. If no response, treatment should be discontinued. If response is demonstrated, the lowest ESA dose sufficient to reduce the need for RBC transfusions should be used, and the Hgb should not exceed 11gm/dl.

C) Indicated for anemia (Hgb < 10 gm/dl or HCT <30%) associated with chronic renal disease ~~failure~~, with or without dialysis.
    1) Reassessment should be made after 12 weeks. If no response, treatment should be discontinued. If response is demonstrated, the lowest ESA dose sufficient to reduce the need for RBC transfusions should be used, and the Hgb should not exceed 11gm/dl. In those not on dialysis, the Hgb level should not exceed 10gm/dl.

Pelvic Congestion Syndrome

Question: Should the diagnosis and treatment of pelvic congestion syndrome be moved to the funded region of the Prioritized List?

Question source: Carl Stevens, CCO medical director

Issue: Pelvic congestion syndrome is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia and postcoital pain and aggravated by standing. The underlying etiology is thought to be related to varices of the ovarian veins, leading to pelvic vascular congestion. Because there are many etiologies of chronic pelvic pain, pelvic congestion syndrome is often a diagnosis of exclusion, with the identification of varices using a variety of imaging methods, such as magnetic resonance imaging, computed tomography, or contrast venography. However, the syndrome is still not well-defined, and it is unclear whether pelvic congestion syndrome causes chronic pelvic pain. Although venous reflux is common, not all women with this condition experience chronic pelvic pain and, conversely, chronic pelvic pain is reported by women without pelvic congestion syndrome.

Initial treatment of pelvic congestion syndrome includes psychotherapy and medical therapy (e.g., nonsteroidal anti-inflammatory drugs) and hormonal therapy. For patients who fail initial therapy, surgical ligation of the ovarian vein may be considered. Embolization therapy and/or sclerotherapy of the ovarian and internal iliac veins has been proposed as an alternative to surgical ovarian vein ligation.

CareOregon has been receiving requests for pelvic vein embolization for pelvic congestion syndrome and would like HERC guidance on treatments for this condition.

Current Prioritized List status

CPT code	**Code description**	**Current Placement**
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)	**327** FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION **547** SUBLINGUAL, SCROTAL, AND PELVIC VARICES **627** BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
ICD-10 Code		
I86.2	Pelvic varices	**547** SUBLINGUAL, SCROTAL, AND PELVIC VARICES
N94.89	Other specified conditions associated with female genital organs and menstrual cycle [includes pelvic congestion syndrome as a subdiagnosis]	**532** CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA
R10.2	Pelvic and perineal pain	**532**

Pelvic Congestion Syndrome

Evidence

1) **Champaneria 2014**, Health Technology Assessment, the relationship between pelvic vein incompetence and chronic pelvic pain in women: systematic reviews of diagnosis and treatment effectiveness. https://www.journalslibrary.nihr.ac.uk/hta/hta20050/#/full-report
    a. Accuracy review N=12 studies (10 ultrasound, 2 MRI vs conventional venography)
        i. There was no single, clearly-defined criterion for a diagnosis that was reported in all of the studies included in the review.
        ii. The proportion of women found to have pelvic vein incompetence (PVI) who reported chronic pelvic pain (CPP) ranged considerably, from 39% to 91%.
    b. Effusiveness review N=22 studies (1 poor quality RCT of 1208 women, 21 case series)
        i. Approximately one-third of patients clearly had bilateral embolisation, with metal coil placement being the dominant technique. Early substantial relief from pain symptoms was observed in approximately 75% of women, a figure which generally increased over time and was sustained. Where pain was measured on a visual analogue scale, statistically significant reductions following treatment were observed in all studies. Reintervention rates were generally low. Where measured, embolisation reduced the diameter of dilated veins to a significant degree, with minimal residual reflux. There were few data on the impact on menstruation, ovarian reserve or fertility, but no concerns were noted. Transient pain was a common occurrence following foam embolisation, while there was a < 2% risk of coil migration
    a. Conclusions: The data supporting the diagnosis and treatment of PCS are limited and of variable methodological quality. There is some evidence to tentatively support a causative association, but it cannot be categorically stated that PVI is the cause of CPP in women with no other pathology. Embolisation appears to provide symptomatic relief in the majority of women and is safe. However, the majority of included studies of embolism were relatively small case series and only the randomized controlled trial was considered at risk of potential biases.

Expert Guideline

1) **ACOG 2020**, Practice Bulletin 218 Chronic Pelvic Pain
    a. Pelvic congestion syndrome is a proposed etiology of chronic pelvic pain related to pelvic venous insufficiency. Although venous congestion appears to be associated with chronic pelvic pain, evidence is insufficient to conclude that there is a cause-and-effect relationship. In addition, there is no consensus on the definition of this condition, and diagnostic criteria are variable. Further research is needed to establish greater consistency in diagnosis and homogeneity in treatment studies.

Other payer policies

1) **Aetna 2021**: Aetna considers embolization (e.g., using metallic coils or foam/gel sclerotherapy) of gonadal veins or ovarian veins, with or without the internal iliac veins, medically necessary for the treatment of pelvic congestion syndrome (PCS) when both of the following criteria are met:
    a. The member has had a definitive diagnostic venography, computed tomography (CT) or magnetic resonance imaging (MRI); *and*
    b. The member has failed a trial of appropriate pharmacotherapy (e.g., analgesics, hormonal therapy).

2) **United Healthcare 2021**: Embolization of the Ovarian Vein or Internal Iliac Vein is unproven and not medically necessary for treating Pelvic Congestion Syndrome due to insufficient evidence of efficacy
3) **Wellmark BCBS 2021**: Endovascular occlusion of the ovarian vein and internal iliac veins is considered investigational as a treatment of pelvic congestion syndrome because the evidence is insufficient to determine the effects of the technology on net health outcomes.

Pelvic Congestion Syndrome

HERC staff summary

Pelvic congestion syndrome is a poorly defined entity with no standardized diagnostic criteria. Pelvic vein embolization for treatment of pelvic congestion syndrome appears promising, but the evidence base to date is very small and at high risk of bias. Most private insurers do not cover treatment for pelvic congestion syndrome. ACOG notes there are no agreed upon diagnostic or treatment criteria.

HERC staff recommendations:

1) Add a new guideline note to line 532 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA as shown below

GUIDELINE NOTE XXX PELVIC CONGESTION SYNDROME

Line 532

Pelvic congestion syndrome is included on this line using ICD-10-CM N94.89. This condition does not pair with any vein embolization procedures due to lack of evidence of effectiveness.

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

ACOG PRACTICE BULLETIN

Clinical Management Guidelines for Obstetrician–Gynecologists

NUMBER 218

Committee on Practice Bulletins—Gynecology. This Practice Bulletin was developed by the American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Gynecology in collaboration with Lee A. Learman, MD, PhD, and Katherine W. McHugh, MD.

Chronic Pelvic Pain

Chronic pelvic pain is a common, burdensome, and costly condition that disproportionately affects women. Diagnosis and initial management of chronic pelvic pain in women are within the scope of practice of specialists in obstetrics and gynecology. The challenging complexity of chronic pelvic pain care can be addressed by increased visit time using appropriate coding modifiers, as well as identification of multidisciplinary team members within the practice or by facilitated referral. This Practice Bulletin addresses the diagnosis and management of chronic pelvic pain that is not completely explained by identifiable pathology of the gynecologic, urologic, or gastrointestinal organ systems. When evidence on chronic pelvic pain treatment is limited, recommendations are extrapolated from treatment of other chronic pain conditions to help guide management. The evaluation and management of potential gynecologic etiologies of pelvic pain (ie, endometriosis, adenomyosis, leiomyomas, adnexal pathology, vulvar disorders) are discussed in other publications of the American College of Obstetricians and Gynecologists (1–4).

Background

Definition

A lack of consensus on the definition of chronic pelvic pain has impeded efforts to understand its prevalence and the success of treatment alternatives (5). The American College of Obstetricians and Gynecologists and the ReVITALize data definitions initiative define *chronic pelvic pain* as "pain symptoms perceived to originate from pelvic organs/structures typically lasting more than 6 months. It is often associated with negative cognitive, behavioral, sexual and emotional consequences as well as with symptoms suggestive of lower urinary tract, sexual, bowel, pelvic floor, myofascial, or gynecological dysfunction" (6). Cyclical pelvic pain is considered a form of chronic pelvic pain if it has significant cognitive, behavioral, sexual, and emotional consequences (6). This Practice Bulletin does not address cyclic pain syndromes (eg, dysmenorrhea, Mittelschmerz) but does discuss dyspareunia as a component of chronic pelvic pain.

Chronic pelvic pain differs from acute pelvic pain in several important ways. Acute pain typically arises from an inflammatory, infectious, or anoxic event or traumatic injury that resolves over time with treatment and repair. When pain persists, a chronic stress phenotype may emerge and is characterized by a vicious cycle of physical and psychologic consequences. Prolonged activity restriction can lead to physical deconditioning. Continued fear, anxiety, and distress can lead to long-term deterioration in mood and social isolation. Although mood symptoms are ubiquitous in chronic pain syndromes, criteria for major depression are met in approximately 12–33% of women across samples of women living with or seeking care for chronic pelvic pain (7–9).

Epidemiology

A systematic review of high-quality studies by the World Health Organization in 2006 found the prevalence to range from approximately 2.1% to 24% for noncyclical pain, 8% to 21.1% for dyspareunia, and 16.8% to 81% for dysmenorrhea (10). An updated review published in 2014 used a more stringent definition (noncyclical pain lasting at least 6 months) and found prevalence estimates that ranged from 5.7% to 26.6% (11). Familiarity with contributors to

Section 5.0

Coverage Guidances

Health Evidence Review Commission (HERC)

Coverage Guidance: High-Frequency Chest Wall Oscillation Devices

DRAFT for VbBS/HERC Meeting 3/10/2022

HERC Coverage Guidance

High-frequency chest wall oscillation devices are recommended for coverage for patients with cystic fibrosis (*weak recommendation*) when there is documentation of frequent exacerbations requiring antibiotics, frequent hospitalization, or rapidly declining lung function measured by spirometry, despite either:

A) having received chest physiotherapy and positive expiratory pressure therapy, OR
B) documentation that chest physiotherapy and positive expiratory pressure devices are not tolerated or not available (e.g., inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are recommended for coverage for patients with non–cystic fibrosis bronchiectasis (*weak recommendation*) when the 4 criteria below are met:

A) The bronchiectasis is confirmed by computed tomography (CT) scan, AND
B) There is evidence of chronic lung infection, AND
C) The patient has experienced either:
    1) daily productive cough for at least 6 continuous months, OR
    2) frequent (> 2 times a year) exacerbations requiring antibiotic therapy, AND
D) The patient has received chest physiotherapy and positive expiratory pressure therapy OR chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are recommended for coverage for patients with neuromuscular disease resulting in chronic lung disease (*weak recommendation*) when there is evidence of chronic lung infection, despite either:

A) having received chest physiotherapy and positive expiratory pressure therapy, OR
B) documentation that chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are not recommended for coverage for patients with chronic obstructive pulmonary disease *(weak recommendation)*.

Note. Definitions for strength of recommendation are in Appendix A, GRADE Table Element Descriptions. Rationales for each recommendation appear below in the GRADE table.

Oregon Health Authority

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Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

The Health Evidence Review Commission (HERC) uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on diagnostic and clinical interventions, evidence is evaluated using an adaptation of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness could depend on the environment in which the intervention is implemented.

GRADE Table

HERC develops recommendations by using the concepts of the GRADE system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and assesses each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by HERC based on the assessment of two independent reviewers from the Center for Evidence-based Policy.

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence considering all available information. Such assessments are informed by clinical epidemiologists from the Center for Evidence-based Policy. Unless otherwise noted, statements regarding resource allocation, values and preferences, and other considerations are the assessments of HERC, as informed by the evidence reviewed, public testimony, and subcommittee discussion.

Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences and other considerations. See Appendix A for more details about the factors that constitute the GRADE table.

GRADE Tables

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with cystic fibrosis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Hospitalizations *(Critical outcome)*	Compared to positive expiratory pressure: no significant difference. ●●○○ *(low confidence, based on 4 RCTs, n = 128)* Compared to conventional chest physiotherapy: No significant difference. ●●○○ *(low confidence, based on 4 RCTs, n = 128)*	Coverage of high-frequency chest wall oscillation would add significant cost compared to chest physiotherapy or positive expiratory pressure devices. However, in situations in which chest physiotherapy is not consistently available or tolerated and positive expiratory pressure devices are not effective or tolerated, the additional cost of the high-frequency chest wall oscillation device would be offset to the extent that it reduces hospitalizations and exacerbations.	Patients may prefer treatment options that can be self-administered, confer greater independence, and ensure reliable and consistent treatment.	Some patients may not be able to tolerate chest physiotherapy or positive expiratory pressure devices. Some patients may not have caregivers who are available or physically able to administer daily chest physiotherapy.
Mortality *(Critical outcome)*	No evidence			
Pulmonary Exacerbations Requiring Antibiotics *(Important outcome)*	Compared to positive expiratory pressure: significantly more exacerbations (median, 2.0; interquartile range, 1.0 to 3.0) than the positive expiratory pressure therapy group (median, 1.0; interquartile range, 0.0 to 2.0; *P* = .007) ●○○○ *(very low confidence, based on 1 RCT, n = 107)* Compared to chest physiotherapy: no significant difference (mean difference, -0.20; 95% CI, -2.32 to 1.92; *P* > .05). ●○○○ *(very low confidence, based on 1 RCT, n = 50)* Compared to other oral or external oscillatory devices: no significant difference ●○○○ *(very low confidence, based on 1 RCT, n = 16)*			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with cystic fibrosis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Exercise Capacity *(Important outcome)*	No evidence	Chest physiotherapy must be provided by a trained caregiver for 20 to 40 minutes, one or more times per day; could be provided by a paid or unpaid caregiver.		
Breathlessness or Cough *(Important outcome)*	No evidence			

Balance of benefits and harms: Based on low-confidence evidence, high-frequency chest wall oscillation devices have similar outcomes to other chest clearance devices or chest physiotherapy for reducing hospitalizations or for reducing exacerbations for patients with cystic fibrosis. There are few harms found for high-frequency chest wall oscillation devices.

Rationale: High-frequency chest wall oscillation devices are not inferior to other alternatives, and have a low rate of harms, but much higher cost. However, we recommend coverage because some patients may need other treatment options. The recommendation is weak because of the low quality of the evidence.

Recommendation: High-frequency chest wall oscillation devices are recommended for coverage for patients with cystic fibrosis (*weak recommendation)* when there is documentation of frequent severe exacerbations requiring antibiotics and/or hospitalization, despite either:

a) having received chest physiotherapy and positive expiratory pressure therapy, OR

b) documentation that chest physical therapy and positive expiratory pressure devices are not tolerated or not available (e.g., inability of a caregiver to perform chest physiotherapy).

Note. GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.
Abbreviations. CI: confidence interval; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation methodology; RCT: randomized controlled trial.

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with non–cystic fibrosis bronchiectasis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Hospitalizations *(Critical outcome)*	No evidence	Coverage of high-frequency chest wall oscillation would add significant cost compared to chest physiotherapy or positive expiratory pressure devices. However, in situations in which chest physiotherapy is not consistently available or tolerated and positive expiratory pressure devices are not effective or tolerated, the additional cost of the high-frequency chest wall oscillation device would be offset to the extent that it reduces hospitalizations and exacerbations.	Patients may prefer treatment options that can be self-administered, confer greater independence, and ensure reliable and consistent treatment.	Appointed expert opinion supported coverage of high-frequency chest wall oscillation devices for bronchiectasis, due to the pathophysiologic similarities of this condition to cystic fibrosis bronchiectasis, but only when there is evidence of chronic infection.
Mortality *(Critical outcome)*	No evidence			
Pulmonary Exacerbations Requiring Antibiotics *(Important outcome)*	Compared to standard pharmacological therapy alone: significantly fewer exacerbations over 12 months on average for 1 group that used high-frequency chest wall oscillation devices: • Respin11 group (mean, 0.52 exacerbations; SD, 0.14) • Pharmacological therapy with other device-delivered interventions (mean, 0.96 exacerbations; SD, 0.40) • Between-group difference, $P < .001$ Compared to standard pharmacological therapy alone: the treatment group that used the SmartVest HFCWO device did not have significantly fewer exacerbations when compared to the group that received standard pharmacological therapy • SmartVest group (mean, not reported; SD, not reported) • Pharmacological therapy with other device-delivered interventions (mean, 0.96 exacerbations; SD, 0.40) • Between-group difference, $P > .05$ ●○○○ *(very low confidence, based on 1 RCT, n = 42)*			
Exercise Capacity *(Important outcome)*	No evidence			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with non–cystic fibrosis bronchiectasis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Breathlessness or Cough *(Important outcome)*	Compared to pharmacological therapy with other device-delivered interventions (e.g., positive expiratory pressure mask): significant reduction in symptoms as measured by the 12-point Breathlessness Cough Sputum Score scale (mean difference, -5.8; 95% CI, -7.21 to -4.39; N = 20; *P* < .05) ●○○○ *(very low confidence, based on 1 RCT, n = 20)* Compared to standard pharmacological therapy alone: significant reduction in symptoms as measured by the 12-point Breathlessness Cough Sputum Score scale: • Respin11 group (mean at 12 months post-baseline, 2.8; SD, not reported) • Pharmacological therapy with other device-delivered interventions group (mean at 12 months post-baseline, 6.1; SD, not reported) • Between-group difference, *P* < .001 ●○○○ *(very low confidence, based on 1 RCT, n = 42)* Compared to standard pharmacological therapy alone: The treatment group that used the SmartVest high-frequency chest wall oscillation device did not demonstrate a significant reduction in symptoms as measured by the 12-point Breathlessness Cough Sputum Score scale: • SmartVest group (mean at 12 months post-baseline, 4.5; SD, not reported) • Pharmacological therapy with other device-delivered interventions group (mean at 12 months post-baseline, 6.1; SD, not reported)			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with non–cystic fibrosis bronchiectasis?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
	• Between-group difference, *P* > .05 ●○○○ *(very low confidence, based on 1 RCT, n = 41)*			

Balance of benefits and harms: There is very low confidence evidence that high-frequency chest wall oscillation devices improve key outcomes for patients with non-cystic fibrosis bronchiectasis. However, expert opinion supports use in this population based on data extrapolated from cystic fibrosis, which is a similar condition, but only when there is evidence of chronic airway infection or chronic daily cough. There are few harms to high-frequency chest wall oscillation devices.

Rationale: The evidence is equivocal regarding whether high-frequency chest wall oscillation improves outcomes for patients with non-cystic fibrosis bronchiectasis, but we recommend coverage of these devices based on low risk of harms and the fact that they may result in cost offsets if they prevent hospitalizations. Expert testimony that pathophysiologic reasoning makes extrapolating evidence from the cystic fibrosis population reasonable. The recommendation is weak because of our very low confidence in the available evidence.

Recommendation: High-frequency chest wall oscillation devices are recommended for coverage for patients with non-cystic fibrosis bronchiectasis (weak recommendation) when the 4 criteria below are met:

A) The bronchiectasis is confirmed by CT scan, AND
B) There is evidence of chronic lung infection, AND
C) The patient has experienced either:
    a) daily productive cough for at least 6 continuous months, OR
    b) frequent (> 2 times a year) exacerbations requiring antibiotic therapy, AND
D) The patient has received chest physiotherapy and positive expiratory pressure therapy OR chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy).

Note. GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.
Abbreviations. CI: confidence interval; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation methodology; RCT: randomized controlled trial; SD: standard deviation.

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with chronic obstructive pulmonary disease?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Hospitalizations *(Critical outcome)*	No evidence	Coverage of high-frequency chest wall oscillation would add significant cost compared to chest physiotherapy or positive expiratory pressure devices. However, in situations in which chest physiotherapy is not consistently available or tolerated and positive expiratory pressure devices are not effective or tolerated, the additional cost of the high-frequency chest wall oscillation device would be offset to the extent that it reduces hospitalizations and exacerbations.	Patients may prefer treatment options that can be self-administered, confer greater independence, and ensure reliable and consistent treatment.	Appointed expert did not recommend high-frequency chest wall oscillation devices for this population.
Mortality *(Critical outcome)*	No evidence			
Pulmonary Exacerbations Requiring Antibiotics *(Important outcome)*	No evidence			
Exercise Capacity *(Important outcome)*	No evidence			
Breathlessness or Cough *(Important outcome)*	Compared to standard pharmacological therapy without oscillatory devices: significantly greater improvement on the 12-point Breathlessness Cough Sputum Score scale over 4 weeks: • The Vest Airway Clearance System Model 205 group (baseline mean, 6.6; SD, 2.8; post-treatment mean, 5.2; SD, 2.2) • Standard pharmacological therapy group (baseline mean, 4.6; SD, 1.7; post-treatment mean, 5.5; SD, 2.1) • Between-group difference, *P* = .007 ●○○○ *(very low confidence, based on 1 RCT, n = 40)*			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with chronic obstructive pulmonary disease?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
	Compared to intrapulmonary percussive ventilation: significantly less improvement on the 12-point Breathlessness Cough Sputum Score scale over 4 weeks: • The Vest Airway Clearance System Model 205 group (baseline mean, 6.6; SD, 2.8; post-treatment mean, 5.2; SD, 2.2) • Intrapulmonary percussive ventilation group (baseline mean, 6.3; SD, 1.4; post-treatment mean, 3.1; SD, 1.7) • Between-group difference, $P < .01$ ●○○○ *(very low confidence, based on 1 RCT, n = 40)*			

Balance of benefits and harms: There is insufficient evidence that high-frequency chest wall oscillation devices improve key outcomes for patients with chronic obstructive pulmonary disease compared to alternatives. Expert opinion does not recommend use in this population. There are few harms to high-frequency chest wall oscillation devices.
Rationale: There is insufficient comparative evidence of benefit for this indication. It is a weak recommendation because of our very low confidence in the evidence.
Recommendation: High-frequency chest wall oscillation devices are not recommended for coverage for children and adults with chronic obstructive pulmonary disease *(weak recommendation).*

Note. GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.
Abbreviations. GRADE: Grading of Recommendations, Assessment, Development, and Evaluation methodology; RCT: randomized controlled trial; SD: standard deviation.

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with pulmonary complications from neuromuscular disease resulting in chronic lung disease?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Hospitalizations *(Critical outcome)*	Compared to standard chest physiotherapy (pediatric patients with neuromuscular disease): there was a nonsignificant difference in the number of control group participants requiring hospitalizations (2/7) compared to the HFCWO device group (0/7; *P* > .05) ●○○○ *(very low confidence, based on 1 RCT, n = 14)*	Coverage of high-frequency chest wall oscillation would add significant cost compared to chest physiotherapy or positive expiratory pressure devices. However, in situations in which chest physiotherapy is not consistently available or tolerated and positive expiratory pressure devices are not effective or tolerated, the additional cost of the high-frequency chest wall oscillation device	Patients may prefer treatment options that can be self-administered, confer greater independence, and ensure reliable and consistent treatment. This group of conditions varies widely in severity and patients may have different preferences based on their condition.	Neuromuscular diseases are a broad range of conditions with very different pulmonary involvement. Many of these conditions have populations that are too small to meaningfully study. Appointed expert recommendation was for use in patients with neuromuscular disease who have evidence of chronic airway infection (defined as persistent culture positivity of organisms known to
Mortality *(Critical outcome)*	No evidence			
Pulmonary Exacerbations Requiring Antibiotics *(Important outcome)*	Compared to standard chest physiotherapy (pediatric patients with neuromuscular disease): There was nonsignificant difference between control group participants requiring antibiotics (3/7) compared to the HFCWO device group (2/7; *P* > .05) ●○○○ *(very low confidence, based on 1 RCT, n = 14)*			
Exercise Capacity *(Important outcome)*	No evidence			

Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with pulmonary complications from neuromuscular disease resulting in chronic lung disease?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Breathlessness or Cough *(Important outcome)*	Compared to no treatment (adult patients with ALS): significantly greater improvement in breathlessness (high-frequency chest wall oscillation group mean difference, -1.28; untreated group mean difference, 0.84; $P < .05$) Compared to no treatment (adult patients with ALS): no statistically significant differences in day or night cough or dyspnea ●○○○ *(very low confidence, based on 1 RCT, n = 35)*	would be offset to the extent that it reduces hospitalizations and exacerbations.		cause respiratory infection).

Balance of benefits and harms: There is no evidence that high-frequency chest wall oscillation devices improve key outcomes compared to standard treatments for patients with neuromuscular disease resulting in chronic lung disease. Expert testimony indicates patients with neuromuscular conditions and evidence of chronic airway infection benefit from these devices. There are few harms to high-frequency chest wall oscillation devices.

Rationale: There is insufficient comparative evidence of benefit for this population, but based on expert opinion and the potential to reduce exacerbations/costs, we recommend coverage for patients with neuromuscular disease when there is evidence of chronic airway infection. The disparate types of diseases and small populations within each disease make high-quality studies difficult to conduct and are not anticipated to be forthcoming. The recommendation is weak because of our very low confidence in the available evidence.

Recommendation: High-frequency chest wall oscillation devices are recommended for coverage for patients with neuromuscular disease resulting in chronic lung disease (*weak recommendation)* when there is evidence of chronic lung infection, despite either:

a) having received chest physiotherapy and positive expiratory pressure therapy, OR

b) documentation that chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy).

Note. GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.
Abbreviations. ALS: amyotrophic lateral sclerosis; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation methodology; RCT: randomized controlled trial.

Background

Individuals with impaired airway clearance are unable to effectively clear mucus from their airways.[1] High-frequency chest wall oscillation (HFCWO) devices are designed to help those with impaired airway clearance clear mucus from their airways. Impaired airway clearance can be a characteristic of several respiratory disorders and neuromuscular diseases, including:

- Chronic obstructive pulmonary disorder (COPD)
- Cystic fibrosis
- Bronchiectasis, which is characterized by chronic cough, bronchial wall thickening, permanent expansion of the airway, and overproduction of thick mucus
- Multiple sclerosis
- Muscular dystrophy
- Spinal muscular atrophy
- Amyotrophic lateral sclerosis (ALS)

The Centers for Disease Control and Prevention estimate that 35,000 individuals have been diagnosed with cystic fibrosis in the US, and 16 million US individuals are living with COPD.[2,3] According to a claims-data analysis using information from 2013, aproximately 340,000 to 522,000 adults receive treatment for bronchiectasis in the US, and about half of patients diagnosed with bronichiectasis have comorbid COPD.[4]

Failing to adequately and regularly clear mucus from the airways can result in exacerbations and worsening of chronic lung disease that require antibiotic treatment, hospitalization and other interventions.[5] Therefore, a key element of managing these diseases is to keep airways clear of excess secretions. When patients are unable to mobilize mucus secretions on their own, airway clearance techniques for patients with many respiratory disorders can include:

- Chest physiotherapy
    - Can be administered by respiratory therapists, family members, or other informal caregivers
    - Has been the standard of care for first-line secretion clearance for individuals with excessive or retained mucus.[6]
    - Typically administered by a trained caregiver over 1 to 3 sessions per day, each lasting 20 to 30 minutes, depending on disease severity.[6]
    - May also be known as percussion and postural drainage.
- Breathing techniques
    - Typically taught to patients by pulmonary rehabilitation professionals.
    - Active cycle breathing techniques include breathing control, thoracic expansion exercises, and the forced expiration technique.[6]
    - Autogenic drainage involves breathing techniques in 3 phases (unstick, collect, and evacuate) at different lung volumes.
    - Breathing techniques do not require devices or assistance and can be self-administered.[6]
- Positive expiratory pressure devices
    - Increase resistance, prevent airway closure, and increase collateral ventilation.[6]

    - Some use oscillatory mechanisms to create vibrations when a patient breathes out.[6]
    - Examples include TheraPEP, Resistex PEP mask, Pari RC Cornet Mucus Clearing Device, Flutter, Acapella, Quake, and Aerobika.
    - The therapy from these devices can be self-administered without assistance.[6]
- Intrapulmonary percussive ventilation
    - A pneumatic device that uses high-frequency oscillatory ventilation through a mouthpiece.[6]
    - An example is the Percussionaire Corporation IPV Ventilator.[6]
- High-frequency chest wall oscillation (HFCWO) devices, which are described in the following section of this document.
    - Therapy from these devices can be self-administered.[6]

Indications

Children and adults with cystic fibrosis, bronchiectasis, COPD, or pulmonary complications from neuromuscular disease resulting in chronic lung disease might be prescribed HFCWO devices to assist in the clearance of mucus in airways as part of their treatment plan. HFCWO devices exert external force on the chest wall to assist in mobilizing mucus and use sound waves or pressure from inflation and deflation at variable intensities and frequencies to generate the force. They are much more expensive than the alternative forms of treatment but require less time from caregivers than chest physiotherapy.

Technology Description

We identified 1 nonwearable HFCWO device and 5 wearable HFCWO devices that are currently approved by the US Food and Drug Administration (FDA) and being manufactured for use in children and adults with cystic fibrosis, bronchiectasis, COPD, or pulmonary complications from neuromuscular disease resulting in chronic lung disease. See Table 1 for a description of each device.

Table 1. HFCWO Device Descriptions

Device Name FDA Approval Date	Manufacturer	Features	Indications
Frequencer V2 and V2x[7] January 26, 2011[8]	Dymedso	• Portable • Not wearable • 4 sizes of adaptors for patients of different sizes • Generates low frequency sound waves within the range of 20-65 Hz and offers an adjustable intensity based on the patient's condition	• Cystic fibrosis • Chronic bronchitis • COPD • Bronchiectasis • Ciliary dyskinesia syndromes • Asthma • Muscular dystrophy • Neuromuscular degenerative disorder • Post-operative atelectasis • Thoracic wall defects

Device Name FDA Approval Date	Manufacturer	Features	Indications
SmartVest SQL System[9] December 19, 2013[10]	Electromed	• Portable • Wearable • 8 different sizes • 16 pounds • Quiet (60 decibels) • 91% decompression (greater percent decompression than other vests) • Wireless capabilities that can connect usage to personal reports or to healthcare provider records	• Bronchiectasis • COPD • Cystic fibrosis • Neuromuscular conditions
The Vest Airway Clearance System Model 105[11] February 21, 2003[12]	Hill-Rom	• Portable • Wearable • 4 styles of garment for different body types (full garment, wrap garment, chest garment, C3 garment) • 17 pounds • Multiple programing options, including several languages • Can program a reminder to cough • Vest covers are washable and dryable • Offers at-home training • Wireless capabilities that can connect usage to personal reports or to healthcare provider records	• Bronchiectasis • COPD • Cystic fibrosis • Neuromuscular conditions • Primary ciliary dyskinesia • Post lung transplant • Spinal cord injury

Device Name FDA Approval Date	Manufacturer	Features	Indications
Respin11[13] July 13, 2012[14]	RespInnovation SAS	• Portable • Wearable • Vest plus control unit weight 11 kilograms • Several sizes for different sizes • Can target specific chest areas • Programmable with several protocols • Uses an air pressure piston which inflates and completely empties each cycle enabling the patient to breathe, speak and cough without restriction • Does not provide constant background pressure which manufacturer claims makes the therapy easy to tolerate and puts no pressure onto the patient's physiological state	• Bronchiectasis • COPD • Cystic fibrosis • Neuromuscular conditions • Emphysema
InCourage Vest[15] June 17, 2005[16]	Philips, via RespirTech	• Portable • Wearable • 17.5 pounds • Several sizes for different ages • Uses triangular waveform technology that manufacturer claims delivers a chest physiotherapy-like "thump" to the chest • Offers at-home training	• Bronchiectasis • COPD • Cystic fibrosis • Certain neuromuscular conditions
AffloVest[17] March 27, 2013[12]	International Biophysics Corporation	• Portable • Wearable • Available in 7 sizes • Battery-operated • Has eight mechanical oscillating motors that target all 5 lobes of the lungs, front and back, for fully mobile use • Programmable settings	• Bronchiectasis • COPD • Cystic fibrosis • Neuromuscular diseases

Device Name FDA Approval Date	Manufacturer	Features	Indications
		• Advertised as the lightest vest option (no weight specified)	

Abbreviations. COPD: chronic obstructive pulmonary disorder; FDA: US Food and Drug Administration; HFCWO: high-frequency chest wall oscillation.

Evidence Review

We identified 2 systematic reviews,[6,18] 4 randomized controlled trials (RCTs),[19-21,44] and a single ongoing RCT[22] for the comparative effectiveness of HFCWO devices for children and adults with cystic fibrosis, bronchiectasis, COPD, or pulmonary complications from neuromuscular disease resulting in chronic lung disease. We did not identify any studies of the comparative cost effectiveness of HFCWO devices.

Cystic Fibrosis

We identified a single systematic review that focused on airway clearance techniques in people diagnosed with cystic fibrosis, and included RCTs and quasi-randomized trials of HFCWO devices.[6] The review included external chest oscillating devices as well as oral oscillatory devices.[6] Morrison and colleagues abstracted information related to the scope of this coverage guidance: exercise tolerance and frequency of exacerbations with or without hospitalization.[6] Morrison and colleagues included 39 studies in the qualitative review and 19 studies in meta-analyses; they rated 85% of these studies as having unclear risk of bias.[6] They rated the quality of evidence summarized in the review as very low to low across outcomes.[6] We rated this systematic review as having low risk of bias, and the authors rated component studies as having unclear to high risk of bias.

The studies in this review did not report symptoms of breathlessness or cough, mortality, or exercise capacity for participants using HFCWO devices.

Exacerbations and Hospitalizations

The single RCT (N = 107) that compared HFCWO devices to positive expiratory pressure therapy reported that the average number of exacerbations requiring antibiotics during the 12-month study period was significantly higher in the HFCWO groups (median, 2.0; interquartile range, 1.0 to 3.0) than the positive expiratory pressure therapy group (median, 1.0; interquartile range, 0.0 to 2.0; $P = .007$).[6]

The single RCT (N = 50) that compared HFCWO devices to conventional physiotherapy for patients with cystic fibrosis admitted to a hospital for an acute exacerbation reported no significant difference between the groups for days of hospitalization or time to pulmonary exacerbation (mean difference, -0.20; 95% CI, -2.32 to 1.92).[6] The participants in this study were between 16 and 25 years of age, and 64.0% were identified as male.[6] Patients in the conventional physiotherapy group received therapy from a respiratory physiotherapist 3 times per day for approximately 30 minutes each time, along with the use of an inhaler prior to sessions with the physiotherapist.[6]

Neither of the 2 RCTs that compared HFCWO devices to breathing techniques for cystic fibrosis reported exacerbations or any other outcome scoped for this review.[6]

Only 1 of 6 studies comparing HFCWO devices to other external and oral oscillatory devices assessed exacerbations (N = 16); it reported that there were no significant differences between groups for frequency of hospitalizations or use of home intravenous therapies.[6]

Bronchiectasis

We identified a single systematic review focused on airway clearance techniques for people diagnosed with bronchiectasis,[18] and a single RCT (Nicollini et al., 2020; N = 60) that was published after the search dates of the systematic review.[19] We rated the systematic review as having a low risk of bias and the RCT as having a moderate risk of bias. The systematic review included 7 RCTs, but only 1 included RCT used HFCWO devices in the intervention group (Nicollini et al., 2013; N = 30).[23] This RCT was rated as having an unclear risk of bias by the authors of the systematic review. Both RCTs focused on adults.[19,23] Neither of these RCTs reported on mortality.

Exacerbations and Hospitalizations

In Nicollini and colleagues' 2020 RCT, both groups that used HFCWO devices had statistically significant improvement in exacerbations during the 12 months of the study compared to the average exacerbations per year prior to baseline.[19] Only the group that used the Respin11 HFCWO device had significantly fewer exacerbations during the 12-month study period, compared to the pharmacological comparison group that only received standard pharmacological care without HFCWO or chest physiotherapy (Respin11: mean, 0.52; standard deviation [SD], 0.14; control: mean, 0.96; SD, 0.40; between-group difference: $P < .001$).[19] The 2 HFCWO devices included in this study are described in Table 1.

Breathlessness or Cough

Nicollini and colleagues' 2013 RCT, identified in the systematic review, reported a statistically significant decrease in breathlessness, cough and sputum on the Breathlessness, Cough, and Sputum Scale (BCSS) in the group treated with HFCWO devices compared to a control group that received chest physiotherapy (mean difference, -5.8; 95% CI, -7.21 to -4.39; N = 20; $P < .05$).[23] This study summed the scores of items across 3 subscales, which makes it challenging to anchor this improvement in patient-response terms; publications that assess the clinical importance of change-scores for this scale rely on reporting the average score across subscales (i.e., mean-scores range from 0 to 4, and sum-scores range from 0 to 12 on this scale). This RCT also reported that use of HFCWO devices was associated with lower scores on a dyspnea scale compared to the group that received chest physiotherapy (mean difference, -1.7; 95% CI, -2.4 to -1; N = 20; $P < .05$). [23]

The additional Nicollini and colleagues' 2020 RCT also reported that the group using the Respin11 HFCWO device demonstrated statistically significant improvement on the BCSS compared to the control group that received pharmacological therapy and standard care without HFCWO (Respin11 mean at 12 months post-baseline, 2.8; SD, not reported; control mean at 12 months post-baseline, 6.1; SD, not reported; $P < .001$).19 The group that used the SmartVest HFCWO device did not demonstrate a significant improvement on the BCSS compared to the control group (SmartVest mean at 12 months post-baseline, 4.5; SD, not reported; control mean at 12 months post-baseline, 6.1; SD, not reported; $P > .05$).

Exercise Capacity

The Nicollini and colleagues' 2020 RCT used a 6-minute walk test to assess exercise capacity but did not report the results of the walk test.[19]

COPD

We identified a single RCT that reported on the safety and effectiveness of HFCWO devices compared to intrapulmonary percussive ventilation in patients with severe COPD, and rated this RCT as having a moderate risk of bias.[20] The listed authors overlapped with the 2 RCTs reviewed in the bronchiectasis section, and the design of all 3 RCTs was similar.[20] Participants in this study had severe or very severe (but stable) COPD and were followed for 4 weeks after being randomized into 3 groups: 1 group received 2 sessions per day (lasting 15 minutes per session) of intrapulmonary percussive ventilation with a respiratory physiotherapist using a percussive ventilator; 1 group received 2 sessions per day (lasting 20 minutes per session) of HFCWO with a respiratory physiotherapy; and 1 group received standard pharmacological therapy alone that the investigators termed "the best medical therapy."[20] Most participants were 70 years or older and had more than 2 exacerbations and 1 hospitalization per year.[20] This study did not report mortality, hospitalizations, exacerbations, or exercise capacity.[20]

Breathlessness or Cough

The average BCSS score for participants in the control group worsened over time, but average BCSS scores for participants in the intrapulmonary percussive ventilation and HFCWO groups improved; both treatment groups had statistically significantly lower BCSS scores when compared to the standard treatment group (control group baseline mean, 4.6; SD, 1.7; control group post-treatment mean, 5.5; SD, 2.1).[20] Symptoms were nearly halved in the group receiving intrapulmonary percussive ventilation (intrapulmonary percussive ventilation group baseline mean, 6.3; SD, 1.4; intrapulmonary percussive ventilation group post-treatment mean, 3.1; SD, 1.7).[20] The intrapulmonary percussive ventilation group BCSS scores were statistically significantly lower than HFCWO group scores after the 4 weeks of treatment (HFCWO group baseline mean, 6.6; SD, 2.8; HFCWO group post-treatment mean, 5.2; SD, 2.2; between-group difference, $P < .01$).[20] In other words, the participants in the intrapulmonary percussive ventilation group improved more on symptoms of breathlessness or cough on average, compared to participants who received HFCWO device therapy.

Pulmonary Complications from Neuromuscular Disease

We identified 2 RCTs that assessed the safety and effectiveness of HFCWO devices for individuals diagnosed with a neuromuscular disease with pulmonary complications.[21,44] One RCT focused on adults diagnosed with ALS.[21] Participants in this study were followed for 12 weeks after being randomized into groups that received HFCWO therapy (N = 19) or no treatment (N = 16).[21] We rated this RCT as having a high risk of bias. This study did not report mortality, exacerbations, hospitalizations, or exercise capacity.

The second RCT included 14 children various neuromuscular diseases (i.e., Duchenne muscular dystrophy, unown mitochondrial myopathy, congenital muscular dystrophy, mitochondrial thymidine kinase 2 deficiency, spinal muscular atrophy type 2, muscle-eye-brain disease, and giant axonal neuropathy).[44] None of the participating children had used cough-assistive devices or intrapulmonary percussive ventilation prior to the trial, but 10 relied on nocturnal noninvasive bilevel ventilation and 1

was dependent on a ventilator.[44] Participants were randomized to receive standard chest physiotherapy (N = 7) or to receive HFCWO device therapy (N = 7) for a mean of 5 months; follow-up periods varied nonsignificantly by participant and group assignment.[44] An additional 9 participants in this RCT were diagnosed with cerebral palsey, but did not have neuromuscular disease diagnoses;[44] we report outcomes from this study when the results were reported separately for participants with cerbral palsey and participants with neuromuscular disease (i.e., pulmonary exacerbations and hospitalizations). We rated this study as having a high risk of bias.

Exacerbations and Hospitalizations

The RCT that included children with neuromuscular disease reported hospitalization and pulmonary exacerbations that required antibiotics. There was a nonsignificant difference in the number of control group participants requiring hospitalizations (2/7) compared to the HFCWO device group (0/7; $P > .05$), and nonsignificant difference between control group participants requiring antibiotics (3/7) compared to the HFCWO device group (2/7; $P > .05$).[44]

Breathlessness or Cough

On average, participants in the HFCWO device group had a statistically significantly greater decrease in breathlessness (HFCWO group mean difference, -1.28; group receiving no care mean difference, 0.84; $P < .05$) in the RCT that included adults with ALS, but no statistically significant differences in day or night cough or dyspnea.[21] Among the 21 participants with impaired lung capacity (forced vital capacity of 40% to 70%) in this RCT, this pattern of improvement in breathlessness for participants using HFCWO devices was further accentuated (HFCWO group mean difference, -1.71; untreated group mean difference, 1.51; $P < .05$).[21]

Harms of HFCWO Devices

We reviewed the RCTs described above for information about harms and adverse events. We also searched the FDA's manufacturer and user facility device experience database (MAUDE) for reports of adverse events for each of the HFCWO devices listed in the technology description.

A single RCT comparing HFCWO devices to positive expiratory pressure therapy for patients with cystic fibrosis reported adverse events.[24] This RCT was included in the systematic review described in the cystic fibrosis section, and used the inCourage System from RespirTech for the HFCWO device.[6,24] The authors for this RCT reported that the number of adverse events was not statistically different between the 2 groups (HFCWO, 200 events; positive expiratory pressure, 163 events; $P > .05$).[23] However, the HFCWO device group had significantly more lower airway adverse events (mean, 2.46; SD, not reported) compared to the positive expiratory pressure group (mean, 1.72; SD not reported; $P = .023$).[24] Lower airway events included increased cough, chest infection, hemoptysis, decreased lung function and chest pain.[24]

Reports identified in the MAUDE database are listed in Table 2, by device.

Table 2. Adverse Events Reported in MAUDE by HFCWO Device

Device Name FDA Approval Date	Manufacturer	Adverse Event(s)

Frequencer V2 and V2x[7] January 26, 2011[8]	Dymedso	• No records
SmartVest SQL System[9] December 19, 2013[10]	Electromed	• No records
The Vest Airway Clearance System Model 105[11] February 21, 2003[12]	Hill-Rom	• No records
Respin11[13] July 13, 2012[14]	RespInnovation SAS	• No records
InCourage Vest[15] June 17, 2005[16]	Philips, via RespirTech	• 8 reports identified classified under injury event type ○ Rib bone fractures in 3 different patients ○ 1 vertebral fracture ○ 1 electromagnetic interference problem with a pacemaker ○ 1 hematoma ○ 1 pneumothorax ○ 1 pressure problem with co-occurring mastitis
AffloVest[17] March 27, 2013[12]	International Biophysics Corporation	• 1 report identified • Fractured ribs

Abbreviations. FDA: US Food and Drug Administration; HFCWO: high-frequency chest wall oscillation; MAUDE: manufacturer and user facility device experience database.

Comparative Cost Effectiveness of HFCWO Devices

We did not identify any comparative cost-effectiveness studies of HFCWO devices.

Ongoing Studies for HFCWO Devices

We identified a single ongoing comparative study for HFCWO devices in the Clinical Trials Registry. This pilot study will evaluate the use of the Vest system for treatment of bronchiectasis patients in the home setting.[25] This study is a nonblinded, multi-site, randomized controlled trial that anticipates enrolling 70 participants, and will compare the Vest HFCWO therapy to oscillating positive expiratory pressure (OPEP) therapy for adults aged 18 years and older diagnosed with bronchiectasis.[25] Assessed outcomes will include .[25] The anticipated study completion date was November 2020.[25]

Evidence Summary

For patients with cystic fibrosis, we have low confidence that HCWFO device therapy is equivalent to conventional chest physiotherapy and positive expiratory pressure devices for prevention of exacerbations requiring antibiotics and for reducing symptoms of coughing and breathlessness. There is no evidence regarding other outcomes.

For patients with bronchiectasis, we have very low confidence that HFCWO device therapy reduces hospitalizations from exacerbations and improves symptoms of breathlessness and cough compared to

pharmacological therapy with other device-delivered interventions (e.g., positive expiratory pressure mask), and compared to pharmacological therapy without other devices. There is no evidence regarding other outcomes.

For patients with COPD, we have very low confidence that HFCWO device therapy is associated with less improvement in breathlessness and cough compared to intrapulmonary percussive ventilation. There is no evidence regarding other outcomes.

For patients with pulmonary complications from neuromuscular disease, we have very low confidence that HFCWO device therapy improves symptoms of breathlessness compared to no treatment or to standard chest physiotherapy. One study only included patients with ALS receiving HFCWO devices compared to no treatment, and the study that included children with neuromuscular disease likely had too few participants to identify whether there was a benefit to using HFCWO devices compared to standard chest physiotherapy. We have very low confidence that HFCWO device therapy does not improve day or night cough, or dyspnea compared to receiving no treatment for patients with ALS. There is no evidence regarding other outcomes for other neuromuscular diseases resulting in chronic lung disease.

We identified few reports of adverse events or harms of HFCWO devices in the reviewed studies and the FDA's database for adverse event reporting for devices.

Policy Landscape

Payer Coverage Policies

We identified HFCWO device coverage policies for Washington State's Medicaid program, a local coverage determination from Medicare, and 4 private payers. Medicare's local coverage determination and all 4 private payer policies require documentation that standard treatments, such as chest physiotherapy, have failed or are not tolerated before covering HFCWO devices; these policies cover HFCWO devices for patients with cystic fibrosis and bronchiectasis, but coverage for neuromuscular diseases with pulmonary complications varies. None of these policies cover HFCWO devices for patients with COPD except when there is comorbid bronchiectasis.

Medicaid

The Washington Health Care Authority's (HCA) policy for respiratory care considers chest physiotherapy to be the standard of care for secretion clearance, but states that there are situations in which conventional chest physiotherapy is unavailable, ineffective, or not tolerated.[26] The HCA covers HFCWO air-pulse generator systems when medically necessary for a person with a diagnosis characterized by excessive mucus production and difficulty clearing secretions.[26] Other airway-clearance devices covered by the HCA include mechanical percussors, oscillatory positive expiratory pressure devices, positive expiratory pressure devices, and cough stimulating devices, including alternating positive and negative airway pressure devices, and replacement batteries.[26] Prior authorization is required, and the policy also states that the rental of a HFCWO device and generator includes all repairs and replacements, and that the manufacturer will replace the vest according to changes in user's size during the rental and purchase period.[26] The HFCWO device is considered to be purchased after 12 months of rental, and there is a limit of 1 HFCWO device per client, per lifetime.[24] The fee schedule, which was last updated in October 2020,

lists the maximum allowable monthly rental fee for a HFCWO device (HCPCS E0483) as $1,224.07, and the maximum allowable fee for replacement parts (HCPCS A7025) as $465.90.[27]

Medicare

The local coverage determination for HFCWO devices (L33785) for Medicare, last updated in 2020, provides the following criteria for medical necessity[28]:

- There is a diagnosis of cystic fibrosis; or
- There is a diagnosis of bronchiectasis that has been confirmed by a high resolution, spiral, or standard CT scan and which is characterized by daily productive cough for at least 6 continuous months and frequent exacerbations requiring antibiotic therapy (2 or more times per year); chronic bronchitis and COPD in the absence of a confirmed diagnosis of bronchiectasis do not meet this criterion; or
- The beneficiary has one of the following neuromuscular disease diagnoses: post-polio; acid maltase deficiency; anterior horn cell diseases; multiple sclerosis; quadriplegia; hereditary muscular dystrophy; myotonic disorders; other myopathies; or paralysis of the diaphragm; and
- There must be well-documented failure of standard treatments to adequately mobilize retained secretions.
- It is not reasonable and necessary for a beneficiary to use both a HFCWO device and a mechanical in-exsufflation device.
- Replacement supplies, HCPCS A7025 and A7026, used with beneficiary owned equipment, are covered if the beneficiary meets the criteria listed above for the base device, HCPCS E0483. If these criteria are not met, the claim will be denied as not reasonable and necessary.

Private Payers

Aetna updated its policy for HFCWO devices in March 2021 and anticipates re-review in January 2022. This policy provides the following criteria for medical necessity[29]:

- Patient has a well-documented failure of standard treatments to adequately mobilize retained secretions; and
- Patient has been diagnosed with bronchiectasis confirmed by CT scan, characterized by daily productive cough for at least 6 continuous months or by frequent (i.e., more than 2 times per year) exacerbations requiring antibiotic therapy; or
- Patient has been diagnosed with cystic fibrosis or immotile cilia syndrome; or
- Patient has been diagnosed with 1 of the following neuromuscular diseases: acid maltase deficiency; anterior horn cell diseases, including amyotrophic lateral sclerosis; hereditary muscular dystrophy; multiple sclerosis; myotonic disorders; other myopathies; paralysis of the diaphragm; post-polio; or quadriplegia regardless of underlying etiology.
- Lung transplant recipients, within the first 6 months post-operatively, who are unable to tolerate standard chest physiotherapy.
- Aetna considers continuous high-frequency chest wall oscillation therapy for the treatment of bronchitis, and secretion-induced atelectasis to be experimental and investigational because there is insufficient evidence of effectiveness.
- Aetna considers high-frequency chest compression systems experimental and investigational for other indications in members who do not meet medical necessity criteria above (e.g., alpha

1antitrypsin deficiency, cerebral palsy, childhood atelectasis, chronic inflammatory demyelinating polyneuropathy, coma, Cri-du-Chat syndrome, individuals with acute pneumonic respiratory failure receiving mechanical ventilation, interstitial lung disease, kyphosis, leukodystrophy, protein alveolar proteinosis, scoliosis, stiff-person (stiff-man) syndrome, and Zellweger syndrome; not an all-inclusive list) because their effectiveness for these indications has not been established.

Cigna updated its policy for HFCWO devices in March 2021 and anticipates reviewing this policy in September 2021. This policy provides the following criteria for medical necessity[30]:

- Patient has been diagnosed with cystic fibrosis and there is a failure, intolerance, or contraindication to home chest physiotherapy, or it cannot be provided; or
- Patient has been diagnosed with bronchiectasis confirmed by high-resolution computed tomography; has daily productive cough for at least 6 months or requires antibiotic treatment of exacerbations 2 or more times per year; and failure of standard treatments (e.g., pharmacotherapy, postural drainage, chest percussion, vibration) to mobilize secretions; or
- Patient has been diagnosed with neuromuscular disease; that disease is characterized by excessive mucus production, infection and difficulty clearing secretions; and there is a failure, intolerance, or contraindication to standard treatment (e.g., pharmacotherapy, postural drainage, daily chest percussion) and standard airway clearance device (e.g., mechanical percussors, positive expiratory pressure device).

Moda updated its policy for HFCWO devices in March 2021, and considers airway oscillating devices, mechanical percussors, positive expiration masks to be medically necessary to assist in mobilizing respiratory tract secretions for patients with cystic fibrosis, chronic bronchitis, bronchiectasis, immotile cilia syndrome, or asthma. Their policy requires prior authorization and provides the following criteria for medical necessity[31]:

- Face-to-face visit with provider within 6 months prior to the request;
- Documentation of failure of standard treatments to adequately mobilize retained secretions;
- Cannot request both HFCWO and mechanical in-exsufflation device; and
- One or more of the following conditions are met:
    - A high resolution, spiral, or standard CT scan documentation of bronchiectasis that is characterized by 1 or more of the following: at least 6 months of daily productive cough, or frequent exacerbations requiring antibiotic therapy (i.e., more than 2 times per year);
    - The patient does not have chronic bronchitis and COPD in the absence of confirmed diagnosis of bronchiectasis
    - Cystic fibrosis or immotile cilia syndrome
    - The patient has one of the following neuromuscular diseases: acid maltase deficiency; anterior horn cell diseases, including amyotrophic lateral sclerosis; hereditary muscular dystrophy; multiple sclerosis; myotonic disorders; other myopathies; paralysis of the diaphragm; post-polio; quadriplegia regardless of etiology; lung transplant recipients who are unable to tolerate standard chest physiotherapy, and who have submitted a request within the first 6 months post-operatively.

- Indications for which HFCWO is considered investigational include alpha 1-antitrypsin deficiency, childhood atelectasis, cerebral palsy, coma, kyphosis, leukodystrophy, scoliosis, and stiff-person syndrome.

Moda's policy specifically names the following devices but notes that the list is not all-inclusive: Frequencer, SmartVest, MedPulse Respiratory Vest System, The Vest Airway Clearance System, ABI Vest, Respin11 Bronchial Clearance System, and InCourage Vest/System.[31]

Regence BlueCross BlueShield updated their policy for oscillatory devices in July 2020 and anticipates starting a new review for their policy in June 2021. This policy required prior authorization and provides the following criteria for medical necessity for use of HFCWO devices[32]:

- Among patients with cystic fibrosis: demonstrated need for airway clearance and documentation that standard chest physiotherapy has failed, is not tolerated, or cannot be performed. Failure is defined as continued frequent severe exacerbations of respiratory distress.
- Among patients with chronic diffuse bronchiectasis: demonstrated need for airway clearance; documentation that standard chest physiotherapy has failed, is not tolerated, or cannot be performed; and high resolution or spiral chest tomography scan to document bronchiectasis, plus either daily productive cough for at least 6 continuous months, or exacerbations requiring antibiotic therapy 3 or more times per year.
- Among patients with COPD or conditions associated with other neuromuscular disorders, HFCWO devices are considered investigational.

Evidence-based Guidelines and Recommendations

National Institute for Health Care and Excellence (NICE)

The NICE guidelines published in 2017 for the diagnosis, treatment, and management of cystic fibrosis explicitly state that HFCWO devices should not be offered as an airway clearance technique for people with cystic fibrosis except in exceptional clinical circumstances.[33] There is a special cystic fibrosis team that decides when circumstances are exceptional; otherwise, the guidance states that based on published evidence, HFCWO is not as effective as other airway clearance techniques.[33]

We did not identify any NICE guidelines for the diagnosis, treatment, and management of bronchiectasis, COPD, or neuromuscular diseases that explicitly included HFCWO devices in the recommendations sections.

European Respiratory Society

The European Respiratory Society published guidelines in 2017 for the management of adult bronchiectasis from determinations made by a task force comprised of respiratory medicine, microbiology, physiotherapy, thoracic surgery, primary care, and patient advocates.[34] Systematic reviews of published evidence were conducted, reviewed, and debated by this task force during 4 in-person meetings that took place over 21 months, with additional communication by email and teleconference when drafting the final recommendations.[34] Any task force members with conflicts of interest were forced to abstain from all voting activities during the process of developing recommendations.[34] The guideline recommends that patients with bronchiectasis be taught to use an airway clearance technique 1 to 2 times daily by a trained physiotherapist, as a weak recommendation based on low quality of evidence.[34] HFCWO therapy was one of multiple airway clearance techniques

that the task force considered while making this recommendation, but there was no statement of which airway clearance technique might be superior to others.[34] There was a strong recommendation for use of pulmonary rehabilitation in patients with impaired exercise capacity.[34]

European Neuromuscular Centre (ENMC)

ENMC convened a meeting in March 2017 with 21 internationally recognized experts in airway clearance techniques for patients with neuromuscular disorders.[35] Several of the participating experts had received funding, honoraria, or expenses for travel paid for by manufacturers of devices that assist in airway clearance.[35] HFCWO devices were addressed in the review that the experts published after the meeting in the section related to peripheral airway clearance techniques, which also included discussion of intrapulmonary percussive ventilation, manual chest compression, and chest wall strapping.[35] Other sections of the review included information about manually assisted cough, assisted inspiration and expiration, mechanical insufflation-exsufflation.[35] The authors concluded that peripheral airway clearance techniques such as HFCWO therapy may be effective, and should be considered for use in management of chronic lung disease associated with neuromuscular disorders alongside manually assisted cough or other equipment to clear secretions from airways.[35] The authors noted that HFCWO devices are expensive in comparison to other available devices and techniques.[35]

American College of Chest Physicians

The American College of Chest Physicians published an expert panel report in 2018 on treating cough due to non–cystic fibrosis bronchiectasis and cystic fibrosis bronchiectasis with nonpharmacological airway clearance after conducting a systematic review of published evidence.[36] The authors were unable to make recommendations due to insufficient evidence, but provided the following consensus-based suggestions[36]:

- For children and adults with productive cough due to bronchiectasis related to any cause, we suggest that they be taught airway clearance techniques by professionals with advanced training in airway clearance techniques.
- For children and adults with productive cough due to bronchiectasis related to any cause, we suggest that the frequency of airway clearance should be determined by disease severity and amount of secretions.
- For children and adults with productive cough due to bronchiectasis related to any cause, we suggest that airway clearance techniques are individualized as there are many different techniques.

American Association for Respiratory Care (AARC)

AARC published clinical practice guidelines about the effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients with impaired secretion clearance, based on a systematic review of published studies.[37] The guidelines provided focused recommendations for adult and pediatric patients without cystic fibrosis; adult and pediatric patients with neuromuscular disease, respiratory muscle weakness, or impaired cough; and postoperative adult and pediatric patients.[37] These guidelines note that HFCWO was not recommended for adult and pediatric patients with neuromuscular disease, respiratory muscle weakness, or impaired cough, due to insufficient evidence.[37] Airway clearance techniques were not recommended for routine treatment of COPD or post-operative care.[37] The authors

propose the following process questions when considering the use of airway clearance techniques in these populations[37]:

- Does the patient have difficulty clearing airway secretions? Are retained secretions affecting gas exchange or lung mechanics? Focus on patient's level of difficulty for mobilizing and expectorating secretions.
- Which therapy is likely to provide the greatest benefit with the least harm?
- What is the cost of the therapy in terms of the device cost and clinician time to apply or supervise the therapy? The authors note that this is especially relevant for devices or therapies to be used at home.
- What factors are important to the patient about performing airway clearance therapy? This is an important consideration, given the lack of high-quality evidence that any one technique is more effective than other techniques.

Recommendations and Guidelines from Professional Societies

American Thoracic Society

The American Thoracic Society published a clinical practice guideline in 2011 for the diagnosis and management of stable COPD in partnership with the American College of Physician, American College of Chest Physicians, and European Respiratory Society.[38] This guideline did not consider oscillation devices as part of standard management of COPD.[38]

Recommendations from Advocacy Organizations

American Lung Association

The American Lung Association does not list HFCWO devices as part of the management and treatment of cystic fibrosis, bronchiectasis, or COPD.[39-41]

Cystic Fibrosis Foundation

The Cystic Fibrosis Foundation promotes the use of clinical practice guidelines from a systematic review of the evidence that the foundation commissioned in 2009 to compare airway clearance techniques and devices.[42] The review concluded that airway clearance should be part of managing cystic fibrosis to maintain lung function and improve quality of life, and assessed that this could provide a moderate net benefit based on fair quality body of evidence.[43] No airway clearance technique or device was found to be superior to others, and the authors recommended that airway clearance technique be individualized to the patient in consideration of age, preference, and history of adverse events.[43]

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Appendix A. GRADE Table Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

Appendix B. GRADE Evidence Profile

Certainty Assessment (Confidence in Estimate of Effect) for Cystic Fibrosis							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Certainty**
Hospitalizations							
4	RCTs	Serious	Not serious	Serious	Not serious	Small samples, short follow-up	Low ●●○○
Mortality							
0							
Pulmonary Exacerbations Requiring Antibiotics							
3	RCT	Serious	Not serious	Serious	Serious	Small samples, short follow-up	Very low ●○○○
Exercise Capacity							
0							
Breathlessness or Cough							
0							

Abbreviation. RCT: randomized controlled trial.

Certainty Assessment (Confidence in Estimate of Effect) for Bronchiectasis							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Certainty**
Hospitalizations							
0							
Mortality							
0							
Pulmonary Exacerbations Requiring Antibiotics							
1	RCT	Serious	Unable to rate (single study)	Not serious	Serious		Very low ●○○○
Exercise Capacity							
0							
Breathlessness or Cough							
1	RCT	Serious	Unable to rate (single study)	Not serious	Serious		Very low ●○○○

Abbreviation. RCT: randomized controlled trial.

Certainty Assessment (Confidence in Estimate of Effect) for COPD							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Certainty**
Hospitalizations							
0							
Mortality							
0							
Pulmonary Exacerbations Requiring Antibiotics							
0							
Exercise Capacity							
0							
Breathlessness or Cough							
1	RCT	Moderate	Unable to rate (single study)	Serious	Serious	Short intervention period and follow-up	Very low ●○○○

Abbreviation. RCT: randomized controlled trial.

Certainty Assessment (Confidence in Estimate of Effect) for Pulmonary Complications from Neuromuscular Disease Resulting in Chronic Lung Disease							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Certainty**
Hospitalizations							
0							
Mortality							
0							
Pulmonary Exacerbations Requiring Antibiotics							
0							
Exercise Capacity							
0							
Breathlessness or Cough							
1	RCT	Serious	Unable to rate (single study)	Serious	Serious	Small sample, short follow-up	Very low ●○○○

Abbreviation. RCT: randomized controlled trial.

Appendix C. Methods

Scope Statement

Populations

Children and adults with cystic fibrosis, bronchiectasis, chronic obstructive pulmonary disorder, or pulmonary complications from neuromuscular disease resulting in chronic lung disease

Population scoping notes: Patients without any of the above conditions are excluded.

Interventions

High-frequency chest wall oscillation devices approved for use in the US

Intervention exclusions: None

Comparators

Home physiotherapy, mechanical percussors, positive expiratory pressure masks, airway clearance devices (e.g., oscillating devices, intrapulmonary percussive ventilation), or other types of high-frequency chest wall oscillation devices not approved for use in the US

Outcomes

Critical: Hospitalizations, mortality

Important: Frequency of pulmonary exacerbations requiring antibiotics, changes in exercise capacity, symptoms of breathlessness or cough

Considered but not selected for GRADE Table: Sputum volume or weight, forced expiratory volume, forced vital capacity, total lung capacity

Key Questions

KQ1: What is the comparative effectiveness of high-frequency chest wall oscillation devices?

KQ2: Does the comparative effectiveness of high-frequency chest wall oscillation devices vary by:

a. Disease type

b. Patient characteristics

c. Device characteristics

KQ3: What are the harms of high-frequency chest wall oscillation devices?

KQ4: What is the comparative cost effectiveness of high-frequency chest wall oscillation devices?

Contextual Questions

CQ1: What resources are required to use the interventions and comparators?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that meet the criteria for the scope described above. Searches of core sources were limited to citations published after 2015.

The following core sources were searched:

Agency for Healthcare Research and Quality (AHRQ)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Online Library)
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

An Ovid MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, using the search terms *chest wall oscillation, high frequency chest wall oscillation, high frequency Chest wall compression, Frequencer, SmartVest, MedPulse Respiratory Vest, Vest Airway Clearance System, ABI Vest, Respin11, bronchial clearance, InCourage Vest,* and *Afflovest*. The search was limited to publications in English published since 2015. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the identified systematic reviews for cystic fibrosis and bronchiectasis. An additional search for randomized controlled trials published since 2006 was conducted for chronic obstructive pulmonary disorder and neuromuscular diseases with pulmonary complications leading to chronic lung disease, because no systematic reviews were identified for these populations. The searches were limited to publications in English.

Searches for clinical practice guidelines were limited to those published since 2015. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Centers for Disease Control and Prevention (CDC), Community Preventive Services
National Institute for Health and Care Excellence (NICE)
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, or clinical practice guidelines.

Appendix D. Applicable Codes

HCPCS	
A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each
A7026	High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each
E0467	Home ventilator, multi-function respiratory device, also performs any or all of the additional functions of oxygen concentration, drug nebulization, aspiration, and cough stimulation, includes all accessories, components and supplies for all functions
E0480	Percussor, electric or pneumatic, home model
E0481	Intrapulmonary percussive ventilation system and related accessories
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each
E0484	Oscillatory positive expiratory pressure device, non-electric, any type, each
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
CPT	
94669	Mechanical chest wall oscillation to facilitate lung function, per session
ICD-10-CM	
B91	Sequelae of poliomyelitis
D81.810	Biotinidase deficiency
D84.1	Defects in the complement system
E84	Cystic fibrosis
G12	Spinal muscular atrophy and related syndromes
G14	Post-polio syndrome
G35	Multiple sclerosis
G71.0-G71.1	Primary disorders of muscles
G72	Other and unspecified myopathies
G73.7	Myopathy in diseases classified elsewhere
G82.5	Quadriplegia
G95	Syringomyelia and syringobulbia
J44	Chronic obstructive pulmonary disease
J47	Bronchiectasis
J98.6	Disorders of diaphragm
M33	Dermatopolymyositis
M34.82	Systemic sclerosis with myopathy
M35.03	Sicca syndrome with myopathy
Q33.4	Congenital bronchiectasis

Note. Inclusion on this list does not guarantee coverage.

Coverage Guidance – High-Frequency Chest Wall Oscillation Devices

Question: How should the Coverage Guidance *High-Frequency Chest Wall Oscillation Devices* be applied to the Prioritized List?

Question source: EbGS

Issue: EbGS approved a coverage guidance regarding High-Frequency Chest Wall Oscillation Devices at their December 2, 2021 meeting. The "blue box" wording is shown below:

HERC Coverage Guidance

High-frequency chest wall oscillation devices are recommended for coverage for patients with cystic fibrosis (*weak recommendation)* when there is documentation of frequent exacerbations requiring antibiotics, frequent hospitalization, or rapidly declining lung function measured by spirometry, despite either:

A) having received chest physiotherapy and positive expiratory pressure therapy, OR
B) documentation that chest physiotherapy and positive expiratory pressure devices are not tolerated or not available (e.g., inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are recommended for coverage for patients with non–cystic fibrosis bronchiectasis (weak recommendation) when the 4 criteria below are met:

A) The bronchiectasis is confirmed by computed tomography (CT) scan, AND
B) There is evidence of chronic lung infection, AND
C) The patient has experienced either:
    1) daily productive cough for at least 6 continuous months, OR
    2) frequent (> 2 times a year) exacerbations requiring antibiotic therapy, AND
D) The patient has received chest physiotherapy and positive expiratory pressure therapy OR chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are recommended for coverage for patients with neuromuscular disease resulting in chronic lung disease (*weak recommendation)* when there is evidence of chronic lung infection, despite either:

A) having received chest physiotherapy and positive expiratory pressure therapy, OR
B) documentation that chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are not recommended for coverage for patients with chronic obstructive pulmonary disease *(weak recommendation)*.

Current Prioritized List status

HCPCS		**Placement**
A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each	Never reviewed
A7026	High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each	Never reviewed
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each	Never reviewed
CPT		**Placement**
94669	Mechanical chest wall oscillation to facilitate lung function, per session	502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS

ICD-10-CM		**Current Placement**
E84	Cystic fibrosis	20 CYSTIC FIBROSIS
J44	Chronic obstructive pulmonary disease	283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE
J47	Bronchiectasis	58 BRONCHIECTASIS
Q33.4	Congenital bronchiectasis	197 CONGENITAL LUNG ANOMALIES
various	Various musculoskeletal conditions causing breathing issues	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES

HERC staff recommendations:

1) Delete CPT 94669 (Mechanical chest wall oscillation to facilitate lung function, per session) from line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS and the associated entry in GN172 as shown below

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
~~94669~~	~~Mechanical chest wall oscillation~~	~~More costly than equally effective therapies~~	~~October, 2016~~

2) Add CPT 94669 to lines 20 CYSTIC FIBROSIS, 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES, and 197 CONGENITAL LUNG ANOMALIES
3) Add HCPCS E0483 High frequency chest wall oscillation system, includes all accessories and supplies, each to lines 20 CYSTIC FIBROSIS, 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES and 197 CONGENITAL LUNG ANOMALIES
4) Add a new guideline to lines 20, 71, and 197 as shown below

GUIDELINE NOTE XXX HIGH-FREQUENCY CHEST WALL OSCILLATION DEVICES

Lines 20, 71, 197

High-frequency chest wall oscillation devices are included on these lines ONLY when:

A) The patient has cystic fibrosis, AND
    1) There is documentation of frequent exacerbations requiring antibiotics, frequent hospitalization, OR rapidly declining lung function measured by spirometry, despite either:
        a) having received chest physiotherapy and positive expiratory pressure therapy, OR
        b) documentation that chest physiotherapy and positive expiratory pressure devices are not tolerated or not available (e.g., inability of a caregiver to perform chest physiotherapy); OR

B) The patient has non-cystic fibrosis bronchiectasis AND the four criteria below are met:
    1) The bronchiectasis is confirmed by computed tomography (CT) scan, AND
    2) There is evidence of chronic lung infection, AND
    3) The patient has experienced either:
        a) daily productive cough for at least 6 continuous months, OR
        b) frequent (> 2 times a year) exacerbations requiring antibiotic therapy, AND
    4) The patient has received chest physiotherapy and positive expiratory pressure therapy OR chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy); OR

C) The patient has neuromuscular disease resulting in chronic lung disease when there is evidence of chronic lung infection, despite either:
    1) having received chest physiotherapy and positive expiratory pressure therapy, OR
    2) documentation that chest physiotherapy and positive expiratory pressure devices are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform chest physiotherapy).

HERC Coverage Guidance: High-Frequency Chest Wall Oscillation Devices
Disposition of Public Comments

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Discussion Table

IDs/#s	Summary of Issue	Subcommittee Response
A3, A4, A6, B2–B8, C3–C6, C8	Evidence not included in this review shows effectiveness of HFCWO for COPD, bronchiectasis, neuromuscular disease, and cystic fibrosis.	Most of the data submitted from commenters were not published in peer-reviewed journals (e.g., posters and conference abstracts) or used noncomparative before-after designs. Others did not appropriately include the relevant populations or appropriate outcomes to address the Key Questions. One study did meet inclusion criteria and has since been added to the coverage guidance, but it did not change conclusions.
B1, B2, B9, C3	The state of the evidence for HFCWO therapy is sparse given the rare diseases it treats, lack of consensus on study endpoints, and inability to use blinding. Lower-quality evidence obtained from real-world data (claims databases) shows this therapy is effective and cost-effective. This lower-quality evidence should be considered, and coverage should be recommended for other conditions.	Although observational before-and-after studies (like those submitted by commenters), do appear to show benefit, the study designs do not permit us to determine whether the effect was caused by HFCWO devices; these study designs cannot control for confounding factors. More robust study designs exist, such as the randomized trial, or if that is not feasible, a matched-cohort or interrupted-time-series study. Though a randomized trial would be very challenging for the heterogenous population with neuromuscular disease, it would be feasible for COPD and bronchiectasis, as they are relatively common conditions. Initially, evidence related to non-CF bronchiectasis and neuromuscular conditions supported non-coverage. However, we have revised our recommendation to allow limited coverage based on the potential benefit and expert recommendation to extrapolate evidence from CF to other non-CF bronchiectasis and on pathophysiological reasoning. For neuromuscular conditions, the variety of disease manifestations makes

IDs/#s	Summary of Issue	Subcommittee Response
		the development of a strong evidence base for each condition unlikely. Thus, we have based our recommendation on expert input and the potential to reduce costs associated with hospitalization and chronic airway infection.
A9, C2, D1, D4	Patients prefer the convenience and independence afforded by HFCWO. The availability of HFCWO devices respects patient preferences and offers several practical advantages. Some patients with varying conditions cannot use chest physiotherapy for practical reasons or because of contraindications related to their conditions.	We note patient preferences for convenience and independence in our GRADE tables and the Values and Preferences section in the report. Patient values and preferences are an important part of the rationale for coverage of HFCWO for patients with cystic fibrosis, for which evidence indicates HFCWO is comparably safe and effective to chest physiotherapy.
A5, C3, C7	Medicare, most state Medicaid programs, and most commercial payers provide coverage for cystic fibrosis, neuromuscular disease, and bronchiectasis. HERC should recommend coverage for patients with these conditions for whom other therapies are ineffective or contraindicated.	The report describes coverage for Medicare, Washington's Medicaid program, and selected payers active in Oregon (e.g., Aetna, Moda, Cigna, and BlueCross BlueShield of Oregon). These payers do cover HFCWO device therapy for cystic fibrosis and bronchiectasis, as well as for certain neuromuscular disorders. However, the subcommittee views other payer policies as contextual information rather than evidence of effectiveness. Step therapy is an appropriate utilization management tool for facilitating limited access to higher-cost services. However, even second-line covered services need to have sufficient evidence of effectiveness for improving critical or important outcomes.
D1–D5	Description of personal experience with a child with Rett's Syndrome and knowledge of other families whose children use the devices and are part of the Children's In-Home Intensive Waiver program.	Personal experiences, including reports of variation in provider and health plan decisions and processes, provide important context for the subcommittee's decisions. HERC's coverage decisions are made at the population level based on available evidence, informed by testimony and expert opinion. These decisions are intended primarily for health plans, including the Oregon Health Plan. The Children's In-Home Intensive Waiver program is not a health plan, and recommendations for that program are outside the scope of this report and outside the purview of the HERC.

HERC Coverage Guidance: High-Frequency Chest Wall Oscillation Devices
Disposition of Public Comments

Commenters

Identification	Stakeholder
A	David Chandler, Senior Director of Payer Relations at American Association for Homecare *[Submitted July 2, 2021]*
B	Gary Hansen, Director of Scientific Affairs at RespirTech *[Submitted June 29, 2021]*
C	Kari Roehrich, Executive Director Managed Care Market Access at Hillrom Respiratory Health *[Submitted July 1, 2021]*
D	Joey Razzano, Oregon Representative for the International Rett Syndrome Foundation, NW Rett Syndrome Association Board member, and mother to child with Rett Syndrome *[Submitted July 5, 2021]*

Public Comments

ID/#	Comment	Disposition
A1	Dear Committee Members, The American Association for Homecare ("AAHomecare") includes a cross section of durable medical equipment ("DME") suppliers, manufacturers, and other stakeholders that furnish DME to acute patients and chronically ill individuals. AAHomecare's members are proud to be part of the continuum of care that assures that individuals receive cost-effective medical equipment and supplies, and related services, in their homes. AAHomecare supports high frequency chest wall oscillation (HFCWO) coverage for patients with airway clearance needs and appreciates the opportunity to comment on the Evidence-based Guidance Subcommittee coverage recommendations for HFCWO. HFCWO is an airway clearance therapy that healthcare professionals have long-used to treat patients with impaired mucociliary clearance and mucus hypersecretion – specifically for the clinical management of cystic fibrosis, neuromuscular disease (NMD), bronchiectasis, and chronic obstructive pulmonary disease (COPD). Due to the lack of coverage criteria and fee schedule for HFCWO in Oregon Medicaid's Durable Medical Equipment (DME), Prosthetics, Orthotics and Supplies	*Thank you for your comments. We have written specific responses to individual sections of your letter in the rows that follow.*

ID/#	Comment	Disposition
	Administrative Rulebook and corresponding fee schedule, there may be access issues for patients with airway clearance concerns. AAHomecare strongly supports the subcommittee's guidance to recommend HFCWO coverage for patients with cystic fibrosis (CF) and urges the committee to consider HFCWO coverage for patients with NMD, bronchiectasis and COPD for the following reasons:	
A2	1) HFCWO therapy is an established technology that has served chronic respiratory patients for decades and is considered the standard of care for cystic fibrosis patients with an estimated 76% of the US CF population using the therapy for airway clearance, according to the 2019 CF Foundation Patient Registry Annual Data Report.	*Our background section acknowledges HFCWO device therapy is a commonly used treatment option for cystic fibrosis.*
A3	2) Respiratory complications are the leading cause of morbidity and mortality for patients with NMD, and HFCWO has been shown to reduce these complications. Some NMD patients are not able to tolerate manual CPT or be put in all of the required positions to receive the treatment.	*Our review found insufficient evidence that HFCWO device therapy reduces exacerbations and hospitalizations for conditions other than cystic fibrosis.*
A4	3) For patients with non-cystic fibrosis bronchiectasis, HFCWO therapy reduces the frequency of acute exacerbations, hospitalizations, antibiotic use and costs.	*For bronchiectasis, our review found very-low-confidence evidence that HFCWO device therapy improves key outcomes.*
A5	4) Medicare, most state Medicaid programs, and nearly all commercial payers, provide HFCWO coverage for CF, NMD and bronchiectasis patients.	*Our policy is to report coverage for Medicare, Washington's Medicaid program, and selected payers active in Oregon (e.g., Aetna, Moda, Cigna, and BlueCross BlueShield of Oregon). These payers do cover HFCWO device therapy for cystic fibrosis and bronchiectasis as well as for certain neuromuscular disorders.*
A6	5) For COPD, airway clearance devices reduce exacerbations and hospitalizations. According to a recent meta-analysis across 18 studies of airway clearance devices, future exacerbations were reduced by 50%. In addition, analysis of real-world data	*We identified the meta-analysis that you refer to (Daynes et al., 2021). The single included study of HFCWO devices that reported exacerbations for patients with COPD in this*

ID/#	Comment	Disposition
	from the Optum claims database found that respiratory-related hospitalizations were reduced by 17% with the application of vest therapy. All-cause hospitalizations were reduced by 40%, ER visits by 27%, and office visits by 12% during the same time in a 2017 study using the Truven MarketScan database.	*meta-analysis was included and summarized in the coverage guidance. The other 17 studies included in this meta-analysis did not report exacerbations for patients with COPD in studies testing the effectiveness of HFCWO devices.* *The 2 other studies that you refer to (Berry et al., 2019; McEvoy et al., 2020) do not meet the study design requirement of the scope of this coverage guidance, as they were retrospective registry studies which additional devices and a broader set of disease entities than was included in this review. The analysis of claims from the Optum database was published as a poster (McEvoy et al., 2020), and is ineligible for inclusion.*
A7	6) Coverage criteria can ensure appropriate utilization by requiring patients to either try and fail other airway clearance therapies or have the therapy be contra-indicated by the patient's prescriber.	*Step therapy is an appropriate coverage tool for enabling access to higher-cost services. However, even second-line covered services need to have sufficient evidence of effectiveness for improving critical or important outcomes.*
A8	7) It is in the best interest of the patient to give physicians access to all therapies and devices to address specific patient needs.	*Thank you for your comment.*
A9	8) Coverage for HFCWO would respect patient preference, increase adherence to therapy, and provide assurance of reliable and consistent treatment, which would ultimately offset costs through reduced exacerbations and hospitalizations. 9) HFCWO offers practical advantages over other airway clearance approaches. For example, unlike chest physical therapy (e.g. chest physiotherapy, which is when a respiratory therapist claps on the chest to loosen mucus from the lungs), HFCWO	*Our review did not look at evidence regarding adherence to therapy and found insufficient evidence that HFCWO device therapy reduces exacerbations and hospitalizations for conditions other than cystic fibrosis. We have noted patient preference for convenience and efficiency in our GRADE table.*

ID/#	Comment	Disposition
	devices make it easier and more efficient to perform chest physical therapy at home without the need for care delivery by a respiratory therapist or caregiver.	*The Values and Preferences section of the coverage guidance details how the lack of trained or willing caregivers can be a barrier to care, as well as how the use of HFCWO device therapy provides independence from caregivers.*
A10	HFCWO reduces respiratory complications for patients with CF, NMD, bronchiectasis and COPD. AAHomecare believes every effort should be made to facilitate access to effective therapies that can improve patient outcomes, reduce hospitalizations, and reduce further burdens to the healthcare system. For these reasons, AAHomecare encourages the committee to provide HFCWO coverage for CF, NMD, bronchiectasis and COPD patient populations. AAHomecare appreciates the opportunity to provide these comments.	*Thank you for your comments.*
B1	To Whom It May Concern: We reviewed the draft guidance for coverage of high-frequency chest wall oscillation (HFCWO) and are pleased with the recommendation for coverage of cystic fibrosis (CF). Thank you for this change and for hearing my testimony at the HERC meeting on June 3. We ask that you reconsider the recommendation for denial of coverage to patients with bronchiectasis (BE), neuromuscular conditions, and COPD in light of real-world evidence that was possibly not considered in the analysis presented. We would first like to comment on the state of evidence for HFCWO therapy. Despite being used for over 20 years, there is a paucity of comparative evidence for any airway clearance technique and a particular paucity of randomized control trials (RCT). There are good reasons for this.	*Thank you for your comments. We have written responses to specific individual sections of your letter in the rows that follow.*

ID/#	Comment	Disposition
	1. HFCWO often treats rare diseases which makes it difficult to recruit cohorts of adequate size. There is little agreement on study endpoints. Prior studies did not identify or control for machine power settings or adherence. 2. Airway clearance studies cannot be blinded, making it impossible to do a double-blind study. HFCWO patients tend to be considerably sicker because of current prescribing habits, making post hoc comparisons between different types of devices difficult to interpret. 3. Lastly, there seems to be little interest among independent researchers on this topic, perhaps because the therapy has been around for so long. These difficulties should be considered when setting expectations for the evidence.	
B2	Here we provide additional evidence about the impact of HFCWO for bronchiectasis, neuromuscular disorders, and COPD that may have been overlooked in the systematic review. This evidence is derived from several objective sources (principally healthcare claims databases) and is complemented by patient-reported outcomes collected in a clinical registry of users of the Philips InCourage System. Collectively, real-world data supports the effectiveness of HFCWO for outcomes such as hospitalization, quality of life, and antibiotic use. We respectfully ask that this evidence be taken into account as you work to finalize the guidance. In 2016, your group expressed enthusiasm about our HFCWO outcomes in bronchiectasis patients and recommended that we publish the results - advice that we followed. We and others have made efforts to address evidence gaps by reporting patient outcomes as well as leveraging external databases of cleared healthcare claims. Collectively, these complementary sources have been published and/or presented at national and international conferences. Based on the data overview provided at the recent HERC meeting, much of this evidence was not considered or shared with the members of the committee.	*Although observational before-and-after studies, such as the real-world studies you refer to, do appear to show benefit, this study design does not permit causal inference, and cannot control for confounding factors. More robust study designs exist, such as the randomized trial or, if that is not feasible, a matched-cohort or interrupted-time-series study.*

ID/#	Comment	Disposition
B3	The RespirTech bronchiectasis registry has been a source of outcomes for our product, the methodology and results appearing in a recent peer-reviewed publication.[4] The results show a reduction in hospitalizations for bronchiectasis patients after the initiation of HFCWO (Figure 1).[4] The authors took specific measures to reduce the risk of bias: (1) registry findings were validated against objective patient chart data, (2) all data were housed and managed by an independent actuarial firm, and (3) all statistics were conducted by a 3d-party biostatistician. While pre-post studies are subject to regression to the mean, these concerns are mitigated by the large sample and the persistent character of the improvement. The data show the response to HFCWO is sustained for up to two years; regression to the mean, if present, would become evident by this point.	*See response to B2 regarding study designs.* *Fundamentally, a before-and-after study may have other limitations in addition to regression toward the mean. In the example of a registry, confounders can include, but are not limited to, the patient characteristics and family context of individuals who have access to HFCWO device therapy, and changes in clinical care aside from the HFCWO device therapy.*
B4	With a larger data set of over 12,000 patients, we extended the results to two years of follow-up, revealing a 72% reduction in hospitalization rate in the two years after initiating vest therapy (Figure 2).[5] Regarding potential cost savings, this works out to be a bit less than one-half of an avoided hospitalization per patient per year. The avoided cost of an expensive inpatient admission compares favorably with the purchase price of the device.	*See response to B2 regarding study designs.*
B5	Real-world evidence from two separate databases of cleared healthcare claims also demonstrates reductions in hospitalization in bronchiectasis patients following initiation of vest therapy. As an example, Weycker showed all-cause hospitalizations were reduced by 33% (n=865 patients).[6] A new study by Basavaraj presented at the 2021 ATS meeting reports that hospitalizations reduced by 73% in year one and by 64% in year two.[7]	*See response to B2 regarding study designs.*
B6	Claims data support the benefits of HFCWO therapy for neuromuscular patients. Analysis of claims data showed a 25% reduction in respiratory-related hospitalizations.[8] In addition, a peer-reviewed publication found a corresponding 20% reduction in inpatient admissions and a 44% reduction in inpatient days.[9]	*Although Lechtzin et al., 2016 is a peer-reviewed publication, the study design was before-after, and the McEvoy et al., 2020 reference cited in this row was presented at a conference and not published in a peer-*

ID/#	Comment	Disposition
		reviewed journal. See response to B2 regarding study design.
B7	Concerning COPD, we bring to your attention a new systematic review and meta-analysis which found that the use of airway clearance devices can improve exacerbation frequency.[10] 18 randomized controlled trials of airway clearance devices for patients with stable COPD were evaluated and reported that using devices to support everyday management reduced future exacerbations by 50%.	*The single included study of HFCWO devices that reported exacerbations for patients with COPD in this meta-analysis was included and summarized in the coverage guidance. The other 17 studies included in this meta-analysis did not report exacerbations for patients with COPD in studies testing the effectiveness of HFCWO devices.*
B8	In terms of hospitalization outcomes from patients with COPD (n=219) within our registry, we found a 54.4% reduction in annualized hospitalization rate for respiratory causes.[11] In addition, a study of Optum claims data found that respiratory-related hospitalization was reduced by 17% in the year after receiving vest therapy.[12] Similarly, a 2017 study using MarketScan data showed that all-cause hospitalization was reduced by 40%.[6]	*All 3 references cited in this row were presented as conference submissions and not published in peer-reviewed journals.*
B9	In summary, this beneficial therapy should be available in the toolkit for physicians in the treatment of patients with bronchiectasis, COPD, and neuromuscular disorders. The difficulties of designing and performing true comparative studies in this area are considerable and the likelihood of new large-scale RCTs being conducted for these disease states is low. However, recent real-world evidence directly addresses critical outcomes identified by this committee. The outcomes for HFCWO have been demonstrated using multiple independent sources. The convergent findings from these studies, specifically as it relates to reducing hospitalizations and improving patient quality of life, should be considered so that this life-altering treatment is available to those who need it.	*Thank you for your comments.* *We reviewed the references that you provided and considered each for inclusion in the coverage guidance. Two references were excluded for not meeting the scope of the coverage guidance (Mikesell et al., 2017; Rubin, 2007). Six references were excluded because they were conference presentations (Barto et al., 2019a; Barto et al., 2019b; Weycker et al., 2017; Basavaraj et al., 2021; McEvoy et al., 2020a; McEvoy et al., 2020b). Three references were excluded due to ineligible study designs (noncomparative observational: Basavaraj et al., 2020; Barto et al., 2020; observational before-after: Lechtzin et al., 2016).*

ID/#	Comment	Disposition
		Your work to address the evidence gaps is helpful and may motivate others to perform more rigorous research on these conditions. However, the subcommittee uses only peer-reviewed studies and generally requires between-group comparison for evidence of treatment effectiveness.
C1	Dear EbGS Committee Members, Hillrom appreciates the opportunity to provide comment on the coverage recommendation for high frequency chest wall oscillation (HFCWO). HFCWO therapy is an established technology that has served chronic respiratory patients for over 30 years. Hillrom strongly supports the EbGS Committee's guidance to recommend HFCWO coverage for patients with cystic fibrosis (CF). Hillrom also requests the committee consider HCFWO coverage for patients with neuromuscular disease (NMD) and bronchiectasis.	*Thank you for your comments. We have written responses to specific individual sections of your comment in the rows that follow.*
C2	HFCWO coverage for patients with CF has expanded across the payer continuum such that at least 45 of the Medicaid fee-for-service plans cover HFCWO for CF beneficiaries. HFCWO is considered standard of care for CF as evidenced by the CF foundation's estimate that 76% of the US CF population uses HFCWO for airway clearance.[1] This is largely attributable to assurance or reliable and consistent treatment, adherence to therapy, and patient preference. Accordingly, providing HFCWO coverage for the CF population would ultimately offset costs through reduced exacerbations and hospitalizations.	*We recognize that HFCWO device therapy is a commonly used treatment option for cystic fibrosis. Though the available evidence shows no difference in hospitalizations compared to chest physiotherapy, we are recommending coverage because of patient preferences and because chest physiotherapy may not be available or feasible for all patients.*
C3	Hillrom strongly encourages the committee also consider coverage for patients with NMD. Respiratory complications are the leading cause of morbidity and mortality for patients with NMD and HFCWO has been shown to reduce these complications. The rationale for the recommendation for coverage for patients with NMD starts that there is no evidence that HFCWO devices improve key outcomes compared to	*No economic studies met our inclusion criteria for this coverage guidance.* *See response to comment A5 regarding other payer coverage.*

ID/#	Comment	Disposition
	standard treatments. Hillrom asserts that sufficient comparative clinical evidence is available that supports the HFCWO therapy on improved key outcomes over standard treatments. Multiple economic outcome studies from highly reputable sources support HFCWO as a cost-saving strategy. Further, including HFCWO coverage for patients with NMD is consistent with Medicare, many Medicaid departments, and an increasing number of commercial payers.	
C4	The Yuan and Landon clinical studies compared the efficacy of HFCWO to chest physiotherapy (CPT). Both studies demonstrated significantly decreased rates of hospitalization for intravenous antibiotics and superior oxygenation for patients using HFCWO as well as superior adherence to the therapy. The investigator-initiated Fitzgerald study demonstrated a 32% reduction in hospitalizations (P<.01) in neurologically impaired children with respiratory symptoms. These studies provide sufficient comparative evidence of the superior benefits of HFCWO over standard treatment for this population.	*The Yuan et al., 2010 reference has been added to the coverage guidance since the submission of this comment. The Landon et al., 2022 reference was excluded because it was a conference abstract. The Fitzgerald et al., 2014 reference reported a before-after study. Although observational before-and-after studies, such as the real-world studies you refer to, do appear to show benefit, this study design does not permit causal inference, and more robust study designs exist, such as the randomized trial or, if that is not feasible, a matched-cohort study.*
C5	In addition, multiple economic outcomes data studies confirm the positive impact of HFCWO therapy on healthcare costs for neuromuscular disorders, which supports the efficacy of HFCWO when compared to standard treatment. Most notable is the 2019 research article published by the National Institute for Health Care Excellence (NICE) which analysed the cost-effectiveness of HFCWO compared to CPT in patients with complex neurological disorders, including neuromuscular disease and cerebral palsy.[5] This analysis revealed that per 1000 patients, the Vest System results in 2,422 less hospitalizations, and 49,868 less bed days compared to CPT, resulting in $8 M in cost savings over a five-year time frame.[5]	*This reference was excluded because the cost effectiveness estimates produced for the health system in the UK are not directly related to cost effectiveness estimates for the health system in the US (Javanbakht et al., 2019). Additionally, this study included information from a before-after study and from the Yuan et al., 2010 study that we have incorporated into the coverage guidance.*

ID/#	Comment	Disposition
C6	Another important economic data study, 2020 Pandya,[6] analysed the claimed of 1008 patients from the Optum healthcare claims repository. The study demonstrated a reduction of respiratory-related hospitalizations by 24.7% ($p<0.005$) in patients receiving HFCWO therapy. Similarly, Lechtzin demonstrated a 41.7% decrease in inpatients costs post intitation of HFCWO.[7] These studies are based on thousands of patient records and clearly show the benefit of HFCWO compared to standard treatment.	*The Pandya et al., 2020 reference was a conference presentation of a before-after study; the other 2 references also utilized a before-after design.*
C7	Additionally, Medicare, most Medicaid departments, and nearly all commercial payers include HFCWO coverage for NMD patients. As of October 1, 2008, all CMS jurisdictions revised the HFCWO Local Coverage Determination to include NMD while over 40 Medicaid departments cover NMD disease state. Consistent with the criteria considerations included in the guidance, payer coverage policies ensure appropriate utilization by requiring patients must either try and fail other airway clearance therapies or have the therapy by contra-indicated by the patient's prescriber.	*See response to comment A5 regarding other payer coverage.*
C8	Hillrom also strongly encourages the committee to approve coverage for patients with non-cystic fibrosis bronchiectasis. In a comparative study, bronchiectasis patients on HFCWO demonstrated superior improvement in dyspnea, pulmonary function tests, and quality of life compared to patients on PEP or CPT.[8] Additional analyses suggest that HFCWO therapy reduces the frequency of acute exacerbations, hospitalizations, antibiotic use and costs in patients with bronchiectasis.[9,10,11,12,13]	*The first reference (Nicolini et al., 2013) is already included in the coverage guidance. The Weycker et al., 2017 and Basavaraj et al., 2021 references are conference abstracts. The remaining 3 references (Barto et al., 2020; Seivert et al., 2018; Sievert et al., 2017) references report studies with noncomparative observational designs. The remaining references are addressed in the previous rows.*
D1	I personally know hundreds of families in the Northwest that have benefited from the use of the HFCWO device aka "The Shaker Vest" when experiencing respiratory distress. The scope of the current coverage guidance is limited to CF and bronchiecstasis. While it refers to other neuromuscular disease resulting in chronic lung disease, Rett Syndrome does not really fall into any of those categories.	*Thank you for your comments and for sharing the story of a patient's care. While individual stories provide context for the Subcommittee's decisions, the Subcommittee makes coverage decisions on a population-level basis and*

ID/#	Comment	Disposition
	Rett Syndrome is like having a child with autism, cerebral palsy, Parkinson's epilepsy and an anxiety disorder all in one. Our daughter also experiences osteoporosis, scoliosis and uses a wheelchair. She is at constant risk for aspiration which can lead to pneumonia literally in a matter of hours. The majority (>80%) of people with Rett Syndrome experience a neurological scoliosis which can require titanium rods to assist with opening the chest cavity. Otherwise, the lung is crushed and tends to fester a chronic infection in one lobe that quickly turns acute. When O2 sats drop, the shaker vest is the first step to increase O2 saturation. In the year before her spinal surgery, [Redacted name] was hospitalized 6 times for pneumonia and this was always the protocol. O2 sats drop, use shaker vest, then on to cough assist, bi-pap, cpap and then trach in that order. If a family has a shaker vest at home, this can often be avoided and it also helps with home care after a hospital stay. During each of these stays the therapists made sure we had this device at home despite having both primary and secondary insurance denying it. We appealed the denial over the course of a year, eventually losing all appeals because this committee has determined that CPT is cost effective and only bronchiecstasis and CF are coverable conditions. We were also at Randall Children's Hospital. My personal experience is that these devices get covered if you go to OHSU but not if you go to Randall. Why the inconsistency? As a parent, the unequal coverage and prescription among hospital systems suggests to me there are magic buzzwords being used that I am not privy to. As a family we were repeatedly assured that we had to go through the appeal and denial process – but that we would be denied eventually due to the current HERC guidance – and that Hill-Rom would gift it to us after that process. That is how I learned that Oregon is the ONLY state that doesn't cover these devices. What is it that 49 other states saw that Oregon does not? At the end of the long and complicated process of applications, appeals and denials, we had to send the device back to the company or pay them	*must base these decisions on evidence and other factors with respect to the population in general.* *Health plans can and sometimes do make individual coverage exceptions for patient circumstances. Appeal and hearing processes are required by law, but outside the Subcommittee's purview.* *The draft coverage guidance recommends coverage for certain patients with cystic fibrosis.* *HERC's coverage decisions are intended primarily for health plans, including the Oregon Health Plan. The Children's In-Home Intensive Waiver program is a separate program, and decisions on which services that program provides are outside the scope of this report.*

ID/#	Comment	Disposition
	$16,000 for the privilege of having it on hand. We made the decision as a family that if her sats drop, we will take her straight to the emergency room because we don't have a shaker vest at home, even though it's the first thing the ER will do after the X-ray confirms diminished breathing in the lower lobes – every single winter….we are just one family on the hundreds of families on the CIIS waivers. Reading this guidance the short version is that: It ONLY covers CF and bronchiectasis and other neuromuscular disease resulting in chronic lung disease. What if you had a MEDICALLY INVOLVED person (as defined by the Children's In Home Intensive Waiver) that resulted in multiple chronic and acute lung and respiratory-related incidents that were not considered 'disease'?	
D2	The current recommendation is "weak" but I find this term vague for a variety of reasons – is it weak because there no empirical evidence or independent analysis on the cost-benefit ratio on the reduction or avoidance of hospitalization? Or is it weak due to the small sample size? IS it weak because the population is limited in scope? Any of those reasons would keep the financial liability limited as well	*According to the subcommittee's methodology (Appendix A), a weak recommendation indicates that "The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors, but further research or additional information could lead to a different conclusion."* *The factors leading to the recommendation are described in the GRADE table.*
D3	CPT is as cost effective as the shaker vest with similar results and can be done by paid or unpaid caregivers for 20-40 minutes per day multiple times a day – try to do that for even 10 minutes on a girl with a T2-Pelvis titanium rod in her back and see how effective that is! It is exhausting and the CPT provider is in constant fear of injuring the patient.	*We did not identify any cost-effectiveness studies that met our inclusion criteria and also addressed the scope of this coverage guidance with information that is relevant to the US health system.* *See response to comment D1 regarding individual patient circumstances.*

HERC Coverage Guidance: High-Frequency Chest Wall Oscillation Devices
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ID/#	Comment	Disposition
	There is not enough evidence because the sample size is too small - but it always will be due to the population making it too small to fall under normal distribution confidence intervals – chicken and egg.	*Evidence is often insufficient, especially for rare conditions, which is why the subcommittee considers public comments and expert testimony, among other factors.*
D4	Evidence showing cost effectiveness has been presented as reduction or avoidance of hospital visits– this committee has disregarded such evidence because it was produced from the manufacturer. Has any analysis been done on any of the population covered by the CIIS waiver? This is the target population that would benefit from this device (even after they turn 18), allowing them to be treated in their home, saving the state money. You could extrapolate what 6 hospitalizations in one year cost the Oregon Health Plan even as secondary provider to determine the cost effectiveness of the shaker vest. I am not including the multiple times that we provided acute care at home during the same time period although there are many. While it would be a sound decision to expand the coverage guidance to people who meet the "medically involved" definition, it would also be financially prudent to cover the shaker vest if the initial expenditure of approximately $16k is less than the cost of even one nights hospitalization which is what the unintended consequence of the current guidance has been. Thank you for your consideration.	*The subcommittee bases decisions regarding effectiveness on peer-reviewed evidence. The Subcommittee does not disregard evidence produced from the manufacturer merely because it was produced by the manufacturer. Registry information from the manufacturers was excluded from the coverage guidance because the way that the information was gathered (a before-after study design) cannot account for competing hypotheses for why individuals using HFCWO device therapy improved or stabilized in terms of symptoms or health care utilization.* *Thank you for your comments.*

References Provided by Commenters

ID	References
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	Rubin BK. Designing clinical trials to evaluate mucus clearance therapy. *Respir Care*. 2007;52(10):1348-1358; discussion 1358-1361. (letter reference #1) Weycker D, Hansen GL, Seifer FD. Outcomes with high-frequency chest wall oscillation among patients with non-CF bronchiectasis or COPD. Presented at: American Thoracic Society Conference; May 21, 2017. P1122. (letter reference #6)
C	<u>Newly included in the coverage guidance</u> Yuan YN, Kane P, Shelton K, Matel J, Becker BC, Moss RB. Safety, tolerability, and efficacy of high-frequency chest wall oscillation in pediatric patients with cerebral palsy and neuromuscular diseases: an exploratory randomized controlled trial, *J. Child Neurol*. 2010;25(7):815–821. (letter reference #2) <u>Already included in coverage guidance</u> Nicolini A, Cardini F, Landucci N, Lanata S, Ferrari-Bravo M, Barlascini C. Effectiveness of treatment with high-frequency chest wall oscillation in patients with bronchiectasis. *BMC Pulm Med*. 2013;13:21. doi: 10.1186/1471-2466-13-21. (letter reference #8) <u>Excluded from the coverage guidance</u> Barto TL, Maselli DJ, Daignault S, et al. Real-life experience with high-frequency chest wall oscillation vest therapy in adults with non-cystic fibrosis bronchiectasis. *Ther Adv Respir Dis*. 2020;14:1753466620932508. (letter reference #9) Basavaraj A, Shah D, DeKoven M, et al. A pre-post analysis assessing the 3-year long-term impact of high frequency chest wall oscillation therapy on clinical outcomes, healthcare cost and utilization in adult patients with non-cystic fibrosis bronchiectasis in the US. ATS 2021 Abstract. 2021:A3944. (letter reference #13) CF Foundation Patient Registry Annual Data Report, 2019. (letter reference #1) Fitzgerald K, Dugre J, Pagala S, et al. High-frequency chest wall compression therapy in neurologically impaired children. *Respir Care.* 2014;59(1):107-112. doi: 10.4187/respcare.02446. (letter reference #4) Javanbakht M, Mashayekhi A, Montazeri M, Hemami MR, Branagan-Harris M. The Vest high frequency chest wall oscillation system compared with chest wall physical therapy for managing airway clearance in patients with complex neurological disorders: a UK-based cost-effectiveness analysis. *Open Pharmacoeconomics Health Econ J.* 2019;7:1-8. doi: 10.2174/1874129001907010001. (letter reference #5) Landon C, Goldie W and Evans JR. Airway clearance therapy utilizing high frequency chest wall oscillation (HFCWO) for medically fragile children [Abstract/Poster]. *J Am Med Dir Assoc.* 2002; 3(2):A17. (letter reference #3) Lechtzin N, Wolfe LF, Frick KD. The impact of high-frequency chest wall oscillation on healthcare use in patients with neuromuscular diseases. *Ann Am Thorac Soc.* 2016;13(6):904-909. (letter reference #7) Pandya P, McEvoy C. A retrospective real-world cohort study demonstrating the impact of HFCWO therapy on healthcare costs in patients with neuromuscular disorders. *CHEST.* 2020;156(4Suppl):A2292. doi: 10.1016/j.chest.2020.08.1943

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D	None provided

HERC Coverage Guidance: High-Frequency Chest Wall Oscillation Devices
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Table of Contents

Discussion Table

IDs/#s	Summary of Issue	Subcommittee Response
A2, C1–C2, C9	Chest physiotherapy and airway clearance devices are not effective for patients with intellectual or developmental disabilities who cannot actively engage with such therapies effectively.	The revised coverage guidance recommendation includes a recommendation for coverage of high-frequency chest wall oscillation (HFCWO) devices for patients for whom chest physiotherapy and positive expiratory pressure device therapy are not tolerated, contraindicated, or not available (e.g., inability of a caregiver to perform).
A3	Some bronchiectasis patients do not have a cough and thus the coverage guidance should remove the daily productive cough as a requirement for HFCWO device therapy	The inclusion of daily productive cough was added as a requirement for HFCWO therapy for patients with non-cystic fibrosis (non-CF) bronchiectasis based on information extrapolated from studies of the cystic fibrosis (CF) population, and as recommended by our appointed ad hoc expert. *For EbGS discussion.*
C3–C4	This coverage guidance should include a list of covered conditions and include Rett Syndrome in that list.	This subcommittee declined to produce a list of covered conditions given the heterogeneity of neuromuscular disorders for whom HFCWO therapy may be effective. Instead, detailed coverage indications ensure that a patient with a very rare disorder may still be eligible for HFCWO therapy provided they meet the criteria.

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Commenters

Identification	Stakeholder
A	Jenna Kelly, parent/caregiver of a child with non-CF bronchiectasis *[Submitted September 24, 2021]*
B	Sharon Skidmore, PT, DPT Physical Therapy for Kids, LLC *[Submitted September 28, 2021]*
C	Joey Razzano, parent/advocate/caregiver of person experiencing Rett Syndrome, International Rett Syndrome Foundation, NW Rett Syndrome Association *[Submitted October 14, 2021]*

Public Comments

ID/#	Comment	Disposition
A1	Please make the vests affordable for families. My child has non-CF-bronchiectasis. It took me years to pay his off and it was a significant struggle for my family.	*Thank you for your comments. We have written specific responses to individual sections of your letter in the rows that follow.*
A2	He also is Autistic and blowing in the little devices was not feasible. He was too young and not able to use them effectively. Once he started using the vest he improved so incredibly much.	*The revised draft coverage guidance includes a pathway to coverage for HFCWO device therapy if other treatments are not tolerated, available or contraindicated.*
A3	Also, I don't like the cough requirement. My son never coughed. He just had a ton of mucus and couldn't/would not expel it on his own, so he would get infections constantly.	*Based on expert testimony, HFCWO device therapy is most effective among patients with non-CF bronchiectasis who have a daily productive cough.*
A4	By expanding the coverage of devices It will also make it easier to get them serviced and sized.	*Thank you for your comment.*
B1	I agree with coverage as the use of High Frequency Chest Wall Oscillation Devices has shown to be very effective and reduces hospitalization when used correctly and consistently which ultimately leads to better patient care and reduced overall cost.	*Thank you for your comment.*

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ID/#	Comment	Disposition
C1	I am just a mom and Rett rep who has personally seen ICU's fill every winter with Rett patients in respiratory distress. When determining criteria for when a HFCWO device should be covered, there are a few observations I've made specific to Rett Syndrome - that is the presence of both scoliosis and hypotonia, often including the use of a wheelchair. Rett patients cannot speak and have no functional hand use to indicate difficulty breathing. Most are at risk of constant aspiration as well. The "cycle" is this: a Rett patient aspirates or is exposed to a virus, develops pneumonia, end up in the emergency room at their O2 sats drop and they will be hospitalized. Respiratory therapy is ordered and the HFCWO device is used, often in conjunction with a cough-assist device.	*Thank you for your comments. We have written specific responses to individual sections of your letter in the rows that follow.*
C2	If scoliosis is present, the kiddo will get well enough to recover at home but a dimness or small amount of infection tends to remain in the lower lobe of one or both lungs. Kiddos with low-tone, scoliosis and a wheelchair can never really expand their chest cavity so the HFCWO provides an effective home therapy that can be done safely and in the home to provide lung clearance. It is not typically prescribed before hospitalization but the pulmonologist will often send the device home as part of routine care following an emergency room visit or hospitalization.	*This level of clinical specificity is not included in the studies identified for this review.*
C3	I would suggest Rett Syndrome or similarly complex syndromes be added to the list defined on page 18 in the background section.	*The subcommittee elected to produce detailed coverage criteria instead of producing a list of covered conditions in order that persons with very rare disorders can obtain access to HFCWO therapy provided they meet the criteria.*
C4	I also suggest that this group look at other states' recommendations for coverage in neuromuscular conditions for more definitive criteria.	*Our policy is to report coverage for Medicare, Washington's Medicaid program, and selected payers active in Oregon (e.g., Aetna, BlueCross BlueShield of Oregon, Cigna, and Moda).*

HERC Coverage Guidance: High-Frequency Chest Wall Oscillation Devices
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ID/#	Comment	Disposition
C5	I also think there should be a return on investment study performed on the neuromuscular population that evaluates the cost of the device versus the expense of a single night in an ICU and I know you will find it is comparatively cheap insurance for this specific population.	*We searched for comparative cost effectiveness studies for this coverage guidance and did not identify any that met our inclusion criteria.* *The subcommittee relies on existing, peer-reviewed published research to make coverage recommendations. It is outside of this group's scope to independently conduct economic studies.*
C6	I also think th4ere's typo on page 24 where it should read CONGENITAL muscular dystrophy under pulmonary complications.	*Thank you for drawing our attention to this typographical error. We have corrected this in the current draft.*
C7	I also wonder if the lungs themselves are considered part of the airway since the wording of the recommendation specifically says "chronic airway infection" - and what defines chronic? My daughter was hospitalized 6 times in one year with pneumonia but we have been able to avoid hospitalization multiple times since then.	*The subcommittee decided against defining "chronic," leaving ability for the exercise of clinical judgment.*
C8	The word CONTRAINDICATED is included in the neuromuscular bronchiecstatis guidance but not the CF guidance. I wonder why they are different.	*We agree and we have updated the wording in both sections.*
C9	The inability of the caregiver to provide chest physiotherapy is an important factor and I am glad to see it included in the criteria for recommendation	*Thank you for your comments.*

Section 6.0

New Discussion Items

Platelet Rich Plasma

Plain Language Summary:
Background: Platelet-rich plasma is used to treat connective tissue injuries, ulcers and wounds. It is blood that contains more platelets than normal blood. Platelets are cell fragments that help blood clot. Research shows a high level of bias and uncertain benefit, and other insurers list this treatment as experimental.
Should OHP cover this treatment? Staff recommends OHP not cover this treatment. Service is costly and evidence doesn't show a clear benefit.

Question: Is platelet rich plasma covered for any indication on the Prioritized List?

Question source: Holly Jo Hodges, CCO medical director

Issue: Platelet-rich plasma (PRP) therapy uses injections of a concentration of a patient's own platelets to accelerate the healing of injured tendons, ligaments, muscles and joints. The mechanism of action of PRP is unclear.

Platelet rich plasma for treatment of knee osteoarthritis was reviewed as part of a coverage guidance, which excluded PRP for this indication; this was added into a guideline. PRP for treatment of spinal conditions was added to Guideline Note 37 at the October 2021 meeting. PRP for treatment of ulcers and wounds was discussed in May 2021 but left on line 662/GN 173.

CCOs would like further direction on coverage, as they get frequent requests for coverage of PRP for a wide variety of indications. Currently, the only code for general PRP is a level III CPT code, 0232T INJECTION(S), PLATELET RICH PLASMA, ANY SITE, INCL. These types of codes are generally considered experimental by Medicaid and not placed on the Prioritized List.

PRP can be used to treat a wide variety of tendinopathies, tendon tears, joint inflammation, plantar fasciitis, osteoarthritis, low back pain, and other musculoskeletal conditions.

Current Prioritized List status

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

Lines 346,529

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
   2) Has neurogenic claudication OR
   3) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
      a) Markedly abnormal reflexes
      b) Segmental muscle weakness
      c) Segmental sensory loss
      d) EMG or NCV evidence of nerve root impingement
      e) Cauda equina syndrome

f) Neurogenic bowel or bladder
g) Long tract abnormalities

Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 529.

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

For all other indications, spine surgery is included on Line 529.

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 529. Diagnostic anesthetic injections for selective nerve root blocks are included on Line 529 for lumbar or sacral symptoms.

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

GUIDELINE NOTE 104, NEWER INTERVENTIONS FOR OSTEOARTHRITIS OF THE KNEE

Lines 431,463

The following treatments are not included on this line for osteoarthritis of the knee:

- Whole body vibration
- Glucosamine/chondrioitin (alone, or in combination)
- Platelet rich plasma
- Viscosupplementation

- Transcutaneous electrical stimulation (TENS)

CPT 20610 and 20611 are included on these lines only for interventions other than viscosupplementation for osteoarthritis of the knee.

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 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
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	Insufficient evidence of effectiveness	May 2021

Evidence

1) **Nazaroff 2021,** systematic review of level I and II studies of platelet rich plasma therapy
    a. N=132 articles
        i. 28 different conditions across eight medical fields. Studies investigating PRP treatment for musculoskeletal (MSK) conditions comprised 74% of all studies. Tendinopathy (n = 29) and osteoarthritis (n = 28) were the two most commonly studied conditions. MSK studies were 76% level 1 evidence while 57% of all other studies were level 1 evidence ($p<0.05$). Cosmetic studies comprised 14% (n = 19) of all studies, and 53% of these were level I evidence.
        ii. Majority of studies were assessed using the Cochranes Risk of Bias Tool, 80% (n = 106). Among these studies, 30% (n = 32) were assessed to be "Low" risk of bias, 25% (n = 26) were found to have "Some Concerns", and 45% (n = 48) were assessed to be "High" risk of bias
    b. Overall, 61% of the studies found PRP to be favorable over control treatment, with no difference in favorable reporting between MSK and other medical specialties.
    c. Conclusions: In summary, the vast majority of level I and II clinical studies investigating PRP have been conducted for MSK injuries, with only a handful of studies conducted for conditions in other medical specialties. Studies that reported details on PRP processing and composition were in the minority, and PROMs were not often used as an outcome measure in non-MSK studies. Rigorous reporting in human clinical studies across all medical specialties is crucial for evaluating the effects of PRP and moving towards disease-specific and individualized treatment.
2) **Gato-Calvo 2019**, evidence review of platelet rich plasma for treatment of osteoarthritis
    a. N=5 systematic reviews and meta-analyses
        i. A total of 19 individual trials were identified in the five reviews but only 9 were level of evidence I RCTs, and many had moderate or high risks of bias.
    b. At present, results from these RCTs seem to favor PRP use over other intraarticular treatments to improve pain scales in the short and medium term (6–12months), but the overall level of evidence is low. As a result, clinical effectiveness of PRP for knee osteoarthritis treatment is still under debate. This is, prominently, the result of a lack of standardization of PRP products, scarceness of high quality RCTs not showing high risks of bias, and poor patient stratification for inclusion in the RCTs.
3) **Chen 2018**, systematic review and meta-analysis of platelet rich plasma on tendon and ligament healing
    a. N=21 studies (1031 patients)
        i. The majority of studies published investigated rotator cuff (38.1%) or lateral epicondylitis (38.1%).
        ii. Other included conditions: patellar tendinopathy (PT), achilles tendinopathy (AT), anterior cruciate ligament injury (ACL), and hamstring tendinopathy (HT).
    b. 17 studies (844 participants) reported short-term VAS data and 14 studies (771 participants) reported long-term VAS data. Overall, long-term follow-up results showed significantly less pain in the PRP group compared to control (WMD: −0.84; 95% CI: −1.23, −0.44; $p<0.01$). Patients treated for rotator cuff injury (WMD: −0.53; 95% CI: −0.98, −0.09; $p=0.02$) and lateral epicondylitis (WMD: −1.39; 95% CI: −2.49, −0.29; $p=0.01$) both reported significantly less pain in the long-term. Substantial heterogeneity was reported at baseline ($I2: 72.0\%$, $p<0.01$), short term follow-up ($I2: 72.5\%$, $p<0.01$), long term follow-up ($I2: 76.1\%$, $p<0.01$), and overall ($I2: 75.8\%$, $p<0.01$). The funnel plot

appeared to be asymmetric, with some missingness at the lower right portion of the plot suggesting possible publication bias.

c. No study reported severe adverse events (SAEs).
d. **Conclusion:** This review shows that PRP may reduce the pain associated with lateral epicondylitis and rotator cuff pathology.

4) **Hussain 2017**, evidence based evaluation of platelet rich plasma in orthopedics
    a. Reviewed conditions:
        i. Knee osteoarthritis, rotator cuff repair, epicondylitis, patellar tendinopathy, Achilles tendinopathy, hamstring injuries and anterior cruciate ligament repair
    b. the evidence appears to suggest that PRP may provide some benefit in patients who present with knee osteoarthritis or lateral epicondylitis. On the other hand, evidence appears to be inconsistent or shows a minimal benefit for PRP usage in rotator cuff repair, patellar and Achilles tendinopathies, hamstring injuries, anterior cruciate ligament (ACL) repair, and medial epicondylitis. There is limited confidence in the conclusions from the published meta-analyses due to issues with statistical pooling, and limited subgroup analyses exploring the substantial heterogeneity across studies. Evidence-based clinicians considering the use of PRP in their patients with musculoskeletal injuries should be wary that the literature appears to be inconsistent and thus far, inconclusive.

<u>Other payer policies</u>

1) CMS LCD 2021: This is a NON-coverage policy for all platelet-rich plasma (PRP) injections and/or applications as a means of managing musculoskeletal injuries and/or joint conditions
    a. While promising, we believe that there is insufficient high-quality evidence to justify the use of PRP for the treatment of any condition except for within the confines of a well-designed clinical trial.
2) All private payers surveyed considered PRP to be experimental.

Platelet Rich Plasma

HERC staff summary

General review of the effectiveness of platelet rich plasma for a wide variety of conditions finds that the literature is highly biased and inconclusive. CMS and all private payers consider PRP experimental, and Medicaid considers CPT level III codes, such as 0232T, to be experimental. HERC staff recommend placing CPT 0232T on line 662/GN173, with individual indications reviewed in the future as evidence matures.

HERC staff recommendation

1) Add CPT 0232T to line 662/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 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
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	Insufficient evidence of effectiveness	March 2022

PLOS ONE

RESEARCH ARTICLE

Reporting in clinical studies on platelet-rich plasma therapy among all medical specialties: A systematic review of Level I and II studies

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Abstract

Background

The clinical practice of platelet-rich plasma (PRP) therapy has grown significantly in recent years in multiple medical specialties. However, comparisons of PRP studies across medical fields remain challenging because of inconsistent reporting of protocols and characterization of the PRP being administered. The purpose of this systematic review was to determine the quantity of level I/II studies within each medical specialty and compare the level of study reporting across medical fields.

Methods

The Cochrane Database, PubMed, and EMBASE databases were queried for level I/II clinical studies on PRP injections across all medical specialties. From these studies, data including condition treated, PRP processing and characterization, delivery, control group, and assessed outcomes were collected.

Results

A total of 132 studies met the inclusion and exclusion criteria and involved 28 different conditions across 8 specialties (cardiothoracic surgery, cosmetic, dermatology, musculoskeletal (MSK), neurology, oral maxillofacial surgery, ophthalmology, and plastic surgery). Studies on PRP for MSK injuries made up the majority of the studies (74%), with knee osteoarthritis and tendinopathy being most commonly studied. Of the 132 studies, only 44 (33%) characterized the composition of PRP used, and only 23 (17%) reported the leukocyte component. MSK studies were more likely to use patient-reported outcome measures to assess outcomes, while studies from other specialties were more likely to use clinician- or imaging-based objective outcomes. Overall, 61% of the studies found PRP to be favorable over control treatment, with no difference in favorable reporting between MSK and other medical specialties.

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

Conclusions

The majority of level I/II clinical studies investigating PRP therapy across all medical specialties have been conducted for MSK injuries with knee osteoarthritis and tendinopathy being the most commonly studied conditions. Inconsistent reporting of PRP composition exists among all studies in medicine. Rigorous reporting in human clinical studies across all medical specialties is crucial for evaluating the effects of PRP and moving towards disease-specific and individualized treatment.

Introduction

The use of platelet-rich plasma (PRP) to treat a multitude of medical conditions has greatly increased over the past decade. As a strategy to deliver a higher concentration of growth factors and cytokines that initiate and regulate tissue healing, PRP therapy has been utilized for a wide range of orthopaedic injuries, including tendinopathies, osteoarthritis, and muscle injuries [1–3]. Recently, PRP has also been increasingly used for the treatment of cosmetic conditions, including hair restoration, breast augmentation, scar treatment, and dermatologic conditions [4–6]. Other reported applications of PRP therapy have included nerve regeneration, periodontal therapies, wound healing, and augmentation of surgical repairs [7–9].

Despite the widespread clinical practice of PRP in all areas of medicine, there remains uncertainty and skepticism among the medical community regarding its efficacy. Much of this skepticism can be attributed to the unawareness of the quantity and quality of evidence investigating PRP treatment, particularly across medical specialties. The practice of evidence-based medicine utilizes the strongest quality of evidence to make informed decisions on the care of individual patients. Although many randomized controlled trials investigating PRP have been conducted for musculoskeletal (MSK) conditions [1,3,10,11], the number of high-quality studies on PRP treatment from other medical specialties compared to orthopaedics, sports medicine, and other MSK fields is unknown. Furthermore, there remain deficiencies in the level of reporting in these studies, particularly regarding the processing and composition of PRP. This has led to calls within orthopaedics for minimal reporting standards in order to allow for reproducibility and comparison across studies [12–15]. Whether the level of reporting is similarly inconsistent within studies from other medical fields is unknown. Detailed reporting in clinical trials for PRP across all medical fields would be beneficial for identifying the key components of PRP and efficiently translating PRP therapy into clinically meaningful treatment.

The purpose of this systematic review was to review the current PRP literature across all medical specialties and determine 1) the quantity of level I and II studies within each medical specialty based on indication, and 2) the level of reporting in these studies with regards to PRP processing, composition, activation, delivery, and outcome assessment. Due to the majority of these studies being from the orthopaedic literature, comparisons in the level of reporting between MSK studies and those from other medical fields were performed.

Materials and methods

Article identification and selection process

A literature search was conducted in June 2019 to identify articles pertaining to PRP therapy according to Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines (Fig 1) [16]. The PubMed (including MEDLINE), Cochrane, and EMBASE

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Platelet-rich plasma in osteoarthritis treatment: review of current evidence

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Abstract: Platelet-rich plasma (PRP) is defined as a volume of plasma with a platelet concentration higher than the average in peripheral blood. Many basic, preclinical and even clinical case studies and trials report PRP's ability to improve musculoskeletal conditions including osteoarthritis, but paradoxically, just as many conclude it has no effect. The purpose of this narrative review is to discuss the available relevant evidence that supports the clinical use of PRP in osteoarthritis, highlighting those variables we perceive as critical. Here, recent systematic reviews and meta-analyses were used to identify the latest randomized controlled trials (RCTs) testing a PRP product as an intra-articular treatment for knee osteoarthritis, compared with an intra-articular control (mostly hyaluronic acid). Conclusions in the identified RCTs are examined and compared. In total, five recent meta-analyses and systematic reviews were found meeting the above criteria. A total of 19 individual trials were identified in the five reviews but only 9 were level of evidence I RCTs, and many had moderate or high risks of bias. At present, results from these RCTs seem to favor PRP use over other intra-articular treatments to improve pain scales in the short and medium term (6–12 months), but the overall level of evidence is low. As a result, clinical effectiveness of PRP for knee osteoarthritis treatment is still under debate. This is, prominently, the result of a lack of standardization of PRP products, scarceness of high quality RCTs not showing high risks of bias, and poor patient stratification for inclusion in the RCTs.

Keywords: allogenic products, anti-inflammatory intra-articular therapies, clinical evidence, clinical trials, knee osteoarthritis, patient stratification, platelet-rich plasma

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Introduction

Platelets, also known as thrombocytes, are small cytoplasmic fragments derived from bone marrow megakaryocytes. Most platelet functions are directly connected with platelet activation, a process that occurs naturally after an injury in the wall of a blood vessel. Platelets are then exposed to collagen and other extracellular matrix proteins that stimulate their activation, resulting in the release of the content of their cytoplasmic granules.[1] Overall, platelets contain over 800 proteins and molecules, comprising cytokines, chemokines, membrane proteins, metabolites, messenger molecules, growth factors (GFs) and numerous soluble proteins.[2] As a result, besides their role in coagulation and hemostasis, platelets are also involved in vasoconstriction, inflammation, immune response, angiogenesis and tissue regeneration and consequently, they participate in numerous physiologic signaling mechanisms and are related to multiple pathologies.[3–5]

The therapeutic use of platelet concentrates was first described by Whitman in 1997,[6] although blood-derived fibrin glues were already used 30 years earlier to seal wounds and stimulate their healing.[7] In 1998, platelet concentrates started to be known as platelet-rich plasma (PRP), generally defined as a volume of autologous plasma containing a higher platelet count than peripheral blood (150,000–350,000 platelets/μl).[8] Thereafter

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The Efficacy of Platelet-Rich Plasma on Tendon and Ligament Healing: A Systematic Review and Meta-Analysis with Bias Assessment

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Abstract

Background: There has been a surge in high level studies investigating platelet rich plasma (PRP) for tendon and ligament injuries. A number of meta-analysis have been published, but few studies have focused exclusively on tendon and ligament pathology.

Purpose: To perform a meta-analysis assessing the ability of PRP to reduce pain in patients with tendon and ligament injuries.

Study Design: Systematic review and meta-analysis

Methods: This study followed the PRISMA (Preferred Reporting Items and Systematic Reviews and Meta-Analyses) guidelines. A comprehensive search of the literature was carried out in April 2017 using electronic databases PubMed, MEDLINE, and the Cochrane Library. Only Level I studies were included. Platelet and leukocyte count, injection volume, kit used, participant age/gender, comparator, and activating agent used were recorded. The short-term and long-term efficacy of PRP was assessed using the visual analog scale (VAS), which measures pain intensity. Pathology subgroups (rotator cuff, tendinopathy, ACL, and lateral epicondylitis) were evaluated. Funnel plots and Egger's test were used to screen for publication bias and sensitivity analysis was performed to evaluate the impact of potential outliers by removing studies one at a time.

Results: Thirty-seven articles were included in this review, 21 (1031 participants) of which could be included in the quantitative analysis. The majority of studies published investigated rotator cuff (38.1%) or lateral epicondylitis (38.1%). 17 studies (844 participants) reported short-term VAS data and 14 studies (771 participants) reported long-term VAS data. Overall, long-term follow-up results showed significantly less pain in the PRP group compared to control (WMD: −0.84; 95% CI: −1.23, −0.44; $p<0.01$). Patients treated for rotator cuff injury (WMD: −0.53; 95% CI: −0.98, −0.09; $p=0.02$) and lateral epicondylitis (WMD: −1.39; 95% CI: −2.49, −0.29; $p=0.01$) both reported significantly less pain in the long-term. Substantial heterogeneity was reported at baseline (I^2: 72.0%, $p<0.01$), short term follow-up (I^2: 72.5%, $p<0.01$), long term follow-up (I^2: 76.1%, $p<0.01$), and overall (I^2: 75.8%, $p<0.01$). The funnel plot appeared to be asymmetric, with some missingness at the lower right portion of the plot suggesting possible publication bias.

Conclusion: This review shows that PRP may reduce the pain associated with lateral epicondylitis and rotator cuff pathology.

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REVIEW ARTICLE OPEN ACCESS

An evidence-based evaluation on the use of platelet rich plasma in orthopedics – a review of the literature

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Abstract – Within orthopedics, the use of platelet-rich plasma (PRP) has been rapidly increasing in popularity, however, its true effectiveness has yet to be fully established. Several studies find that injecting PRP to the site of injury does not provide any significant benefit with respect to clinical outcomes; however, many others report the contrary. Due to the conflicting evidence and multiple meta-analyses conducted on the topic, a literature review of high-quality evidence on the use of PRP for common orthopaedic conditions was performed. Thus far, the evidence appears to suggest that PRP may provide some benefit in patients who present with knee osteoarthritis or lateral epicondylitis. On the other hand, evidence appears to be inconsistent or shows a minimal benefit for PRP usage in rotator cuff repair, patellar and Achilles tendinopathies, hamstring injuries, anterior cruciate ligament (ACL) repair, and medial epicondylitis. There is limited confidence in the conclusions from the published meta-analyses due to issues with statistical pooling, and limited subgroup analyses exploring the substantial heterogeneity across studies. Evidence-based clinicians considering the use of PRP in their patients with musculoskeletal injuries should be weary that the literature appears to be inconsistent and thus far, inconclusive.

Key words: Platelet rich plasma, Orthobiologics, Evidence-based medicine, Review.

Platelet-rich plasma in orthopedics

Within orthopedics, the use of platelet-rich plasma (PRP) has been increasing in popularity. United States estimates alone suggest that approximately 86,000 athletes are treated with PRP annually [1]. Even though its popularity is rising, its true effectiveness has yet to be fully established. Several studies find that injecting PRP to the site of injury does not add any significant benefit to clinical outcomes; however, many others report the contrary. This becomes even more of a concern since the cost of treatment can be relatively high. Peerbooms et al. (2010) reported that the cost for a single PRP injection is approximately $840.00 USD whereas a simple corticosteroid injection is around $300.00 USD [2]. With the conflicting evidence and high cost of PRP treatment, it is imperative that a more definitive answer regarding its efficacy is found. Given the continued uncertainty of PRP with regard to its efficacy at improving various clinical outcomes in a broad spectrum of orthopedic conditions, we undertook this review to help clinicians better understand the basics behind PRP and the clinical evidence surrounding it.

What is platelet-rich plasma?

The platelets contained within autologous blood play an important role in healing since they secrete several growth factors to the site of injury [3]. Briefly, among other roles, these platelets serve to promote mitogenesis of healing capable cells and angiogenesis in the tissue [4]. Autologous blood, which contains such platelets in higher than normal concentrations, is commonly referred to as platelet-rich plasma (PRP). For instance, the normal platelet count in healthy individuals is around $1.5–4.5 \times 10^5/\mu L$; however, to be considered PRP, the platelet should be 4–5 times above this amount [5]. This relatively recent biotechnology has been reported to enhance the healing process since an increased number of platelets results in an increased number of secreted growth factors, thereby theoretically improving the healing process [4, 6]. Some of the growth factors in PRP include: platelet-derived growth factor (PDGF), transforming growth factor beta (TGF-β), vascular endothelial growth factor (VEGF), and epithelial growth factor (EGF) [1, 3, 6]. Thus, unlike recombinant technology which is synthetic, PRP takes advantage of the naturally occurring proteins in the healing process. In addition to these factors, PRP contains adhesion molecules which

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Breast Reconstruction After Lumpectomy

Plain Language Summary:
Background: If a patient wants breast reconstruction on one or both breasts after surgery to remove a breast due to cancer, a federal law requires that insurance pay for it. Currently, if the breast is only partially removed (lumpectomy), it is unclear whether OHP and federal law require reconstruction of one or both breasts. Lumpectomies can range from removing a small lump to a large portion of the breast. If reconstruction after lumpectomy is not covered, some patients may choose to have their breast removed completely.
Should OHP cover breast reconstruction after cancer is removed from one breast? Staff recommends clarifying that OHP does cover reconstruction after lumpectomy because coverage of this procedure is currently unclear and to avoid unintentional incentives for unnecessary complete mastectomy.

Question: Is breast reconstruction after lumpectomy a covered service on the Prioritized List?

Question source: Kristin Garrett, CCO medical director

Issue: The Women's Health and Cancer Rights Act requires insurance to cover breast reconstruction including surgery on the contralateral breast after "mastectomy." Currently, GN79 BREAST RECONSTRUCTION states that "breast reconstruction is only covered after mastectomy." Dr. Garrett is requesting clarification of coverage of reconstruction after lumpectomy for breast cancer. Lumpectomy is a surgery where only a portion of the breast is removed, and it is becoming increasingly common for certain stages of breast cancer. Lumpectomy generally has fewer risks than mastectomy, and requires fewer follow up procedures. The CPT codes used for lumpectomy list the procedure as "mastectomy, partial."

In some cases, lumpectomy removes only a small portion of breast tissue and no reconstruction is desired. In other cases, lumpectomy can remove a considerable portion of breast tissue, leaving significant disproportion between breasts. Most private insurance payers will cover breast reconstruction or contralateral breast reduction or similar surgeries after lumpectomy.

There is concern that limited coverage for reconstruction to only after mastectomy might incentivize patients on OHP to opt for mastectomy when a lumpectomy would be a reasonable treatment approach. Mastectomy is a much more morbid procedure, and generally the reconstruction afterwards involves multiple steps and procedures.

From CMS
https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet (accessed October 19, 2021)

> The Women's Health and Cancer Rights Act of 1998 (WHCRA) is a federal law that provides protections to patients who choose to have breast reconstruction in connection with a mastectomy.
>
> If WHCRA applies to you and you are receiving benefits in connection with a mastectomy and you elect breast reconstruction, coverage must be provided for:
>
> - All stages of reconstruction of the breast on which the mastectomy has been performed;

- Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
- Prostheses and treatment of physical complications of all stages of the mastectomy, including lymphedema.

This law applies to two different types of coverage:

1. Group health plans (provided by an employer or union);
2. Individual health insurance policies (not based on employment).

Current Prioritized List status

CPT 19301-19302 (Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy) are on line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER

GUIDELINE NOTE 79, BREAST RECONSTRUCTION

Line 191

Breast reconstruction is only covered after mastectomy as a treatment for breast cancer or as prophylactic treatment for the prevention of breast cancer in a woman who qualifies under Guideline Note 3, and must be completed within 5 years of initial mastectomy.

Breast reconstruction may include contralateral reduction mammoplasty (CPT 19318) or contralateral mastopexy (CPT 19316). Mastopexy is only to be covered when contralateral reduction mammaplasty is inappropriate for breast reconstruction and mastopexy will accomplish the desired reconstruction result.

Breast Reconstruction After Lumpectomy

Expert guidelines

1) **NCCN Breast Cancer** treatment guideline, version 8.2021
    a. After lumpectomy, prior to radiation therapy
        i. No reconstruction required if ratio of tumor to breast volume is small and minimal cosmetic deformity with result, OR
        ii. Consider oncoplastic reduction or mastopexy and simultaneous or delayed contralateral matching procedure, OR
        iii. Consider bilateral breast reduction if symptoms warrant, or
        iv. Local tissue rearrangement, regional flap
    b. After lumpectomy and radiation therapy
        i. Delayed fat grafting
        ii. Delayed flap for correction of contour defects
        iii. Contralateral reduction/mastopexy for symmetry

Other payer policies

1) Aetna 2021
    - Aetna considers reconstructive breast surgery medically necessary after a medically necessary mastectomy or a medically necessary lumpectomy that results in a significant deformity (i.e., mastectomy or lumpectomy for treatment of or prophylaxis for breast cancer and mastectomy or lumpectomy performed for chronic, severe fibrocystic breast disease, also known as cystic mastitis, unresponsive to medical therapy).
2) Cigna 2021
    - Breast reconstruction following mastectomy or lumpectomy is considered medically necessary for EITHER of the following:
        - breast reconstruction procedures performed on the diseased/affected breast (i.e., breast on which the mastectomy/lumpectomy was performed),
        - breast reconstruction procedures performed on the nondiseased/unaffected/contralateral breast, in order to produce a symmetrical appearance
3) Anthem BCBS 2021
    - The Women's Health and Cancer Rights Act of 1998 (WHCRA) mandated that reconstructive breast surgery for women and men who have undergone mastectomy be covered by their benefits for those who have opted to have breast reconstruction. In individuals who have undergone a medically necessary lumpectomy, surgery to create a more normal anatomy is considered reconstructive.
4) MODA 2020
    - Reconstructive breast surgery is performed following a mastectomy, lumpectomy or prophylactic mastectomy for high-risk patients to re-establish symmetry between the two breasts.

Expert input

Danielle Bertoni and John Vetto, breast surgeons: both felt that reconstruction after lumpectomy was standard of care.

HERC staff summary

Due to concern that WHCRA requires coverage for reconstruction after partial mastectomy (lumpectomy) and a desire to not create an incentive to elect a mastectomy when a lumpectomy is sufficient treatment, HERC staff recommend revising GN79 to clarify that breast reconstruction after lumpectomy is a covered service.

HERC staff recommendation:

1) Modify Guideline Note 79 as shown below

GUIDELINE NOTE 79, BREAST RECONSTRUCTION

Line 191

Breast reconstruction is only covered after mastectomy, or lumpectomy that results in a significant deformity or asymmetry, as a treatment for breast cancer or as prophylactic treatment for the prevention of breast cancer in a woman who qualifies under Guideline Note 3, and must be completed within 5 years of initial mastectomy or lumpectomy.

Breast reconstruction may include contralateral reduction mammoplasty (CPT 19318) or contralateral mastopexy (CPT 19316). Mastopexy is only to be covered when contralateral reduction mammaplasty is inappropriate for breast reconstruction and mastopexy will accomplish the desired reconstruction result.

Breast MRI Guidelines

Question: How best can the coverage of breast MRI be clarified on the Prioritized List?

Question source: Several CCO medical directors

Issue: There are currently 3 guidelines that relate to breast MRI on the Prioritized List, and the CCO medical directors frequently have questions about how they relate to one another. They have previously requested clarification of these guidelines, but even those clarifications are not sufficient for the CCO PA process. There have also been questions from CCOs and providers about the lack of Prioritized List coverage for MRI after breast cancer diagnosis, which has generally become standard of care.

From Max Kaiser, CCO medical director

> The main impetus are cases where members meet [criteria] for breast MRI screening, but haven't had the screening, and are now diagnosed with a new breast cancer. As the member met for screening, the surgeon uses that as reasoning to request screening of the uninvolved breast so they could treat any identified breast cancer at the same time and image the involved breast for other occult lesions. That scenario may warrant clarification with the NCCN caveat that false-positives are common and should be confirmed with tissue sampling. We had also talked about aligning D6 and ~~D6~~[26] to indicated when after the member's original treatment an MRI is covered for future screening. Currently it's covered annually. Does this mean 1 year after treatment or would it also be covered, as with the mammogram, 6 months after radiotherapy if treated with breast conserving therapy? I also get fairly regular requests for a breast MRI in a newly diagnosed member that I approve by exception as they align with NCCN, such as poorly defined disease on mammogram/ultrasound or multifocal/multicentric

Current Prioritized List status:

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

Annual screening mammography and annual screening MRI are covered only for women at above-average risk of breast cancer. This coverage, beginning at 30 years of age, includes women who have one or more of the following:

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

For women with a history of high dose chest radiation (≥ 20 Gray) before the age of 30, annual screening MRI and annual screening mammography are covered beginning 8 years after radiation exposure or at age 25, whichever is later.

For women with both a personal history and a family history of breast cancer which give a greater than 20% lifetime risk of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are covered.

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

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

For surveillance for a treated breast cancer, see Guideline Note 26 BREAST CANCER SURVEILLANCE.

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

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

GUIDELINE NOTE 26, BREAST CANCER SURVEILLANCE
Line 191
History and physical exam is indicated every 3 to 6 months for the first three years after primary therapy, then every 6-12 months for the next 2 years, then annually thereafter.

Mammography is indicated annually, and patients treated with breast-conserving therapy, initial mammogram of the affected breast should be 6 months after completion of radiotherapy.

No other surveillance testing is indicated.

For ongoing screening for a new breast cancer, see Guideline Note 2006 BREAST CANCER SCREENING IN ABOVE-AVERAGE RISK WOMEN.

Expert guidelines

1) **NCCN Breast Cancer** treatment guideline, version 2.2022
    a. Clinical indications and applications for breast MRI
        i. May be used for staging evaluation to define extent of cancer or presence of multifocal or multicentric cancer in the ipsilateral breast, or as screening of the contralateral breast cancer at time of initial diagnosis (category 2B). there are no high-level data to demonstrate that the use of MRI to facilitate local therapy decision-making improves local recurrence or survival
        ii. May be helpful for breast cancer evaluation before and after preoperative systemic therapy to define extent of disease, response to treatment, and potential for breast-conserving therapy
        iii. May be useful in identifying otherwise clinically occult disease in patients presenting with axillary nodal metastases (cT0, CN+), with Paget disease, or with invasive lobular carcinoma poorly (or inadequately) defined on mammography, ultrasound or physical examination
        iv. False-positive findings on breast MRI are common. Surgical decisions should not be based solely on the MRI findings. Additional tissue sampling of areas of concern identified by breast MRI is recommended
        v. The utility of MRI in follow-up screening of patients with prior breast cancer is undefined. It should generally be considered only in those whose lifetime risk of a second primary breast cancer is >20% based on models largely dependent on

family history, such as those with the risk associated with inherited susceptibility to breast cancer.

b. Specific clinical situations:
    i. DCIS: breast MRI has not been shown to increase likelihood of negative margins or decrease conversion to mastectomy. Data to support improved long-term outcomes is lacking
    ii. Non-metastatic (M0) invasive breast cancer and higher stage invasive breast cancer: breast MRI is optional, may be useful for characterizing axillary and/or internal mammary nodal disease. MRI findings tend to overestimate extent of disease resulting increase in frequency of mastectomies. Two prospective randomized studies have examined the utility of pre-operative MRI in determining disease extent, and neither demonstrated improvement in rates of post-lumpectomy re-excision. One systematic review found MRI staging altered surgical treatment in 7.8-33.3% of women; however, no differences in local recurrent or survival has been demonstrated.

2) **NCCN Breast Cancer screening and diagnosis**, version 1.2021
    a. Recommend annual MRI screening:
        i. For individuals with a genetic mutation, or a first-degree relative of gene mutation carrier
        ii. For individuals who received thoracic radiation therapy between the ages of 10 and 30 years
            1. Begin 8 years after radiation therapy but not prior to age 25 years
        iii. For individuals with a lifetime risk of ≥ 20% as defined by models that are largely dependent on family history
            1. To begin 10 years prior to when the youngest family member was diagnosed with breast cancer, not prior to age 25 years or age 40 years (whichever comes first)
3) **American Society of Breast Surgeons 2017**: consensus guideline on diagnostic and screening MRI of the breast
    a. The ASBrS does not recommend routine diagnostic MRI in newly diagnosed breast cancer patients except as part of a scientific study.
    b. The ASBrS supports the use of MRI in the following situations:
        i. To search for occult breast cancer in patients with Paget's disease of the nipple or in patients with axillary node metastasis when clinical examination and conventional breast imaging fail to detect a primary breast cancer. MRI identifies an ipsilateral cancer focus in 60-70% of patients who present with axillary nodal metastases and no cancer identified on clinical examination, mammography, or ultrasound.
        ii. For determining the extent of cancer or presence of multi-focal or multi-centric tumor or the presence of contralateral cancer, in patients with a proven breast cancer and associated clinical or conventional indeterminate imaging findings suspicious for malignancy. This may include patients with invasive lobular carcinoma or extremely dense breast tissue (limiting mammographic sensitivity), or when there are significant discrepancies in the estimated tumor size as measured on clinical exam, mammogram, and ultrasound. The American College of Radiology Appropriateness Criteria and a recent meta-analysis by Houssami et al conclude there are no proven criteria for any patient sub-

population that benefits the most from routine MRI based on specific patient, tumor, or mammographic characteristics.

iii. To aid the assessment for eligibility and response to neoadjuvant endocrine therapy or chemotherapy before, during, or after treatment. MRI can help identify those patients who are candidates for breast conservation, and assist in determining the extent of resection40,41. After neoadjuvant chemotherapy (NAC), MRI has a sensitivity of 92% to detect residual disease and a specificity of 60% for pathologic complete response (pCR), based on a meta-analysis of studies including 2050 patients reported by Marinovich et al in 2013. Compared to mammography, MRI was better in assessing response to NAC, but a negative MRI did not always exclude residual microscopic disease. In two updated metaanalyses (2016 and 2017) assessing pCR, Gu et al and Sheikhbahaei et al reported pooled sensitivities and specificities of 64%/88% and 92%/55% respectively. MRI is not mandatory in patients undergoing neoadjuvant systemic therapy.

iv. For the further evaluation of suspicious clinical or imaging findings that remain indeterminate after complete mammographic and sonographic evaluations. If lesions meet the criteria for biopsy by clinical examination or conventional imaging, then it may be preferable to perform minimally invasive needle biopsy, targeted by mammogram or US, rather than obtain an MRI.

v. For evaluation of suspected breast implant rupture, especially in patients with silicone implants, if the MRI findings will aid the decision-making for implant removal or aid the diagnostic evaluation of indeterminate clinical or conventional imaging findings in patients with implants. The MRI protocol for detection of silicone leak is different from the protocol for detection of breast cancer. Thus, it is important to clearly define the purpose of the breast MRI if the concern is a silicone leak.

<u>Expert input</u>:

Steve Kornfeld, breast surgeon:

Dr. Kornfeld recommended against including coverage for first degree relatives of mutation carriers, as confirmation testing is readily available and inexpensive. The relative has a 50% chance of having the mutation. If she does not carry it, then she is normal risk and should be screened with mammograms.

Dr. Kornfeld also felt that preoperative breast MRI is standard of care for women, specifically if breast conservation (lumpectomy) is being considered over mastectomy. The rationale is to look for multifocal tumors. This is listed in NCCN as an option (2B recommendation).

Danielle Bertoni, breast surgeon:

I think there is one major group missing which is patients who have a genetic mutation or are at high risk for genetic mutation and are planning breast conservation. If we have a patient who is newly diagnosed with breast cancer and meets criteria for genetic testing or has extensive family history of breast cancer and is planning breast conservation, then we may need to follow them for screening going forward with breast MRI. If this is the case, then we would want the breast MRI prior to going to surgery for their cancer treatment. We would not want to wait until they are due for MRI screening in 6 months and then find a new lesion in the same or contralateral breast that we could have and should have addressed at diagnosis. This is more of

a concern in patients who also have dense breast tissue and are more likely to have things missed by conventional imaging. IF they know they want breast conservation regardless of genetic testing results, we often go to surgery prior to results coming back. In many cases, even if results are negative, they are still high risk based on family history and we would want to screen them with MRI going forward, again especially with dense breast tissue. Ultimately, if someone meets the high risk criteria and has cancer, they should be approved for an MRI at diagnosis.

The other time we have had difficulty getting them approved is if someone has a breast MRI and it has a birads 3 finding. They are recommended for 6 month follow up and it is getting denied.

Winnie Henderson, breast surgeon:

Our practice follows the ASBrS recommendations [see above]

Breast MRI Guidelines

HERC staff summary

The current three guidelines regarding breast cancer screening modalities continue to be confusing to CCOs and difficult to administer. There are generally few barriers to mammography or breast ultrasound; therefore, staff feel that the guidelines should be simplified by removing mammogram/breast ultrasound coverage wording and only outline when breast MRI is covered. Furthermore, GN26 BREAST CANCER SURVEILLANCE is a practice guideline, not a coverage guideline and therefore staff recommends deletion.

Staff recommend combining these three guidelines coverage regarding breast MRI and clarifying criteria based on NCCN recommendations. Furthermore, staff recommend retiring the coverage guidances related to breast cancer screening for women at above average risk and MRI for breast cancer diagnosis and MRI for breast cancer screening.

NCCN addresses coverage of MRI only for two situations: 1) screening for breast cancer in high-risk women, and 2) peri-operative MRI. In terms of perioperative MRI, the current NCCN guidelines give a "may" recommendation, and note that no differences have been found in the rate of re-excision, conversion to mastectomy from planned lumpectomy, local recurrence or survival with pre-operative MRI. The breast surgeons consulted on this topic argue that preoperative breast MRI is standard of care, particularly in women pursuing breast conserving therapy (lumpectomy).

Expert guidelines address coverage of breast MRI in two additional situations: 1) evaluation of suspicious lesions when other imaging is equivocal and 2) evaluation of possible breast implant rupture.

HERC staff recommendations:

1) Retire the following Coverage Guidances
    a. Breast Cancer Screening in Women at Above Average Risk
    b. PET For Breast Cancer (recently revised PET coverage criteria)
    c. MRI for Breast Cancer Diagnosis (last affirmed 2016)
    d. MRI for Breast Cancer Screening (outdated)
2) Delete Diagnostic Guideline D9 and Guideline Note 26
3) Revise Diagnostic Guideline D6 with the guideline shown below:
    a. Shown first without markup for ease of review; shown second with revisions noted
    b. Includes NCCN recommended screening for high-risk women [current coverage]
    c. Includes perioperative coverage only for women who would otherwise qualify for high risk MRI screening, based on expert input [clarification of current coverage]
    d. Includes expert guideline recommendations regarding evaluation of possible breast cancer in equivocal cases and for evaluation of possible implant rupture [new coverage]

DIAGNOSTIC GUIDELINE D6 BREAST MRI

Breast MRI is covered in the following circumstances:

A) Annual breast MRI screening for high-risk patients
    1) For individuals with a genetic mutation known to confer a greater than 20% lifetime risk of breast cancer (e.g. BRCA1, BRCA2, Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, or Li-Fraumeni syndrome), beginning 10 years prior to when the youngest family member was diagnosed with breast cancer (but not prior to age 25 years) or age 40 years, whichever comes first
    2) For individuals who received high dose chest radiation (≥ 20 Gray) between the ages of 10 and 30 years beginning 8 years after radiation exposure or at age 25, whichever is later
    3) For individuals with a lifetime risk of ≥ 20% as defined by models that are largely dependent on family history, beginning 10 years prior to when the youngest family member was diagnosed with breast cancer (but not prior to age 25 years) or age 40 years, whichever comes first
B) Evaluation of possible breast cancer
    1) To search for occult breast cancer in patients with Paget's disease of the nipple or in patients with axillary node metastasis when clinical examination and conventional breast imaging fail to detect a primary breast cancer
    2) For the further evaluation of suspicious clinical or imaging findings that remain indeterminate after complete mammographic and sonographic evaluations in lesions that do not meet criteria for breast biopsy
C) Preoperative breast MRI
    1) ONLY covered for patients with recently diagnosed breast cancer who qualify for MRI screening based on the high-risk criteria in section A above
D) Evaluation of suspected breast implant rupture
    1) Breast MRI is covered for evaluation of suspected breast implant rupture, if the MRI findings will aid the decision-making for implant removal or aid the diagnostic evaluation of indeterminate clinical or conventional imaging findings in patients with implants

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

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

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

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

~~Annual screening mammography and annual screening MRI are covered only for women at above-average risk of breast cancer. This coverage, beginning at 30 years of age, includes women who have one or more of the following:~~

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

~~For women with a history of high dose chest radiation (≥ 20 Gray) before the age of 30, annual screening MRI and annual screening mammography are covered beginning 8 years after radiation exposure or at age 25, whichever is later.~~

~~For women with both a personal history and a family history of breast cancer which give a greater than 20% lifetime risk of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are covered.~~

A) Annual breast MRI screening for high-risk patients
   1) For individuals with a genetic mutation known to confer a greater than 20% lifetime risk of breast cancer (e.g. BRCA1, BRCA2, Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, or Li-Fraumeni syndrome), beginning 10 years prior to when the youngest family member was diagnosed with breast cancer (but not prior to age 25 years) or age 40 years, whichever comes first
   2) For individuals who received high dose chest radiation (≥ 20 Gray) between the ages of 10 and 30 years beginning 8 years after radiation exposure or at age 25, whichever is later
   3) For individuals with a lifetime risk of ≥ 20% as defined by models that are largely dependent on family history, beginning 10 years prior to when the youngest family member was diagnosed with breast cancer (but not prior to age 25 years) or age 40 years, whichever comes first

B) Evaluation of possible breast cancer
   1) To search for occult breast cancer in patients with Paget's disease of the nipple or in patients with axillary node metastasis when clinical examination and conventional breast imaging fail to detect a primary breast cancer
   2) For the further evaluation of suspicious clinical or imaging findings that remain indeterminate after complete mammographic and sonographic evaluations in lesions that do not meet criteria for breast biopsy

C) Preoperative breast MRI

3) ONLY covered for patients with recently diagnosed breast cancer who qualify for MRI screening based on the high-risk criteria in section A above

D) Evaluation of suspected breast implant rupture

4) Breast MRI is covered for evaluation of suspected breast implant rupture, if the MRI findings will aid the decision-making for implant removal or aid the diagnostic evaluation of indeterminate clinical or conventional imaging findings in patients with implants

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

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

~~For surveillance for a treated breast cancer, see Guideline Note 26 BREAST CANCER SURVEILLANCE.~~

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

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

~~Annual screening mammography and annual screening MRI are covered only for women at above-average risk of breast cancer. This coverage, beginning at 30 years of age, includes women who have one or more of the following:~~

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

~~For women with a history of high dose chest radiation (≥ 20 Gray) before the age of 30, annual screening MRI and annual screening mammography are covered beginning 8 years after radiation exposure or at age 25, whichever is later.~~

~~For women with both a personal history and a family history of breast cancer which give a greater than 20% lifetime risk of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are covered.~~

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

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

~~For surveillance for a treated breast cancer, see Guideline Note 26 BREAST CANCER SURVEILLANCE.~~

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

~~**DIAGNOSTIC GUIDELINE D9, MRI FOR BREAST CANCER DIAGNOSIS**~~

~~In women with recently diagnosed breast cancer, preoperative or contralateral MRI of the breast is not a covered service.~~

~~**GUIDELINE NOTE 26, BREAST CANCER SURVEILLANCE**~~

~~*Line 191*~~

~~History and physical exam is indicated every 3 to 6 months for the first three years after primary therapy, then every 6-12 months for the next 2 years, then annually thereafter.~~

~~Mammography is indicated annually, and patients treated with breast-conserving therapy, initial mammogram of the affected breast should be 6 months after completion of radiotherapy.~~

~~No other surveillance testing is indicated.~~

~~For ongoing screening for a new breast cancer, see Guideline Note 2006 BREAST CANCER SCREENING IN ABOVE-AVERAGE RISK WOMEN.~~

THE AMERICAN SOCIETY OF Breast Surgeons - Official Statement -

Consensus Guideline on Diagnostic and Screening Magnetic Resonance Imaging of the Breast

Purpose

To outline the recommended practice of diagnostic and screening magnetic resonance imaging (MRI) of the breast.

Associated ASBrS Guidelines or Quality Measures

1. This document replaces the previous ASBrS Statements of "Position Statement on the Use of Magnetic Resonance Imaging in Breast Surgical Oncology" (July 27, 2010) and "The Use of Magnetic Resonance Imaging in Breast Oncology" (May 6, 2007).

2. The ASBrS Choosing Wisely® Campaign endorses the statement "Don't routinely order breast MRI in new breast cancer patients." There are no other ASBrS Guidelines or Quality Measures on breast MRI.

Methods

A comprehensive, but not a systematic review of the literature, was performed, inclusive of recent randomized controlled trials and meta-analyses evaluating the efficacy of screening and diagnostic breast MRI. The ASBrS Research Committee developed a consensus document which was reviewed and approved by the ASBrS Board of Directors.

Summary of Data Reviewed

Diagnostic MRI in the Breast Cancer Patient

MRI of the breast has been used for breast cancer detection since its approval by the FDA more than 25 years ago. MRI of the breast has higher sensitivity than mammography for cancer detection (> 90%) but variable specificity (range 30-90%).[1-6] MRI may aid diagnostic evaluation of the breast and surgical decision-making in selected patient populations as indicated below.[7-10] False-positive findings on breast MRI are common. Therefore, histologic confirmation of suspicious indeterminate MRI findings is necessary if the identification of new cancer(s) would change patient treatment from breast conserving to ipsilateral, contralateral, or bilateral mastectomy.[2,11,12] Multiple studies confirm an association between receipt of breast MRI in patients with cancer and increased ipsilateral and contralateral mastectomy rates, including contralateral prophylactic mastectomy, as well as increased time to treatment.[13-19]

MRI has been shown to increase identification of ipsilateral and contralateral malignancies. In 2008, a meta-analysis by Houssami et al reported on 2610 patients with breast cancer who underwent MRI.[3] Additional disease was identified in 16% of patients (range 6% to 34%). The impact of these MRI findings was a change from wide-local excision to mastectomy in 8.1% of women (95% CI 5.9–11.3) and a larger local excision in 11.3% of women (95% CI 6.8–18.3). In 2012, a systematic review of the literature by Lehman reported 617 (13.7%) of 4500 women undergoing MRI with known breast cancer had additional ipsilateral breast cancer detected, and 151 (3.6%) of 4147 women had additional contralateral cancers detected by MRI.[20] These MRI- detected findings impacted surgical decision-making. A separate meta-analysis by Brennan et al addressed the rate of MRI-detected contralateral breast cancer detection in women with presumed unilateral disease.[4] They reported on 22 studies including 3253 patients. MRI found a synchronous contralateral cancer in 4.1% of patients; 35% were DCIS, and 65% were invasive cancers.

The receipt of MRI in patients with breast cancer is an independent risk factor for the patient receiving mastectomy, even when adjusted for stage and tumor characteristics. In 2013, a meta- analysis by Houssami et al reviewed the outcomes after MRI in 3112 breast cancer patients captured from 7 comparative cohort studies and prospective randomized trials.[19] A significant increase in both the initial and overall mastectomy rates was seen in the MRI group (16.4% and 25.5%, respectively) compared with the no-MRI group (8.1% and 18.2%, respectively), with a consistent increase in mastectomy rates after adjusting for age (initial mastectomy adjusted OR 3.06, 95% CI 2.03–4.62, p<.001; overall mastectomy adjusted OR 1.51, 95% CI 1.21–1.89, p<.001).

The accuracy of MRI to determine tumor size has been compared to conventional imaging in the neoadjuvant setting. The level of agreement between MRI and pathologic tumor size is better than clinical examination and mammography but similar to ultrasound by meta-analysis.[21]

The comparative effectiveness of breast MRI between patients who had a preoperative MRI and those patients who did not for the outcomes of re-excision rates, ipsilateral breast tumor recurrence (IBTR) and overall survival (OS) were reported in the Houssami meta-analysis (2013) above, and in two randomized trials.[12,18,19] There is no convincing evidence that MRI reduces re- excision lumpectomy rates, local recurrence, or overall survival in patients with invasive breast cancer or ductal carcinoma in situ.[22,23]

The decision to use breast MRI as an adjunct to clinical examination, mammography, and ultrasound in newly diagnosed breast cancer patients should be made by the physician and patient after joint consideration of the benefits as well as the consequences of MRI, such as frequent false-positive findings of the breast, increased ipsilateral and contralateral mastectomy rates and increased time to treatment.[2,4,7,11,17,24,25] The performance of MRI is associated with increased costs of care and may be associated with increased patient anxiety.[7,12,26] Well-informed patients may have less distress when false-positive findings necessitate additional biopsies.

Actinic Keratoses

Plain Language Summary:
Background: Sun damage causes a pre-cancerous skin patches called actinic keratoses. While 0.5-2% of these patches develop into skin cancer (squamous or basal cell carcinoma) each year, 25% resolve over a years' time. Treatment of actinic keratoses does not appear to prevent the squamous cell carcinoma. If squamous cell carcinoma develops, it is treatable.
Should OHP cover actinic keratoses treatment? Staff recommends OHP not cover this treatment because it does not appear to prevent squamous cell carcinoma and any benefits appear to be cosmetic.

Question: Should actinic keratoses be moved to a funded line?

Question source: Abigail Haberman, MD dermatologist

Issue: Dr. Haberman is requesting re-review of non-coverage of actinic keratoses. Actinic keratoses (AKs) are pre-cancerous skin lesions (rough scaly patches) caused by sun damage. AKs can develop into squamous cell carcinoma (SCC), a type of cancer. They are treated with freezing with liquid nitrogen, or chemical agents applied to the skin such as 5-fluoruracil (5-FU).

Currently, actinic keratoses diagnosis (ICD-10-CM L57.0) is on line 627 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES.

According to Dr. Haberman, this is an oversight in line placement, as "actinic keratosis is considered a premalignant condition." Dr. Abigail Haberman is requesting an examination of the code pairing for these codes (L57.0 with destruction of benign skin lesions) as they are (in her practice) treating premalignant keratosis, she is asking that it be added to Line 242 DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU.

HSC/HERC history
At the May 2006 HOSC/HSC meetings, the following was discussed: "only 2% of skin cancers originating in AKs metastasize, and 20-25% regress over the course of a year. There was discussion over whether this should be on a funded line. Saha suggested that it would not be unreasonable to wait until they become squamous cell cancer, given the very low rate of metastasis and the high regression rate. It was noted that biopsy results in cure, hence is part of the diagnostic procedure. However, treatment with liquid nitrogen or 5FU would not be covered if this were on a lower line. Olson opined that movement to a lower line likely would not affect practice, as more severe lesions would still be biopsied. Coffman pointed out that, in the past, CMS has objected to not funding actinic keratoses, resulting in its current placement on Line 351."

The HSC moved actinic keratoses to line 586 Benign neoplasms of skin, as a biennial review change.

In April 2012, as part of the ICD-10 dermatology review, the dermatologists agreed with keeping actinic keratoses on line 655 (benign skin lesion line).

Evidence
Natural history of AKs

1) **Werner 2013,** systematic review of natural history of AKs
    a. N=24 studies

   i. 15 RCTs (data extracted from non-intervention arms), 6 prospective cohort studies, 3 RCTs of sunscreen vs no sunscreen
   ii. Quality of included studies was low
b. Progression rates of AK to SCC ranged from 0% to 0.075% per lesion-year, with a risk of up to 0.53% per lesion in patients with prior history of nonmelanoma skin cancer. Rates of regression of single lesions ranged between 15% and 63% after 1 year.
c. In general, the available data are limited. Important methodological limitations apply. Currently, no reliable estimates concerning the frequency of AK developing into invasive carcinoma can be given, and further studies are needed.

2) Madani 2021

a. Database cohort study, California Kaiser population
b. N=220,236 patients with AK and 220,236 matched control patients
c. Patients were treated with cryotherapy, 5-FU, imiquimod, photodynamic therapy and/or aminolevulinic acid
d. Risk of cSCC increased with each year of follow-up by 1.92% (95%CI, 1.89%-1.95%) in patients with AK and 0.83% (95%CI, 0.81%-0.85%) in matched control patients (subdistribution HR, 1.90; 95%CI, 1.85-1.95). At 10 years, the cumulative incidence of cSCC reached 17.1% (95%CI, 16.9%-17.4%) in patients with AK and 5.7% (95%CI, 5.5%-5.9%) in control patients. Increased numbers of AKs were modestly associated with increased cSCC risk (≥15 AKs vs 1 AK: subdistribution HR, 1.89; 95%CI, 1.75-2.04). Older patients had much higher risk of cSCC than younger patients (compared with those ≤ 49 years of age at AK diagnosis; ≥ 80 years of age: subdistribution HR, 8.18; 95%CI, 7.62-8.78). Other than AK, risk factors for cSCC included older age, White race (a proxy for skin type), history of basal cell carcinoma, and male sex.
e. From discussion: The relative effectiveness and safety of watchful waiting, cryotherapy, and field therapy for treating AKs have not been adequately studied

3) Criscione 2009

a. N=7784 AKs (169 patients)
   i. VA high risk population
   ii. AKs were not treated in this study
b. The risk of progression of AK to primary SCC (invasive or in situ) was 0.60% at 1 year and 2.57% at 4 years. Approximately 65% of all primary SCCs and 36% of all primary BCCs diagnosed in the study cohort arose in lesions that previously were diagnosed clinically as AKs. The majority of AKs (55%) that were followed clinically were not present at the 1-year follow-up, and the majority (70%) were not present at the 5-year follow-up.

<u>Expert guidelines</u>

1) **Eisen 2021**, American Academy of Dermatology guidelines for management of actinic keratosis
   a. Estimates of the risk of progression of AK to SCC vary from less than 0.1% to 20%.
   b. The spontaneous regression rate of AKs is highly variable and has been reported to be from 15% to 63% per year.
   c. Although these guidelines are focused on the treatment of AKs, there are some situations in which nontreatment is a potential option. For patients with limited life expectancy or for whom the morbidity of treatment outweighs the potential benefits, observation may be considered.
   d. Strong recommendations (moderate quality of evidence) for:

   i. Field treatment with 5-flurorouracil
   ii. Field treatment with imiquimod
e. Strong recommendation (good practice level of evidence)
   i. Cryotherapy

HERC staff summary

Actinic keratoses are common skin disorders. The natural history of these lesions is that many regress spontaneously, and some small percent can progress to become squamous cell carcinoma (SCC). The estimated rate of progression for an AK to SCC is approximately 0.5-2% per year. Effective treatments exist for AKs; however, one study looking at the natural history of treated AKs found that they still had an approximately 2% risk of progression to SCC per year even after treatment. If AKs progress to SCC, these lesions are typically treatable with minimal risk to the patient. The Dermatology ICD-10 review group did not recommend moving treatment of these lesions into the funded region of the Prioritized list.

HERC staff recommendation:

1) Make no change in the placement of ICD-10 L57.0 (Actinic keratoses) on line 627 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES.

BJD
British Journal of Dermatology

The natural history of actinic keratosis: a systematic review

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Summary

Knowledge about the development of untreated actinic keratosis (AK) and risk of progression into squamous cell carcinoma (SCC) is important. Therefore, we set out to synthesize primary data on the natural history of AK. We carried out a systematic literature search (Medline, Medline in Process, Embase, Cochrane) of studies on the natural course of AK, regarding (i) progression and regression rates per lesion-year, (ii) changes in total lesion counts over time, and (iii) spontaneous field regression and recurrence rates, taking into account studies on participants without immunosuppression and history of skin cancer, immunosuppressed patients and participants with a history of skin cancer and sunscreen use. Twenty-four eligible studies were identified providing data on at least one of the outcomes. Progression rates of AK to SCC ranged from 0% to 0·075% per lesion-year, with a risk of up to 0·53% per lesion in patients with prior history of nonmelanoma skin cancer. Rates of regression of single lesions ranged between 15% and 63% after 1 year. The data available on recurrence rates of single lesions 1 year after regression indicate a recurrence rate of 15–53%. Data on the relative change of total AK count over time are heterogeneous, and range from −53% to +99·1%. Spontaneous complete field regression rates range from 0% to 21%, with recurrences in 57%. In general, the available data are limited. Important methodological limitations apply. Currently, no reliable estimates concerning the frequency of AK developing into invasive carcinoma can be given, and further studies are needed.

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Conflicts of interest

A.N. has received honoraria for continuing medical education-certified talks that received indirect sponsorship from Abbott and Jansen Cilag. R.N.W., A.S., R.E., V.H. and A.N. are affiliated to the Division of Evidence Based Medicine, which has received research grants from Pfizer and Abbott. E.S. is a consultant for Almirall, Meda and LEO.

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What's already known about this topic?

- Actinic keratosis (AK) is a common skin lesion with the potential of malignant progression.
- Progression and regression rates are a matter of debate, and available data have not been summarized systematically.

What does this study add?

- Rates of progression of single AKs into squamous cell carcinoma range between 0% and 0·53% per year, but due to methodological limitations in the identified publications, any estimate of progression rates remains highly uncertain.
- Rates of regression of single lesions ranged between 15% and 63% per year, with recurrence rates of 15–53%.
- Spontaneous complete field regression of observed fields on the face and scalp occurred in 0–7·2% of patients.

Actinic keratosis (AK; or solar keratosis, senile keratosis) is a condition that was described by the end of the nineteenth century,[1,2] and the debate about the malignant potential of AK reaches back to the early twentieth century.[2,3] AKs may be considered as intraepithelial keratinocytic dysplasia, and thus a 'premalignant' skin lesion, or as *in situ* squamous cell carcinoma

JAMA Dermatology | Original Investigation

Ten-Year Follow-up of Persons With Sun-Damaged Skin Associated With Subsequent Development of Cutaneous Squamous Cell Carcinoma

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IMPORTANCE Risk of cutaneous squamous cell carcinoma (cSCC) after the diagnosis of actinic keratosis (AK) has not been studied during long follow-up periods.

OBJECTIVE To estimate the risk up to 10 years and identify risk factors for cSCC development.

DESIGN, SETTING, AND PARTICIPANTS This longitudinal cohort study, performed from January 1, 2009, to February 29, 2020, examined Kaiser Permanente Northern California patients with AK and control patients matched 1:1 on age, sex, race/ethnicity, medical center, and date of the initial diagnosis plus 30 days in the patients with AK.

EXPOSURES Patients with AK and control participants were followed up for up to 10 years for incidence of cSCC.

MAIN OUTCOMES AND MEASURES Incident cSCC was obtained from pathologic data, and subdistribution hazard ratios (HRs) and 95% CIs were estimated using Cox proportional hazards regression analysis, accounting for competing risks, calendar year, demographic factors, and number of AKs.

RESULTS The study included 220 236 patients with AK and 220 236 matched control patients (mean [SD] age, 64.1 [12.2] years; 231 248 [52.5%] female). After losses to follow-up were accounted for, risk of cSCC increased with each year of follow-up by 1.92% (95% CI, 1.89%-1.95%) in patients with AK and 0.83% (95% CI, 0.81%-0.85%) in matched control patients (subdistribution HR, 1.90; 95% CI, 1.85-1.95). However, among patients 49 years or younger, those diagnosed with AK were nearly 7 times more likely to be diagnosed with cSCC than those without AK (HR, 6.77; 95% CI, 5.50-8.32). At 10 years, the cumulative incidence of cSCC reached 17.1% (95% CI, 16.9%-17.4%) in patients with AK and 5.7% (95% CI, 5.5%-5.9%) in control patients. Increased numbers of AKs were modestly associated with increased cSCC risk (≥15 AKs vs 1 AK: subdistribution HR, 1.89; 95% CI, 1.75-2.04). Older patients had much higher risk of cSCC than younger patients (compared with those ≤49 years of age at AK diagnosis; ≥80 years of age: subdistribution HR, 8.18; 95% CI, 7.62-8.78). Other than AK, risk factors for cSCC included older age, White race (a proxy for skin type), history of basal cell carcinoma, and male sex. Risk decreased between 2009 and 2019 (2018-2019 vs 2009-2010: subdistribution HR, 0.67; 95% CI, 0.63-0.72).

CONCLUSIONS AND RELEVANCE The results of this longitudinal cohort study can be used to develop recommendations to increase early detection of cSCC. Additional research is needed to understand the effect of AK treatment on cSCC risk and outcomes of cSCC.

Supplemental content

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Actinic Keratoses

Natural History and Risk of Malignant Transformation in the Veterans Affairs Topical Tretinoin Chemoprevention Trial

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BACKGROUND: Actinic keratoses (AKs) are established as direct precursors of squamous cell carcinoma (SCC), but there is significant controversy regarding the rate at which AKs progress to SCC. The authors of this report studied a high-risk population to estimate the risk of progression of AK to SCC and to basal cell carcinoma (BCC) and the risk of spontaneous regression of untreated AKs. **METHODS:** Data were obtained from participants in the Department of Veterans Affairs Topical Tretinoin Chemoprevention Trial. Participants were examined every 6 months for up to 6 years. At each examination, the locations on the face and ears of clinically diagnosed AKs and lesions scheduled for biopsy were marked, and high-resolution digital photographs were taken. These photographs were used later to map and track the presence, absence, or biopsy of each AK across visits. **RESULTS:** In total, 7784 AKs were identified on the face and ears of 169 participants. The risk of progression of AK to primary SCC (invasive or in situ) was 0.60% at 1 year and 2.57% at 4 years. Approximately 65% of all primary SCCs and 36% of all primary BCCs diagnosed in the study cohort arose in lesions that previously were diagnosed clinically as AKs. The majority of AKs (55%) that were followed clinically were not present at the 1-year follow-up, and the majority (70%) were not present at the 5-year follow-up. **CONCLUSIONS:** In the current study, the authors quantified the malignant potential of clinically diagnosed AKs for both SCC and BCC, although many did not persist, and the results

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We thank Kimberly Marcolivio, national project coordinator, and Lisa Perry, Oklahoma City data coordinator, for their outstanding work.

Key personnel of the Department of Veterans Affairs Topical Tretinoin Chemoprevention (VATTC) Trial include the following: Study Chairman's Office: Martin A. Weinstock (Chair) and Kimberly Marcolivio (Providence, RI). Executive Committee: Martin Weinstock (Providence, RI), Stephen Bingham (Perry Point, Md), John DiGiovanna (Providence, RI), Russell Hall (Durham, NC), Mark Naylor (Oklahoma City, Okla), J. Richard Taylor (Miami, Fla), Julia Vertrees (Albuquerque, NM), and Clifton White (Portland, Ore). Clinical Centers: Durham, NC (Russell Hall and Deborah Hannah); Chicago, Ill (Hines) (David Eilers, Tehming Liang, Nadia Sakla, and Ann Kreuger); Long Beach, Calif (Gary Cole, Edward Jeffes, and Terri Labrador); Miami, Fla (J. Richard Taylor, Robert Kirsner, Jonette E. Kerri, Anna G. Falabela, and Margarita Givens); Oklahoma City, Okla (Mark Naylor, Mary Beth Benson, and Lisa Perry); and Phoenix, Ariz (James Kalivas, Catherine Yanni, Selma Targovnik, Janet Austin, and Susan Collier). Cooperative Studies Program Coordinating Center (Perry Point, Md): Joseph F. Collins, Stephen Bingham, Beverly Calvert, Philip Connor, Colleen Crigler, Dawn Davis, Pat Grubb, Judy Kelly, Gail Kirk, Karen Lawson, Linda Linzy, Lorrine Palmer, and Maxine Rhoads. Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (Albuquerque, NM): Mike Sather, Erica Copeland, Carol Fye, William Gagne, Patricia Grimes de Naranjo, Chad Messick, and Julia Vertrees. Dermatopathologists: Michael Piepkorn (Bellevue, Wash) and Clifton White (Portland, Ore). Data and Safety Monitoring Board: Robert Lew (Boston, Mass), Irwin Braverman (New Haven, Conn), Bernard Cole (Lebanon, NH), Richard Kalish (Stony Brook, NY), David McLean (Vancouver, BC, Canada), and Bruce Thiers (Charleston, SC).

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suggested that AKs may play a greater role in the overall burden of keratinocyte carcinomas than previously documented. **Cancer 2009;115:2523–30. Published 2009 by the American Cancer Society.***

KEY WORDS: actinic keratoses, squamous cell carcinoma, basal cell carcinoma, nonmelanoma skin cancer, epidemiology.

Actinic keratoses (AKs) are dysplastic keratinocytic lesions confined to the epidermis that are caused by ultraviolet (UV) radiation.[1] They are 1 of the most common conditions treated by dermatologists,[2] with an estimated prevalence of 39.5 million in the US in 2004 and annual costs totaling $1.04 billion.[3] Although the most common reason for treatment is prevention of malignancy, lesions also are treated for cosmetic purposes and to provide relief from symptoms, such as tenderness or itch. It is generally accepted that these lesions can be direct precursors of squamous cell carcinoma (SCC), but there has been a paucity of investigations into the frequency of malignant transformation; thus, there is significant controversy over the rate at which AKs progress to SCC. Annual rates of transformation ranging from 0.025% to 20% have been reported,[4] yet we are aware of only 1 study that directly quantifies this risk using primary data.[5] That study was conducted in a general population sample, and the maximum follow-up of individual lesions was 1 year. The dearth of direct study of this phenomenon is remarkable.

For the current investigation, we used prospectively collected data from 1 center of a randomized, multicenter trial in a high-risk population with up to 6 years of follow-up, including photography and dermatologist examination, to estimate the risk of progression of AKs to keratinocyte carcinomas (KCs) and to assess the natural history of AKs.

MATERIALS AND METHODS

Data were collected from the participants at 1 of the 6 sites of the Department of Veterans Affairs (VA) Topical Tretinoin Chemoprevention (VATTC) trial, a randomized, multicenter trial of topical tretinoin 0.1% for the prevention of KCs of the face and ears. Additional details of that study are described elsewhere.[6,7] Although quantifying the times to onset of new basal cell carcinoma (BCC) or SCC were the primary focus of the trial, understanding the natural history of AKs was a secondary objective and, for this purpose, a subprotocol was implemented for the 182 participants at 1 site (the Oklahoma City VA Medical Center). All participants had been diagnosed with $\geq$2 KCs in the 5 years before enrollment in the study and hence represent a high-risk population. The study dermatologist (an experienced clinician who had been practicing clinical dermatology actively for 14 years) examined all participants at approximately 6-month intervals. There was no specific treatment of AKs (other than biopsy if they became bothersome or clinically suspect for KC) during the trial, although all participants were offered free sunscreen and encouraged to use it. Participants were queried at each visit regarding biopsies and dermatologic treatments that took place outside of the Oklahoma VA Medical Center. Participants did not report any biopsies and only reported 38 treatments outside of the VA (7.1% of all treatments) during the trial. During each examination, a standardized set of 3 high-resolution digital photographs of the face and ears was taken. Then, all AKs were identified by clinical criteria and were marked in red on the patient's face or ears. Lesions that were suspected carcinoma were scheduled for biopsy and marked in black. The photographs then were repeated to document these markings for later analysis. The investigators did not refer to images from previous visits during subsequent visits. After completion of the trial, the photographs were used to evaluate the presence, absence, or biopsy designation of each distinct face/ears lesion at each study visit. All lesions that were biopsied from the face or ears were evaluated by a local pathologist and by 1 of 2 central reference dermatopathologists who were blinded to the original diagnosis. The interobserver reliability of these diagnoses is documented elsewhere.[8] The diagnosis made by the central reference dermatopathologists was used for study purposes. Only biopsies of lesions that once had been photographed and marked as AKs were included in our analyses of AK prognosis. AKs that were not located on the face or ears were excluded from all data considered in this study.

Guidelines of care for the management of actinic keratosis

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Sacramento, California; Boston, Massachusetts; Madison, Wisconsin; Scottsdale and Tucson, Arizona; Aurora, Colorado; New York, New York; New Haven, Connecticut; Washington, DC; Rosemont, Illinois; and Charleston, South Carolina

Background: Actinic keratoses (AK) are rough scaly patches that arise on chronically ultraviolet-exposed skin and can progress to keratinocyte carcinoma.

Objective: This analysis examined the literature related to the management of AK to provide evidence-based recommendations for treatment. Grading, histologic classification, natural history, risk of progression, and dermatologic surveillance of AKs are also discussed.

Methods: A multidisciplinary Work Group conducted a systematic review to address 5 clinical questions on the management of AKs and applied the Grading of Recommendations, Assessment, Development, and Evaluation approach for assessing the certainty of the evidence and formulating and grading clinical recommendations. Graded recommendations were voted on to achieve consensus.

Results: Analysis of the evidence resulted in 18 recommendations.

Limitations: This analysis is based on the best available evidence at the time it was conducted. The pragmatic decision to limit the literature review to English language randomized trials may have excluded data published in other languages or limited identification of relevant long-term follow-up data.

Conclusions: Strong recommendations are made for using ultraviolet protection, topical imiquimod, topical 5-fluorouracil, and cryosurgery. Conditional recommendations are made for the use of photodynamic therapy and diclofenac for the treatment of AK, both individually and as part of combination therapy regimens. (J Am Acad Dermatol 2021;85:e209-33.)

Key words: actinic keratosis; actinic keratosis guidelines; clinical guidelines for actinic keratosis; cryosurgery; dermatology; photodynamic therapy; topical agents.

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Drs Eisen and Schlesinger are co-chairs.

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Radiofrequency Ablation of Renal Tumors

Question: Should radiofrequency ablation of renal tumors be moved to a funded line?

Question source: Alison Little, CCO medical director

Issue: Conventional treatment of renal cancer is total or partial nephrectomy (open or laparoscopic). For some smaller tumors, cryoablation or radiofrequency ablation may be selected. Radiofrequency ablation (RFA) is one of several less invasive approaches that have been investigated for the treatment of kidney cancer. In RFA, an electric current from a radiofrequency (RF) generator delivers energy into the tumor, via an electrode. Tissue impedance leads to heat generation, production of lethal temperatures, and ablation of tissue. RFA has been used most often for adults with small kidney tumors. Indications include comorbidities that preclude surgery, a single kidney, and multifocal renal cell carcinoma.

Radiofrequency ablation of renal tumors (CPT 50592) is on line 662/GN173 and has not been reviewed in 15+ years.

Current Prioritized List status

CPT Code	**Code Description**	**Current Placement**
50240	Nephrectomy, partial	21 VESICOURETERAL REFLUX 49 CONGENITAL HYDRONEPHROSIS 86 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM 214 CANCER OF KIDNEY AND OTHER URINARY ORGANS 271 CANCER OF BLADDER AND URETER
50250	Ablation, open, 1 or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed	86,214,271
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS 86,214,271 511 BENIGN NEOPLASM OF KIDNEY AND OTHER URINARY ORGANS
50543	Laparoscopy, surgical; partial nephrectomy	47,86,214,271,511
50592	Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency	662
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy	ANCILLARY PROCEDURES

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
50592	Radiofrequency ablation, 1 or more renal tumor(s)	Insufficient evidence of effectiveness	December 2005

Radiofrequency Ablation of Renal Tumors

Evidence

1) **NICE 2010**, percutaneous radiofrequency ablation for renal cell cancer
    a. Current evidence on the safety and efficacy of percutaneous radiofrequency ablation (RFA) for renal cancer in the short and medium term appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit, and provided that patients are followed up in the long term
    b. A meta-analysis of 47 studies (non-randomized comparative studies and case series) including a total of 1375 tumors treated by RFA (n = 775) or cryoablation (n = 600) reported local tumor progression (defined as radiographic or pathological evidence of residual disease after initial treatment, regardless of time to recurrence) in 13% (100/775) and 5% (31/600) of tumors respectively at a mean 19-month follow-up ($p < 0.001$). The meta-analysis reported progression to metastatic disease in 2% (19/775) of tumors treated by RFA and 1% (6/600) of tumors treated by cryoablation (p = not significant)
    c. In a non-randomized comparative study of 233 patients (260 tumors), residual or recurrent tumor on follow-up magnetic resonance imaging (MRI) was reported in 11% (9/81) of tumors treated by percutaneous RFA and 2% (3/ 179) of tumors treated by laparoscopic cryotherapy (1-year and 3-year median follow-up respectively).
    d. Adverse events:
        i. Hemorrhage was reported in 6% (5/85) of patients in a case series of 85 patients.
        ii. Hematoma requiring blood transfusion was reported in 1% (1/104) of patients in a case series and 1% (1/82) of RFA procedures in the non-randomized comparative study of 233 patients. Hematoma not requiring blood transfusion was reported in 5% (4/82) (3 perirenal requiring no treatment; 1 retroperitoneal) of RFA procedures in the non-randomized comparative study of 233 patients. Asymptomatic perirenal hematoma development was reported in 12% (4/34) (managed conservatively with no sequelae) of RFA procedures in the case series of 31 patients.
    e. The Specialist Advisers indicated that there was uncertainty about the procedure's efficacy in tumors 4 cm or greater in diameter.

Expert guidelines

1) NCCN Guideline Kidney Cancer Version 2.2022
    a. Thermal ablation (e.g. cryosurgery, radiofrequency ablation) is an option for the management of patients with clinical stage T1 renal lesions
        i. Thermal ablation is an option for masses <3 cm, but may also be an option for larger masses in select patients. Ablation in masses >3cm is associated with higher rates of local recurrence/persistence and complications
        ii. Biopsy of small lesions confirms a diagnosis of malignancy for surveillance, cryosurgery, and radiofrequency ablation strategies

2) American Urological Association 2017
    a. Physicians should consider thermal ablation **(TA)** as an alternate approach for the management of cT1a renal masses <3 cm in size. For patients who elect TA, a percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity. **(Conditional Recommendation; Evidence Level: Grade C)**

b. Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation. **(Conditional Recommendation; Evidence Level: Grade C)**
c. A renal mass biopsy should be performed prior to ablation to provide pathologic diagnosis and guide subsequent surveillance. **(Expert Opinion)**
d. Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical extirpation, which may be addressed with repeat ablation if further intervention is elected. **(Strong Recommendation; Evidence Level: Grade B)**

Other payer policies

1) Aetna 2021

a. Aetna considers radiofrequency ablation (RFA) medically necessary for the following indications
    i. Renal cell carcinoma, up to 4-cm in size, in persons who meet the following criteria:
        1. High-risk surgical candidates; *or*
        2. Persons with renal insufficiency, as defined by a glomerular filtration rate of less than or equal to 60 ml/min/m^2; *or*
        3. Persons with a solitary kidney.

2) ConnectiCare (Connecticut Medicaid) 2020

a. Members with small undefined renal lesions (≤ 4 cm in diameter) that are suspected to be malignant, or with malignant potential, are eligible for coverage of either cryoablation or RFA by any modality (eg laparoscopically or percutaneously) when either of the following criteria is met:
    i. Medically or surgically inoperable tumor(s).
    ii. Poor candidacy for standard treatments (i.e., nephrectomy).

Radiofrequency Ablation of Renal Tumors

HERC staff summary

Treatment of small renal cell carcinomas (<3cm) by radiofrequency ablation or cryotherapy in patients who are poor surgical candidates is recommended by NCCN and the American Urological Association. A highly trusted evidence-based source (NICE) has found sufficient evidence of effectiveness in this population to recommend use. Only two private payer policies were found, but both recommended coverage in limited circumstances.

HERC staff recommendations:

1) Add CPT 50592 (Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency) and 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy) to line 214 CANCER OF KIDNEY AND OTHER URINARY ORGANS
    a. Advise HSD to remove CPT 50593 from the Ancillary Procedures File
    b. Delete CPT 50592 from line 662/GN173
2) Add a new guideline to line 214 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 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
~~50592~~	~~Radiofrequency ablation, 1 or more renal tumor(s)~~	~~Insufficient evidence of effectiveness~~	~~December 2005~~

GUIDELINE NOTE XXX THERMAL ABLATION OF RENAL CELL CARCINOMA

Line 214

Thermal ablation (e.g., cryosurgery, radiofrequency ablation; CPT 50592, 50593) is included on this line only when:

1) The patient has biopsy-confirmed stage T1 renal cell cancer of <3 cm size; AND
2) The patient either has a surgically inoperable tumor(s) or is a poor candidate for standard treatments (i.e., nephrectomy).

Percutaneous radiofrequency ablation for renal cancer

Interventional procedures guidance
Published: 28 July 2010
www.nice.org.uk/guidance/ipg353

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG91.

1 Guidance

This guidance replaces previous guidance on percutaneous radiofrequency ablation of renal cancer (interventional procedure guidance 91).

1.1 Current evidence on the safety and efficacy of percutaneous radiofrequency ablation (RFA) for renal cancer in the short and medium term appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit, and provided that patients are followed up in the long term.

1.2 Patient selection for percutaneous RFA for renal cancer should be carried out by a urological cancer multidisciplinary team.

1.3 NICE encourages data collection to provide information about the outcomes of this procedure in the long term. Further research should compare the long-term outcomes of RFA with those of other treatments for renal cancer.

2 The procedure

2.1 Indications and current treatments

2.1.1 There are few symptoms in the early stages of renal cancer. Typically, symptoms develop as the disease progresses. The first symptom is often blood in the urine; pain and flank mass are other classic symptoms.

2.1.2 Renal cancer may be diagnosed incidentally on imaging studies or patients may present with symptoms. Conventional treatment for renal cancer is total or partial nephrectomy (open or laparoscopic). One of a range of non-resectional ablative procedures such as cryoablation and RFA may be selected for some smaller tumours.

2.2 Outline of the procedure

2.2.1 Percutaneous RFA for renal cancer is carried out with the patient under either local anaesthesia and sedation or general anaesthesia. Hydrodisplacement may be used to displace the bowel away from the tumour. One or more

radiofrequency electrodes are inserted percutaneously into the tumour under imaging guidance. Radiofrequency energy is delivered via the electrode(s) to coagulate and destroy the tumour tissue in the target area. The procedure can be repeated if necessary.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 A meta-analysis of 47 studies (non-randomised comparative studies and case series) including a total of 1375 tumours treated by RFA (n = 775) or cryoablation (n = 600) reported local tumour progression (defined as radiographic or pathological evidence of residual disease after initial treatment, regardless of time to recurrence) in 13% (100/775) and 5% (31/600) of tumours respectively at a mean 19-month follow-up ($p < 0.001$). The meta-analysis reported progression to metastatic disease in 2% (19/775) of tumours treated by RFA and 1% (6/600) of tumours treated by cryoablation (p = not significant).

2.3.2 In a non-randomised comparative study of 233 patients (260 tumours), residual or recurrent tumour on follow-up magnetic resonance imaging (MRI) was reported in 11% (9/81) of tumours treated by percutaneous RFA and 2% (3/179) of tumours treated by laparoscopic cryotherapy (1-year and 3-year median follow-up respectively).

2.3.3 A non-randomised comparative study of 264 patients (301 tumours) reported radiographic success (defined as no evidence of central or nodular enhancement after treatment) in 85% (62/73) of patients treated by percutaneous RFA and 90% (125/139) of patients treated by laparoscopic cryoablation at 6-month follow-up.

2.3.4 The case series of 151 patients reported a 3-year recurrence-free survival probability of 92% for all patients and 87% for the 84 patients with confirmed renal cell carcinoma. The case series of 31 patients reported disease-specific survival of 100%, recurrence-free survival of 89% and overall survival of 63% (all at 80 months).

2.3.5 The Specialist Advisers listed key efficacy outcomes as radiological confirmation of tumour devascularisation, imaging follow-up to confirm tumour involution at 2 and 5 years, and overall and disease-free survival. They indicated that there is uncertainty about the procedure's efficacy in tumours 4 cm or greater in diameter.

2.4 Safety

2.4.1 Haemorrhage was reported in 6% (5/85) of patients in a case series of 85 patients. Life-threatening haematuria approximately 42 hours after RFA treatment which required transcatheter embolisation was described in a case report.

2.4.2 Haematoma requiring blood transfusion was reported in 1% (1/104) of patients in a case series and 1% (1/82) of RFA procedures in the non-randomised comparative study of 233 patients. Haematoma not requiring blood transfusion was reported in 5% (4/82) (3 perirenal requiring no treatment; 1 retroperitoneal) of RFA procedures in the non-randomised comparative study of 233 patients. Asymptomatic perirenal haematoma development was reported in 12% (4/34) (managed conservatively with no sequelae) of RFA procedures in the case series of 31 patients.

2.4.3 Ureteric stricture development was reported after 1% (1/120) of treatments and in 1% (1/85) and 2% (2/104) of patients in case series of 97, 85 and 104 patients respectively.

2.4.4 Urinoma (a collection of fluid resulting from a urine leak) was reported in 1 patient each in the case series of 97 and 85 patients. Ureteropelvic junction obstruction requiring nephrectomy was described in a case report.

2.4.5 Thermal injury to the duodenum requiring laparotomy was reported in 1 patient in the case series of 97 patients.

2.4.6 Renoduodenal fistula was diagnosed 5 days after the procedure in 1 patient in a case report. A computed tomography (CT) scan at 6 months showed that the tumour (a clear cell carcinoma) was growing again and an open nephrectomy was performed.

2.4.7 Neuromuscular complications after RFA treatment were reported in 3 of 48 patients in one series. One patient developed persistent laxity of flank muscles. The other 2 developed sensory loss and paraesthesia of the lateral abdominal wall (resolved after 3 months).

2.4.8 The Specialist Advisers stated that theoretical adverse events include bowel perforation, perirenal haematoma, pelvicalyceal injury, and pain due to intercostal nerve damage.

3 Further information

3.1 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 91.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

3 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

Approved by the AUA Board of Directors April2017

Authors' disclosure of potential conflicts of interest and author/staff contributions appear at the end of the article.

Panel Nomination Acknowledgment:

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RENAL MASS AND LOCALIZED RENAL CANCER: AUA GUIDELINE

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Purpose

This AUA Guidelines focuses primarily on the evaluation and management of clinically localized sporadic renal masses suspicious for renal cell carcinoma (RCC) in adults, including solid enhancing renal tumors and Bosniak 3 and 4 complex cystic renal masses. Some patients with clinically localized renal masses may present with findings suggesting aggressive tumor biology or may be upstaged on exploration or final pathology. Management considerations pertinent to the urologist in such patients will also be addressed. Practice patterns regarding such tumors vary considerably. The literature regarding evaluation and management has been rapidly evolving. Notable examples include controversies about the role of renal mass biopsy and concerns about overutilization of radical nephrectomy. Please also refer to the associated Renal Mass and Localized Renal Cancer treatment algorithm.

Methodology

The systematic review utilized in the creation of this guideline was completed in part through the Agency for Healthcare Research and Quality (AHRQ) and through additional supplementation that further addressed additional key questions and more recently published literature. A research librarian experienced in conducting literature searches for comparative effectiveness reviews searched in MEDLINE®, Embase ®, the Cochrane Library, the Database of Abstracts of Reviews of Effects, the Health Technology Assessment Database, and the UK National Health Service Economic Evaluation database to capture both published and gray literature published from January 1, 1997 through May 1, 2015. A supplemental search was conducted adding additional literature published through August 2015, and a final update search was conducted through July 2016. When sufficient evidence existed, the body of evidence for a particular treatment was assigned a strength rating of A (high), B (moderate) or C (low) for support of Strong, Moderate, or Conditional Recommendations. In the absence of sufficient evidence, additional information is provided as Clinical Principles and Expert Opinions.

GUIDELINE STATEMENTS

EVALUATION AND DIAGNOSIS

1. In patients with a solid or complex cystic renal mass, physicians should obtain high quality, multiphase, cross-sectional abdominal imaging to optimally characterize and clinically stage the renal mass. Characterization of the renal mass should include assessment of tumor complexity, degree of contrast enhancement (where applicable), and presence or absence of fat. (Clinical Principle)
2. In patients with suspected renal malignancy, physicians should obtain comprehensive metabolic panel, complete blood count, and urinalysis.

Metastatic evaluation should include chest imaging to evaluate for possible thoracic metastases. (Clinical Principle)

3. For patients with a solid or complex cystic renal mass, physicians should assign CKD stage based on GFR and degree of proteinuria. (Expert Opinion)

COUNSELING

4. In patients with a solid or Bosniak 3/4 complex cystic renal mass, a urologist should lead the counseling process and should consider all management strategies. A multidisciplinary team should be included when necessary. (Expert Opinion)
5. Physicians should provide counseling that includes current perspectives about tumor biology and a patient-specific risk assessment inclusive of sex, tumor size/complexity, histology (when obtained), and imaging characteristics. For cT1a tumors, the low oncologic risk of many small renal masses should be reviewed. (Clinical Principle)
6. During counseling of patients with a solid or Bosniak 3/4 complex cystic renal mass, physicians must review the most common and serious urologic and non-urologic morbidities of each treatment pathway and the importance of patient age, comorbidities/frailty, and life expectancy. (Clinical Principle)
7. Physicians should review the importance of renal functional recovery related to renal mass management, including the risk of progressive CKD, potential short- or long-term need for renal replacement therapy, and long -term overall survival considerations. (Clinical Principle)
8. Physicians should consider referral to nephrology in patients with a high risk of CKD progression. Such patients may include those with eGFR less than 45 ml/min/1.73m2, confirmed proteinuria, diabetics with preexisting CKD, or whenever eGFR is expected to be less than 30 ml/min/1.73m2 after intervention. (Expert Opinion)
9. Physicians should recommend genetic counseling for all patients ≤ 46 years of age with renal malignancy and consider genetic counseling for patients with multifocal or bilateral renal masses, or if personal or family history suggests a familial renal neoplastic syndrome. (Expert Opinion)

RENAL MASS BIOPSY (RMB)

10. Renal mass biopsy should be considered when a mass is suspected to be hematologic, metastatic, inflammatory, or infectious. (Clinical Principle)
11. In the setting of a solid renal mass, RMB is not required for: 1) young or healthy patients who are unwilling to accept the uncertainties associated with RMB; or 2) older or frail patients who will be managed conservatively independent of RMB findings. (Expert Opinion)
12. When considering the utility of RMB, patients should be counseled regarding rationale, positive and negative predictive values, potential risks and non-diagnostic rates of RMB. (Clinical Principle)
13. For patients with a solid renal mass who elect RMB, multiple core biopsies are preferred over fine needle aspiration. (Moderate Recommendation; Evidence Level: Grade C)

MANAGEMENT:

PARTIAL NEPHRECTOMY (PN) AND NEPHRON-SPARING APPROACHES

14. Physicians should prioritize PN for the management of the cT1a renal mass when intervention is indicated. In this setting, PN minimizes the risk of CKD or CKD progression and is associated with favorable oncologic outcomes, including excellent local control. (Moderate Recommendation; Evidence Level: Grade B)
15. Physicians should prioritize nephron-sparing approaches for patients with solid or Bosniak 3/4 complex cystic renal masses and an anatomic or functionally solitary kidney, bilateral tumors, known familial RCC, preexisting CKD, or proteinuria. (Moderate Recommendation; Evidence Level: Grade C)
16. Physicians should consider nephron-sparing approaches for patients with solid or Bosniak 3/4 complex cystic renal masses who are young, have multifocal masses, or comorbidities that are likely to impact renal function in

the future, such as moderate to severe hypertension, diabetes mellitus, recurrent urolithiasis, or morbid obesity. (Conditional Recommendation; Evidence Level: Grade C)

17. In patients who elect PN, physicians should prioritize preservation of renal function through efforts to optimize nephron mass preservation and avoidance of prolonged warm ischemia. (Expert Opinion)
18. For patients undergoing PN, negative surgical margins should be a priority. The extent of normal parenchyma removed should be determined by surgeon discretion taking into account the clinical situation, tumor characteristics including growth pattern, and interface with normal tissue. Tumor enucleation should be considered in patients with familial RCC, multifocal disease, or severe CKD to optimize parenchymal mass preservation. (Expert Opinion)

RADICAL NEPHRECTOMY (RN)

19. Physicians should consider RN for patients with a solid or Bosniak 3/4 complex cystic renal mass where increased oncologic potential is suggested by tumor size, RMB, and/or imaging characteristics and in whom active treatment is planned. (Conditional Recommendation; Evidence Level: Grade B) In this setting, RN is preferred if all of the following criteria are met: 1) high tumor complexity and PN would be challenging even in experienced hands; 2) no preexisting CKD or proteinuria; and 3) normal contralateral kidney and new baseline eGFR will likely be greater than 45 ml/min/1.73m^2. (Expert Opinion)

SURGICAL PRINCIPLES

20. For patients who are undergoing surgical excision of a renal mass with clinically concerning regional lymphadenopathy, physicians should perform a lymph node dissection for staging purposes. (Expert Opinion)
21. For patients who are undergoing surgical excision of a renal mass, physicians should perform adrenalectomy if imaging and/or intraoperative findings suggest metastasis or direct invasion of the adrenal gland. (Clinical Principle)
22. In patients undergoing surgical excision of a renal mass, a minimally invasive approach should be considered when it would not compromise oncologic, functional and perioperative outcomes. (Expert Opinion)
23. Pathologic evaluation of the adjacent renal parenchyma should be performed after PN or RN to assess for possible intrinsic renal disease, particularly for patients with CKD or risk factors for developing CKD. (Clinical Principle)

THERMAL ABLATION (TA)

24. Physicians should consider thermal ablation (TA) as an alternate approach for the management of cT1a renal masses <3 cm in size. For patients who elect TA, a percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity. (Conditional Recommendation; Evidence Level: Grade C)
25. Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation. (Conditional Recommendation; Evidence Level: Grade C)
26. A renal mass biopsy should be performed prior to ablation to provide pathologic diagnosis and guide subsequent surveillance. (Expert Opinion)
27. Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical extirpation, which may be addressed with repeat ablation if further intervention is elected. (Strong Recommendation; Evidence Level: Grade B)

ACTIVE SURVEILLANCE (AS)

28. For patients with small solid or Bosniak 3/4 complex cystic renal masses, especially those <2cm, AS is an option for initial management. (Conditional Recommendation; Evidence Level: Grade C)
29. For patients with a solid or Bosniak 3/4 complex cystic renal mass, physicians should prioritize active surveillance/expectant management when the anticipated risk of intervention or competing risks of death outweigh the potential oncologic benefits of active treatment. (Clinical Principle)

30. For patients with a solid or Bosniak 3/4 complex cystic renal mass in whom the risk/benefit analysis for treatment is equivocal and who prefer AS, physicians should repeat imaging in 3-6 months to assess for interval growth and may consider RMB for additional risk stratification. (Expert Opinion)
31. For patients with a solid or Bosniak 3/4 complex cystic renal mass in whom the anticipated oncologic benefits of intervention outweigh the risks of treatment and competing risks of death, physicians should recommend active treatment. In this setting, AS with potential for delayed intervention may be pursued only if the patient understands and is willing to accept the associated oncologic risk. (Moderate Recommendation; Evidence Level: Grade C)

Clarification of the Treatment for Benign Prostate Enlargement Guideline

Question: Should the guideline regarding treatments for benign prostate enlargement with lower urinary tract symptoms (LUTS) be modified to clarify what is meant by "severe symptoms" and what is meant by "drug treatment and conservative management options" which have been unsuccessful or are not appropriate?

Question source: Holly Jo Hodges, MD, CCO medical director

Issue: A new guideline was added to the Prioritized List in 2015 regarding treatments options for lower urinary tract symptoms (LUTS) other than transurethral resection of the prostate (TURP) based on a coverage guidance regarding alternatives to TURP. This guideline requires that symptoms be "severe" but does not define severe. The American Urologic Association (AUA) and other expert groups have developed a symptom index known as the International Prostate Symptom Score (IPSS). This list of questions is scored with 0-7 being considered "mild" LUTS, 8-19 "moderate" LUTS, and 20-35 "severe" LUTS. Dr. Hodges is requesting that GN145 be clarified to indicate that "severe" symptoms are defined as an IPSS score of 20-35.

The American Urologic Association revised their guidelines for treatment of LUTS in 2021. In that guideline, the AUA recommends using the IPSS at initial evaluation of LUTS and to follow up on any interventions to evaluate effectiveness.

Dr. Hodges has also requested that the requirement for "drug treatment and conservative management options" to fail or not be appropriate to be clarified. Do a certain number of drugs need to be failed? What is considered failure? What are conservative management options?

The AUA 2021 guideline recommends the following medications as treatment options for LUTS:

1) Alpha blockers (e.g., tamsulosin, terazosin, doxazosin, etc.). Evidence level Grade A
2) 5 alpha reductase inhibitors for LUTS with prostate volume >30 cc, PSA >1.5 ng/dl, or palpable prostate enlargement of digital rectal exam. Evidence Level Grace B
3) Tadalafil as a treatment option. Evidence Level Grace B
4) Combination of various medications in certain clinical situations

The AUA recommends the following conservative treatment options for LUTS:

1) Alter modifiable factors such as caffeine, fluids, contributing medications when possible
2) Lifestyle counseling

In the AUA 2021 guideline, only the surgical interventions which are currently covered on the Prioritized List. Therefore, staff do not feel that any new procedures be considered as part of this review.

Current guideline:

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

Line 327

For men with lower urinary tract symptoms (LUTS) due to benign prostate enlargement, surgical procedures are included on these lines only if symptoms are severe, and if drug treatment and conservative management options have been unsuccessful or are not appropriate.

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

- Age 50 or older

- Estimated prostate volume < 80 cc
- International Prostate Symptom Score (IPSS) ≥ 13
- No obstructive median lobe of the prostate identified on cystoscopy at the time of the procedure

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

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

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

Expert input
Brian Duty, MD, OHSU urology:

I would recommend eliminating conservative management from the guideline and changing it to read…

For men with lower urinary tract symptoms (LUTS) due to benign prostate hyperplasia (BPH), surgical procedures are included for patients with…
- Refractory urinary retention
- Recurrent urinary tract infections due to BPH
- Recurrent bladder stones or gross hematuria due to BPH
- Severe symptoms (IPSS score of 20-35) in patients who are not candidates for drug treatment due to intolerable side effects or have failed combination therapy with an alpha-blocker and 5-alpha reductase inhibitor for at least 3 months

HERC staff recommendation:

1) Modify GN145 as shown below

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

Line 327

For men with lower urinary tract symptoms (LUTS) due to benign prostate ~~enlargement, surgical procedures are included on these lines only if symptoms are severe, and if drug treatment and conservative management options have been unsuccessful or are not appropriate.~~ hyperplasia (BPH), surgical procedures are included on this line for patients with one of the following:

A) Refractory urinary retention; OR
B) Recurrent urinary tract infections due to BPH; OR
C) Recurrent bladder stones or gross hematuria due to BPH; OR
D) Severe symptoms (International Prostate Symptom Score (IPSS) of 20-35) in patients who are not candidates for drug treatment due to intolerable side effects or have failed combination therapy with an alpha-blocker and 5-alpha reductase inhibitor for at least 3 months.

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

- Age 50 or older
- Estimated prostate volume < 80 cc
- IPSS ≥ 13
- No obstructive median lobe of the prostate identified on cystoscopy at the time of the procedure

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

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

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

Approved by the AUA Board of Directors

August 2021

Authors' disclosure of potential conflicts of interest and author/staff contributions appear at the end of the article.

American Urological Association (AUA)

Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE

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EXECUTIVE SUMMARY

Purpose

Benign prostatic hyperplasia (BPH) is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone. The prevalence and the severity of lower urinary tract symptoms (LUTS) in the aging male can be progressive and is an important diagnosis in the healthcare of patients and the welfare of society. In the management of bothersome LUTS, it is important that healthcare providers recognize the complex dynamics of the bladder, bladder neck, prostate, and urethra. Further, symptoms may result from interactions of these organs as well as with the central nervous system or other systemic diseases (e.g., metabolic syndrome, congestive heart failure). Despite the more prevalent (and generally first line) use of medical therapy for men suffering from LUTS attributed to BPH (LUTS/BPH), there remain clinical scenarios where surgery is indicated as the initial intervention for LUTS/BPH and should be recommended, providing other medical comorbidities do not preclude this approach. It is the hope that this revised Guideline will provide a useful reference on the effective evidence-based management of male LUTS/BPH. Please see the accompanying algorithm for a summary of the procedures detailed in the Guideline.

Methodology

For the surgical management of BPH, the Minnesota Evidence Review Team searched Ovid MEDLINE, the Cochrane Library, and the Agency for Healthcare Research and Quality (AHRQ) database to identify studies indexed between January 2007 and September 2017. Following initial publication in 2018, this Guideline underwent an amendment in 2019 that included literature published through January 2019. An additional literature search was conducted through September 2019 and serves as the basis for a 2020 amendment. The Guideline underwent an additional amendment in 2021 to capture eligible literature published between September 2019 and September 2020.

For the medical management of BPH, the Minnesota Evidence Review Team searched Ovid MEDLINE, Embase, the Cochrane Library, and the AHRQ databases to identify eligible studies published and indexed between January 2008 and April 2019. An updated search was completed to capture studies published between April 2019 and December 2020. Search terms included Medical Subject Headings (MeSH) and keywords for pharmacological therapies, drug classes, and terms related to LUTS or BPH. Limits were used to restrict the search to English language publications. The review team also reviewed articles for inclusion identified by Guideline Panel Members.

When sufficient evidence existed, the body of evidence was assigned a strength rating of A (high), B (moderate), or C (low) for support of Strong, Moderate, or

Sensory Integration Therapy

Question: Should sensory integration therapy be paired with autism spectrum conditions or any other condition on the Prioritized List?

Question source: Linda Williams, School-Based Health Services Program at OHA

Issue: Sensory integration therapy (SIT) is a type of occupational therapy that seeks to improve integration of sensory information and thereby help children with learning disabilities improve their sensorimotor skills. In theory, this will result in improved behavior and academic performance. It is typically done as part of treatment for children with autism spectrum disorder.

Currently, sensory integration therapy is on line 662/GN173. The entry in GN173 lists the date of last review as 2010; however, the last in depth review of this therapy was earlier than 2006.

Current Prioritized List 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
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands	Insufficient evidence of effectiveness	August 2010

Evidence

1) **AHRQ 2017**, Comparative Effectiveness Review: Interventions targeting sensory challenges in children with autism spectrum disorder-an update https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/asd-interventions_research-2017.pdf
    a. N=24 studies (inclusion criteria: 10 or more children with autism spectrum disorder (ASD) aged 2-12 for RCTs, 20 or more children for other study designs)
        i. 20 RCTs, 1 non-randomized trial, 3 retrospective cohort studies
        ii. 3 low, 10 moderate, 11 high risk of bias
        iii. Severity of ASD and sensory dysfunction varied across studies
    b. Key points:
        i. Four studies addressing sensory integration (SI)-based approaches were small and short-term (typically <6 months), with no follow-up beyond the immediate treatment period. No study reported harms of intervention.
        ii. Sensory-related outcomes improved in children receiving an SI-based intervention compared with those receiving usual care or other treatment (statistically significant improvements in three of four studies addressing the outcome). We have low confidence in this conclusion (low strength of evidence).
        iii. Motor skills outcomes were improved in children receiving SI-based treatment compared with those receiving usual care or other treatment (statistically significant improvements in three of three studies addressing the outcome). We have low confidence in this conclusion (low strength of evidence).
        iv. We could not assess the effects of SI-based treatment on adaptive behavior given differences in outcomes measures (insufficient strength of evidence).
        v. Only two studies conducted a follow-up after treatment ended. Follow-up occurred at two and five months in each study. Additionally, many of the outcome measures were based upon parent reports rather than using standardized interactive assessments. Therefore, little existing evidence at this time contributes to predicting long-term functional outcomes.
    c. Relative to usual care or other interventions, SI-based approaches improved measures related to sensory and motor skills in the short term (3 RCTs with high, moderate, and low risk of bias (ROB) and 1 high ROB retrospective cohort study). Four small RCTs (2 moderate and 2 high ROB) of auditory integration–based approaches reported mixed results. Additional RCTs (moderate and high ROB) of interventions with sensory-related components (tactile stimulation exercises, weighted blankets) reported few significant differences between treatment groups.
    d. **Conclusions.** Some interventions targeting sensory challenges may produce modest short-term (<6 months) improvements, primarily in sensory-related outcomes and outcomes related to ASD symptom severity; however, the evidence base for any category of intervention is small, and durability of effects beyond the immediate intervention period is unclear. Sensory integration–based approaches improved outcomes related to sensory challenges (low strength of evidence (SOE)) and motor skills (low SOE). Data on longer term results are lacking, as are data on characteristics that modify outcomes, effectiveness of interventions across environments or contexts, and components of interventions that may drive effects. In sum, while some therapies may hold promise and warrant further study, substantial needs exist for continuing improvements in methodologic rigor in the field.

Other payer policies

1) **United Health Care 2021**:
    a. The following are unproven and not medically necessary for treating any condition due to insufficient evidence of efficacy:
        i. Sensory integration therapy (SIT)
        ii. Auditory integration training (AIT)
1) **Aetna 2021**: Aetna considers sensory integration therapy and auditory integration therapy (also known as auditory integration training) experimental and investigational for the management of persons with various communication, behavioral, emotional, and learning disorders and for all other indications.
2) **Wellmark BCBS 2021**: Sensory integration therapy (SIT) and auditory integration therapy (AIT) is considered investigational for all indications. The evidence is insufficient to determine the effects of this therapy on net health outcomes.

HERC staff summary:
Sensory integration therapy may produce modest short term improvements in behavior but there is insufficient evidence of long term benefit. No private insurer surveyed covers this therapy.

HERC staff recommendation:

1) Make no change in current non-coverage of sensory integration therapy
2) Update the GN173 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 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
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands	Insufficient evidence of effectiveness	~~August 2010~~ March 2022

Congenital Foot Deformity Code Review

Question: Where should various diagnoses in the Q66 (congenital foot deformities) code family be prioritized?

Question source: Bhavesh Rajani, MD, CCO medical director

Issue: There are multiple subdiagnoses in the Q66 family. Most were placed on the same line as the "mother code" as "daughter codes" when they were released as new ICD-10 codes without specific in-depth review. Dr. Rajani requested a review of this code family, as some of these codes are on funded lines and code for conditions such as flat feet which are not intended for coverage.

On review, several of the codes in this family should be moved to other lines.

Current Prioritized List status:

ICD-10-CM Code	Code description	Current code placement	Condition description
Q66.0	Congenital talipes equinovarus	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	"club foot"
Q66.1	Congenital talipes calcaneovarus	359	A form of club foot
Q66.21	Congenital metatarsus primus varus	543 DEFORMITIES OF FOOT	Related to bunions
Q66.22	Congenital metatarsus adductus	359	Causes "pigeon toe"
Q66.3	Other congenital varus deformities of feet	359	Subdiagnoses: Congenital hallux varus Talipes varus
Q66.4	Congenital talipes calcaneovalgus	359	"rocker bottom foot"
Q66.5	Congenital pes planus	579 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES	Flat feet
Q66.6	Other congenital valgus deformities of feet	359	Subdiagnoses: Congenital hallux valgus, pes planus, talipes vulgus
Q66.7	Congenital pes cavus	359	Extremely high arch
Q66.80-Q66.82	Congenital vertical talus deformity	543	"rocker bottom foot"
Q66.89	Other specified congenital deformities of feet	543	Subdiagnoses: Hammer toes, claw toes, contracture of toes
Q66.9	Congenital deformity of feet, unspecified	359	Subdiagnoses: Congenital toe deformities

Q66.6 (Other congenital valgus deformities of feet) is mainly used for pes planus (flat foot). The other subdiagnoses on this line include congenital hallux valgus which is a bunion like condition, as well as congenital talipes vulgus which is a rare and debilitating condition.

Q66.7 (congenital pes cavus) refers to a high-arched foot. This condition rarely needs treatment, other than an orthotic in a shoe.

Q66.9 codes mainly for congenital toe anomalies, most of which are found on line 543 DEFORMITIES OF FOOT.

HERC staff recommendations:

1) Add ICD-10-CM Q66.7x (Congenital pes cavus) and Q66.9x (Congenital deformity of feet, unspecified) to line 543 DEFORMITIES OF FOOT and remove from line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
2) Add ICD-10-CM Q66.6 (Other congenital valgus deformities of feet) to line 579 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES
    a. Leave on line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
3) Add a new guideline note to lines 359 and 579 as shown below

GUIDELINE NOTE XXX OTHER CONGENITAL VALGUS DEFORMITIES OF FEET
Lines 359,579
ICD-10-CM Q66.6 (Other congenital valgus deformities of feet) is included on line 359 when used to represent congenital talipes vulgus. Otherwise, this code is included on line 579.

Gait Analysis Testing and Surface Electromyography

Question: Should gait analysis testing be covered as a diagnostic test?

Question source: Max Kaiser, CCO medical director

Issue: There are several CPT codes for gait analysis which are currently on the Ancillary file. These tests are generally not covered by private insurance as experimental. Dr. Kaiser received a request for this testing and is asking for clarification as to HERC's intent for coverage. It appears from old minutes that these codes were not intended to be covered. These codes were moved to the Diagnostic Workup File in 2012 as part of the neuroimaging back pain discussion. This appears to be due to the mistaken impression that these codes are used for standard electromyography (EMG), when actually this service is coded with CPT codes 95860-95870.

Gait analysis is used to study a variety of conditions, most commonly cerebral palsy. Studies have been conducted to evaluate whether gait analysis affects surgical planning or outcomes in cerebral palsy. It is also used for studies of athletes and human kinetics.

Gait analysis consists of the visual assessment of walking, augmented by videotaping with the use of slow-motion and split-screens to view the child's gait simultaneously from the front, back and side to capture the range of joint motion (kinematics) occurring in the sagittal, coronal and transverse planes over the entire gait cycle. The subject walks on force plates embedded in the floor, which calculates the joint moments and power (kinetics). Kinematic and kinetic data are presented as waveforms over the entire gait cycle, along with the typical waveforms of normal gait for comparison. Subjects may also undergo dynamic electromyography (EMG) to record the timing of activation of specific muscles/muscle groups during the gait cycle and measurement of energy expenditure or oxygen consumption during walking. These data are used collectively to guide the choice of interventions to optimize gait efficiency and quality.

Surface electromyography (sEMG) can be used to assess the integrity of the neuromuscular system and its impairment in neurological disorders. Multi-muscle sEMG recordings provide information on muscular recruitment/de-recruitment capability, fatigue, synergistic activation, co-contractions, as well as contribute to the evidence for the efficacy of the rehabilitation plan

HSC/HERC history:
April 2004: 96000-96004 Motion analysis. These codes are currently not on the List. The Subcommittee members felt they should remain off the list. Action: add to the Never Covered list.

November 2012: It was pointed out that electromyelography (CPT 96002-4) is used for diagnosis of a variety of conditions. The proposal was to not cover this service for the diagnosis of low back pain; however, the group agreed that it should be covered for diagnosis for other conditions and moved from the Ancillary to the Diagnostic List. The intention is to not cover EMG for diagnosis of low back pain.

NOTE: electromyography is coded with CPT codes 95860-95870 (Needle electromyography of various muscles are areas) which are all Diagnostic Procedures

CPT Code	Code Description	Current Placement
96000	Comprehensive computer-based motion analysis by video-taping and 3D kinematics;	ANCILLARY PROCEDURES

Gait Analysis Testing and Surface Electromyography

CPT Code	Code Description	Current Placement
96001	Comprehensive computer-based motion analysis by video-taping and 3D kinematics; with dynamic plantar pressure measurements during walking	ANCILLARY PROCEDURES
96002	Dynamic surface electromyography, during walking or other functional activities, 1-12 muscles	DIAGNOSTIC PROCEDURES
96003	Dynamic fine wire electromyography, during walking or other functional activities, 1 muscle	DIAGNOSTIC PROCEDURES
96004	Review and interpretation by physician or other qualified health care professional of comprehensive computer-based motion analysis, dynamic plantar pressure measurements, dynamic surface electromyography during walking or other functional activities, and dynamic fine wire electromyography, with written report	DIAGNOSTIC PROCEDURES

Evidence

Gait Analysis

1) **Narayanan 2012** review of management of children with cerebral palsy
    a. The use of gait analysis to guide clinical (surgical) decision-making before multilevel orthopedic surgery remains an area of controversy among pediatric orthopedic surgeons. There is good evidence that gait analysis does alter surgical decision-making at least some of the time. However, there remain concerns about the reliability (reproducibility) of these decisions or whether implementing these recommendations would result in different, let alone better outcomes
    b. A systematic review of the literature on the use of gait analysis in children with walking disorders reported that there was little published evidence that outcomes of surgery based on gait analysis are any better than outcomes of surgery based on observational analysis alone
    c. Conclusion: insufficient evidence regarding the utility of gait analysis improving surgical outcomes

Surface EMG

1) **Cappellini 2020** review of surface electromyography in cerebral palsy
    a. Despite the uniqueness of the sEMG technology and the successes in clinical applications for planning and assessment of treatment of children with cerebral palsy, clinical application and practice in rehabilitation departments remain very limited because of many barriers.

Other payer policies

1) **Aetna 2021**: Aetna considers gait analysis (also known as motion analysis studies), dynamic electromyography or the use of an electrodynogram experimental and investigational for conditions that result in gait deviations and for all other indications because there is insufficient peer-reviewed medical literature demonstrating the clinical value of these technologies.
2) **Cigna 2021**:
    a. Computerized gait analysis is considered medically necessary when BOTH of the following criteria are met:

   i. A child or adolescent has a diagnosis of cerebral palsy.
   ii. The procedure is performed as part of a preoperative assessment, and the results will be used in surgical planning.
b. Gait analysis for any other indication is considered experimental, investigational or unproven

3) Wellmark BCBS 2021

a. Surface electromyography (sEMG) including but not limited to the following, for the evaluation of neuromuscular disorders and to evaluate abnormal patterns of electrical activity in the paraspinal muscles for any indication is considered investigational. There is insufficient evidence in the medical literature to support the use of any type of surface electromyography (sEMG) as the diagnostic utility is unknown and the role in patient management has not been established.

HERC staff summary

There is very little evidence published on the clinical utility of either gait analysis or surface electromyography. Most private insurers do not cover these tests, considering them experimental. Surface electromyography appeared to be mistakenly removed from the Excluded file as the procedure codes were inaccurately thought to represent standard EMG testing.

HERC staff recommendation:

1) Add CPT 96000-96004 to line 662/GN173
   a. Advise HSD to remove these codes from the Ancillary and Diagnostic Procedures files

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
96000-96004	Comprehensive computer-based motion analysis by video-taping and 3D kinematics Dynamic surface electromyography	Insufficient evidence of effectiveness	March 2022

Management of Children With Ambulatory Cerebral Palsy: An Evidence-based Review

Unni G. Narayanan, MBBS, MSc, FRCS(C)†*

Abstract: This article reviews the current best evidence for musculoskeletal interventions in children with ambulatory cerebral palsy (CP). The effectiveness of interventions in CP must first consider what CP and its associated pathophysiology are and take into account the heterogeneity and natural history of CP to put definitions of "effectiveness" into perspective. This article reviews the current standards of the definition and classification of CP, discusses the natural history and specific goals for the management of ambulatory CP, as well as the outcome measures available to measure these goals. The current best evidence of effectiveness is reviewed for specific interventions in children with ambulatory CP including spasticity management with botulinum toxin A injections and selective dorsal rhizotomy; multilevel orthopaedic surgery to address contractures and bony deformity; and the role of gait analysis for surgical decision-making before orthopaedic surgery.

Key Words: cerebral palsy, ambulatory children, evidence-based medicine, treatment outcomes, effectiveness, orthopaedic surgery, multilevel surgery, gait analysis

(*J Pediatr Orthop* 2012;32:S172–S181)

Cerebral Palsy (CP) is the most common cause of chronic physical disability in children affecting between 2 and 3 per 1000 children.[1] The impact is lifelong and affects not only the child with CP, but also their parents and caregivers, the family, the health care system, and potentially society at large. In the absence of a cure, children with CP are subjected to numerous interventions to address the secondary consequences of the primary neurological pathology. This article reviews the current best evidence for the (musculoskeletal) interventions for children with ambulatory CP, with much of the content derived and updated from 2 systematic reviews on the subject.[2,3]

Any discussion about the effectiveness of interventions in CP must first consider what CP and its associated pathophysiology are and take into account the heterogeneity and natural history of CP in order to put definitions of "effectiveness" into perspective. This article will review the current standards of the definition and classification of CP and discuss the functional trajectory associated with the natural history, before outlining the specific goals for the management of ambulatory CP, as well as the list of validated outcome measures available to measure whether these goals are achieved. This background is essential to contextualize the current best evidence about the effectiveness of various musculoskeletal interventions to achieve these goals for children with ambulatory CP.

DEFINITION OF CP AND PATHOPHYSIOLOGY OF MUSCULOSKELETAL CONSEQUENCES

The term CP refers to a heterogeneous group of disorders of the development of movement and posture that are permanent and attributable to nonprogressive disturbances that occurred in the developing fetal or infant brain.[4] The primary disorder in the brain is associated with abnormal muscle tone, most often hypertonia, accompanied by loss of selective motor control, muscle weakness, and impaired balance.[5] The motor disorders contribute to secondary musculoskeletal problems including muscle contractures, bony deformities, and joint instability. Normal muscle growth occurs in response to the stimulus of stretch derived from typical physical activities associated with normal motor development. Hypertonia and the limited use of muscles due to developmental delay result in dynamic contractures, which become static joint contractures over time as the tight muscles fail to grow in proportion to the long bones which they traverse.[6] The growing skeleton remodels in response to typical stresses associated with the motor milestones, which when delayed, or absent, result in retention of infantile morphology and development of secondary bony deformities and joint instability, which contribute to lever-arm dysfunction.[7] The interaction of joint contractures, muscle weakness, bony deformities, and joint instability at multiple levels affect the quality and efficiency of gait and other aspects of physical function in children who are ambulant or deformities of the trunk and limbs in those who are nonambulant.

CLASSIFICATION CP: GROSS MOTOR FUNCTIONAL CLASSIFICATION SYSTEM (GMFCS) IS THE GOLD STANDARD

Children with CP have wide variability in presentation and severity. Conventionally, CP has been

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REVIEW
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Clinical Relevance of State-of-the-Art Analysis of Surface Electromyography in Cerebral Palsy

Germana Cappellini[1,2]*, *Francesca Sylos-Labini*[1], *Carla Assenza*[2], *Laura Libernini*[2], *Daniela Morelli*[2], *Francesco Lacquaniti*[1,3] *and Yury Ivanenko*[1]

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Surface electromyography (sEMG) can be used to assess the integrity of the neuromuscular system and its impairment in neurological disorders. Here we will consider several issues related to the current clinical applications, difficulties and limited usage of sEMG for the assessment and rehabilitation of children with cerebral palsy. The uniqueness of this methodology is that it can determine hyperactivity or inactivity of selected muscles, which cannot be assessed by other methods. In addition, it can assist for intervention or muscle/tendon surgery acts, and it can evaluate integrated functioning of the nervous system based on multi-muscle sEMG recordings and assess motor pool activation. The latter aspect is especially important for understanding impairments of the mechanisms of neural controllers rather than malfunction of individual muscles. Although sEMG study is an important tool in both clinical research and neurorehabilitation, the results of a survey on the clinical relevance of sEMG in a typical department of pediatric rehabilitation highlighted its limited clinical usage. We believe that this is due to limited knowledge of the sEMG and its neuromuscular underpinnings by many physiotherapists, as a result of lack of emphasis on this important methodology in the courses taught in physical therapy schools. The lack of reference databases or benchmarking software for sEMG analysis may also contribute to the limited clinical usage. Despite the existence of educational and technical barriers to a widespread use of, sEMG does provide important tools for planning and assessment of rehabilitation treatments for children with cerebral palsy.

Keywords: cerebral palsy, abnormal development, muscle pathophysiology, surface electromyography, spinal locomotor output, rehabilitation, clinical application

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INTRODUCTION

Cerebral palsy (CP) is the most common form of motor disability in childhood. It describes a group of permanent disorders of movement and posture, caused by disturbances in the fetal or infant brain (1). The clinical manifestations of CP vary greatly in the type of movement disorder and the degree of functional disability. It is often characterized by impaired coordination, muscle weakness, spasticity, hyperreflexia, hypertonia, clonus, spasms and co-contraction (2, 3). Children with CP have a variety of symptoms and CP is often accompanied by other disorders such as cognitive dysfunction, communication problems, deficits of vision, epilepsy, etc. (4, 5). Currently there are

Section 7.0

Previously Discussed Items

Polydactyly Clarification 2022

Question: Does the HERC intend to have polydactyly both above and below the funding line? If yes, is there a guideline required?

Question source: HERC staff

Issue: In August 2020, polydactyly (having multiple toes) was discussed at VBBS and HERC. The staff proposal was to leave the diagnosis on an uncovered line, and add to a covered line with a guideline that stated the diagnosis was on the covered line only when the child could not be fitted with shoes by age 1. The VBBS did not feel that a guideline was needed, but did approve the addition of the diagnosis to a funded line. The issue summary and the meeting minutes both reflect that the approved decision was to add the diagnosis to a funded line, leave on the unfunded line, and not have a guideline. HERC staff are requesting clarification regarding whether VBBS/HERC intended polydactyly to only be included on the upper line, or be included on both lines. If on both lines, how are CCOs and HSD to determine when to cover treatment?

HERC staff recommendations:

1) Remove ICD-10-CM Q69.9 (Polydactyly, unspecified) from line 579 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES
2) Rename line 579 CAVUS DEFORMITY OF FOOT; FLAT FOOT; ~~POLYDACTYLY AND~~ SYNDACTYLY OF TOES

Section 8.0

Biennial Review

2024 Biennial Review
Agenesis of Lung

Question: Should Line 647 AGENESIS OF LUNG be deleted?

Question source: HERC staff

Issue: ICD-10-CM Q33.3 (Agenesis of lung) currently appears on two lines, 197 CONGENITAL LUNG ANOMALIES and 647 AGENESIS OF LUNG. There are claims for DME and for medical therapy for this condition in the past 5 years. There is no guideline or other guide as to when this is a funded diagnosis. Staff recommends deleting line 647 with the next biennial review.

HERC staff recommendations:
Effective 1/1/2024:

1) Delete Line 647 AGENESIS OF LUNG

~~**Line: 647**~~
~~Condition: AGENESIS OF LUNG~~
~~Treatment: MEDICAL THERAPY~~
~~ICD-10: Q33.3~~
~~CPT: 98966-98972,99051,99060,99070,99078,99091,99184,99203-99239,99281-99285,99291-99404,99411-99416,99421-99449,99451-99453,99457,99458,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607~~
~~HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2251,G2252~~

Dorsal Rhizotomy for Spastic Cerebral Palsy

Question: Should dorsal rhizotomy be reprioritized as a treatment for spastic cerebral palsy?

Question source: Drs. Siana and Williams, pediatric neurology, OHSU

Issue: Cerebral palsy (CP) is a condition that can result from various disease processes affecting the brain either during gestation or in early childhood. About 75% of patients with CP have lower limb spasticity (increased muscle tone and rigidity). Selective dorsal rhizotomy (SDR) is a neurosurgical technique developed to reduce spasticity and improve mobility in children with CP and lower extremity spasticity. It involves the selective division of lumbosacral afferent (sensory) rootlets at the conus or at the intervertebral foramina under intraoperative neurophysiological guidance. Early procedures were effective at reducing spasticity but were associated with significant morbidity; however, technical advancements have reduced the invasiveness of the procedure.

Spastic diplegic cerebral palsy can also be treated with oral medication, orthotic devices, physiotherapy, botulinum intramuscular injections, corrective orthopedic procedures such as a tendonotomy, electrical stimulation and continuous intrathecal baclofen infusion.

Currently, spastic diplegic cerebral palsy (ICD-10-CM G80.1) is the only ICD10 code on line 491 SPASTIC DIPLEGIA; Treatment: RHIZOTOMY. The procedure is currently on 3 other lines that do not include spasticity diagnoses.

OHSU pediatric neurology has requested a review of the lack of coverage for this procedure for spastic CP. CCO medical directors have indicated that this is a frequent exceptions request. HERC staff review of HSC and HERC minutes found no history of any discussion on rhizotomy or spastic diplegia. The pairing of spastic diplegic CP with dorsal rhizotomy has been in the unfunded region on all previous versions of the Prioritized List.

Current Prioritized List status:

Code	Code Description	Placement
63185	Laminectomy with rhizotomy; 1 or 2 segments	346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS 361 SCOLIOSIS 491 SPASTIC DIPLEGIA Treatment: RHIZOTOMY 530 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
63190	more than 2 segments	346,361,491,530
M62.4X	Contracture of muscle	292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
G80.1	Spastic diplegic cerebral palsy	Dysfunction lines (71,292,345,377) 491

Evidence:

1) **Health Quality Ontario 2017,** Lumbosacral Dorsal Rhizotomy for Spastic Cerebral Palsy: A Health Technology Assessment https://www.hqontario.ca/Portals/0/Documents/evidence/reports/hta-dorsal-rhizotomy-06-2017-en.pdf
    a. Eighty-four studies (1 meta-analysis, 5 randomized controlled studies [RCTs], 75 observational pre-post studies, and 3 case reports) were reviewed. A meta-analysis of RCTs involving dorsal rhizotomy and physical therapy versus physical therapy confirmed reduced lower-limb spasticity and increased gross motor function (4.5%, *P* = .002). Observational studies reported statistically significant improvements in gross motor function over 2 years or less (12 studies, GRADE moderate) and over more than 2 years (10 studies, GRADE moderate) as well as improvements in functional independence in the short term (10 studies, GRADE moderate) and long term (4 studies, GRADE low).
    b. Major operative complications were infrequently reported (4 studies). Bony abnormalities and instabilities monitored radiologically in the spine (15 studies) and hip (8 studies) involved minimal or clinically insignificant changes after surgery.
    c. For children whose lower limb spasticity significantly limits motor development, dorsal rhizotomy effectively reduces spasticity and (with physical therapy) increases motor function and functional independence. Motor gains are related to level of disability. Less disabled children with some mobility are more likely to achieve motor skills like running or jumping. More disabled children generally gain skills like crawling, sitting, or standing. Functional independence and caregiver burden also improve for many children after surgery.
    d. Major surgical complications are infrequent.
2) **NICE 2006**, evidence review of selective dorsal rhizotomy for spasticity in cerebral palsy
    a. Effectiveness:
        i. A meta-analysis of three randomized controlled trials comparing selective dorsal rhizotomy (SDR) and physiotherapy with physiotherapy alone found that gross motor function improved by an additional 4% with SDR and physiotherapy than with physiotherapy alone (i.e., an 8% over a 4% improvement respectively, p=0.008). The follow up period in the primary studies was between 9 and 12 months
        ii. In a non-randomized controlled trial of 61 patients undergoing SDR, botulinum toxin type A injection, or rehabilitation therapy there were no significant differences in scores of walking speed in any of the three groups between baseline and 20 moths follow up. However, patients treated by SDR showed a transient but significant decrease in walking velocity at 3 months compared to baseline
        iii. The gross motor performance measure of patients undergoing SDR was found to increase at 2 years of follow up (54.6 to 63.4 points) in a non- randomized controlled study. This was not significantly different to the improvement among patients having corrective orthopedic surgery (54.1 to 60.7 points) (p=0.751). Similarly, self-case score increased from 73.7 points to 84.1 points following SDR, and from 75.2 to 83.4 points with orthopedic surgery (p=0.932).
        iv. Case series studies have found that SDR reduced median muscle spasticity scores in abductor muscles from 2 to 0 points (Ashworth scale) in children with Cerebral Palsy categorized as walkers (p=0.007) and also from 2 to 0 points in children characterized as non-locomotors defined as non-walkers and non-

crawlers. (p=0.001) at 12 months follow up; and from 2.9 to 0.4 points in a mixed cohort of patients with spasticity at 4 years.

v. 81% (169/208) of patients in a case series of children with Cerebral Palsy receiving SDR demonstrated improvement in ambulatory function at 1 year follow up

b. Safety
   i. Case series studies have found that SDR reduced median muscle spasticity scores in abductor muscles from 2 to 0 points (Ashworth scale) in children with Cerebral Palsy categorized as walkers (p=0.007) and also from 2 to 0 points in children characterized as non-locomotors defined as non-walkers and non-crawlers. (p=0.001) at 12 months follow up; and from 2.9 to 0.4 points in a mixed cohort of patients with spasticity at 4 years.
   ii. Common bowel and bladder complications that were reported include constipation 20% (49/250), and urinary retention in between 5% (13/250) and 10% (20/208) of patients. Other, less common but more serious complications reported include intra-operative bronchospasm in 5% (13/250) of patients undergoing SDR, and postoperative aspiration pneumonia at a rate of about 1% (2/208) and (3/250)
c. Conclusion [updated in NICE 2010]: Current evidence on selective dorsal rhizotomy for spasticity in cerebral palsy shows that there is a risk of serious but well-recognized complications. The evidence on efficacy is adequate.

Other payer policies

1) Aetna 2021

a. Aetna considers neurosurgical procedures medically necessary for the management of members with refractory spasticity when *all* of the following selection criteria are met:
   i. The member has good intrinsic lower extremity motor power, but is limited in ambulation by spasticity; *and*
   ii. The member has the functional capacity and motivation to participate in post-operative rehabilitation; *and*
   iii. The member has tried and failed non-surgical, medical management for spasticity including baclofen or other muscle relaxants.
b. Aetna considers the following procedures medically necessary for the management of members with spasticity:
   i. Longitudinal myelotomy
   ii. Microsurgical dorsal root entry zone lesion (DREZotomy)
   iii. Percutaneous radiofrequency (or thermal) rhizotomy
   iv. Peripheral neurotomy
   v. Selective posterior (dorsal) rhizotomy.
c. Members 2 to 6 years of age are optimal candidates for selective posterior rhizotomy.
d. Based on a review of the medical literature, Aetna considers selective posterior rhizotomy experimental and investigational when the member has *any* of the following contraindications:
   i. Concomitant dystonia or rigidity; *or*
   ii. Profound weakness in lower extremity muscles such that the spasticity actually serves to assist in standing; *or*
   iii. Progressive neurological disorders, choreoathetosis, or cerebellar ataxia; *or*

iv. Severe damage to basal ganglia; *or*
v. Severe fixed joint deformities or scoliosis.

2) HealthNet 2020

a. selective dorsal rhizotomy is medically necessary for children with spastic CP when meeting all of the following:
   i. Spastic diplegia, or spastic quadriplegia with no significant ataxia or dystonia;
   ii. Gross Motor Function Classification System (GMFCS) level II or III;
   iii. Age > 2 to < 10 years;
   iv. No significant weakness;
   v. Functional and intellectual ability to participate in physical rehabilitation;
   vi. Failure of or inability to tolerate other conservative treatment (e.g., pharmacotherapy, orthopedic management, physical therapy);
   vii. No botulinum toxin A injection has been given within the last 6 months;
   viii. No orthopedic surgery within the last year;
   ix. No significant scoliosis;
   x. Periventricular leukomalacia (PVL) on MRI with no involvement of the thalamus, basal ganglia or cerebellum;
   xi. Reimers index < 40%, (i.e. no significant femoral head subluxation on pelvic radiograph.)
b. selective dorsal rhizotomy is not medically necessary for children with spastic hemiplegia, or ataxic or athetoid spasticity

Dorsal Rhizotomy for Spastic Cerebral Palsy

HERC staff summary

Dorsal rhizotomy is an established treatment for spastic diplegic cerebral palsy. Two highly regarded evidence review sources (NICE and Health Quality Ontario) found sufficient evidence of effectiveness for improvement in motor function with this procedure. All private payers surveyed covered this procedure for certain patients with spastic diplegic cerebral palsy.

HERC staff recommendations

Effective October 1 2022:

1) Add CPT 63185 and 63190 (laminectomy with rhizotomy) to line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
2) Adopt the new guideline shown below for line 292
3) Strike through line 491 SPASTIC DIPLEGIA Treatment: RHIZOTOMY for the 10/1/22 Prioritized List
    a. Formally delete Line 491 with the 2024 biennial review Prioritized List

GUIDELINE NOTE XXX DORSAL RHIZOTOMY FOR SPASTIC CEREBRAL PALSY

Line 292

Dorsal rhizotomy (CPT 63185 and 63190) is only included on this line for patients who meet ALL of the following criteria:

A) Has spastic diplegic cerebral palsy (ICD-10-CM G80.1); AND
B) Is a child aged 2 to 10 years; AND
C) Has good intrinsic lower extremity motor power, but is limited in ambulation by spasticity; AND
D) Has the functional capacity and motivation to participate in post-operative rehabilitation; AND
E) Has failed or been unable to tolerate other conservative treatment (e.g., pharmacotherapy, orthopedic management, physical therapy); AND
F) Has no contraindications to the procedure (e.g., significant scoliosis, progressive neurological disorders, severe fixed joint deformities)

~~**Line: 491**~~
~~Condition: SPASTIC DIPLEGIA (See Guideline Note 170)~~
~~Treatment: RHIZOTOMY~~
~~ICD-10: G80.1,Z45.49~~
~~CPT: 21720,21725,62320-62323,62350-62370,63185,63190,63295,95990,98966-98972,99051, 99060,99070,99078,99184,99203-99239,99281-99285,99291-99404,99411-99449,99451, 99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607~~
~~HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427, G0463,G0466,G0467,G0490,G0508-G0511,G2011,G2012,G2211,G2212,G2214,G2251, G2252~~

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of selective dorsal rhizotomy for spasticity in cerebral palsy

A surgical procedure aimed to ease muscle rigidity and improve mobility in people with cerebral palsy. The operation consists of cutting of some of the nerves in the spine that are responsible for muscle rigidity

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in February 2006.

Procedure name

- Selective dorsal rhizotomy (SDR)
- Limited dorsal rhizotomy
- Selective posterior dorsal rhizotomy

Specialty societies

- British Paediatric Neurology Association
- British Orthopaedic Association
- Society of British Neurological Surgeons
- British Paediatric Neurosurgical Group

Description

Indications

Cerebral Palsy is a condition that can result from various disease processes affecting the brain either during gestation or in early childhood. About 75% of patients with Cerebral Palsy have lower limb spasticity (increased muscle

tone and rigidity). Other symptoms may include movement or balance abnormalities, and speech, or visual difficulties

Current treatment and alternatives

Current conservative treatment options include oral medication, orthotic devices, physiotherapy. Botulinum Intramuscular injections may also be used. In other cases corrective orthopedic procedures, such as a tendonotomy may be appropriate. Electrical stimulation and continuous intrathecal baclofen infusion are other treatment options.

What the procedure involves

Muscular tone (tension) is normally controlled by nerve centres in the brain, however in patients with Cerebral Palsy such centres may be affected. In such patients muscle tone greatly depends on a sensory-motor reflex arc between muscles and spinal cord nerves. This reflex involves sensory nerves bringing information from a muscle back to the spinal cord, and a motor nerve that goes back to the muscle, causing it to contract. The aim of selective dorsal rhizotomy is to down-regulate this spastic reflex by reducing sensory input.
Selective Dorsal Rhizotomy is a surgical procedure carried out under general anaesthesia to the lower area of the spine. The duration of the operation is about five hours During surgery, an incision is made along the lower back and a laminectomy in one or more vertebrae is made to uncover and test small nerve rootlets that make up the spinal sensory nerves. Usually 3-5 rootlets are identified. Some rootlets found to have abnormal electromyographic responses are subsequently selectively cut. All motor nerve rootlets are preserved so leg movement is not affected.

Intensive physiotherapy will be required for around three months to one year, as patient who was previously able to walk has to learn to walk again.

Efficacy

A meta analysis of three randomised controlled trials comparing selective dorsal rhizotomy (SDR) and physiotherapy with physiotherapy alone found that gross motor function improved by an additional 4% with SDR and physiotherapy than with physiotherapy alone (i.e. an 8% over a 4% improvement respectively, p=0.008). The follow up period in the primary studies was between 9 and 12 months[1].

In a non-randomised controlled trial of 61 patients undergoing SDR, botulinum toxin type A injection, or rehabilitation therapy there were no significant differences in scores of walking speed in any of the three groups between baseline and 20 moths follow up. However, patients treated by SDR showed a transient but significant decrease in walking velocity at 3 months compared to baseline[2].

The gross motor performance measure of patients undergoing SDR was found to increase at 2 years of follow up (54.6 to 63.4 points) in a non-

randomised controlled study. This was not significantly different to the improvement among patients having corrective orthopaedic surgery (54.1 to 60.7 points) (p=0.751). Similarly, self case score increased from 73.7 points to 84.1 points following SDR, and from 75.2 to 83.4 points with orthopaedic surgery (p=0.932)[3].

Case series studies have found that SDR reduced median muscle spasticity scores in abductor muscles from 2 to 0 points (Ashworth scale) in children with Cerebral Palsy categorised as walkers (p=0.007) and also from 2 to 0 points in children characterised as non-locomotors defined as non walkers and non crawlers. (p=0.001) at 12 months follow up[4]; and from 2.9 to 0.4 points in a mixed cohort of patients with spasticity at 4 years[5].

81% (169/208) of patients in a case series of children with Cerebral Palsy receiving SDR demonstrated improvement in ambulatory function at 1 year follow up[5]..

Safety

Neither the meta analysis of 3 randomised controlled trials, nor the non-randomised controlled trials report on SDR safety outcomes. Therefore, there are no comparative data available from the studies included in this overview to consider the safety profile of SDR against that of other therapeutic options for spasticity.

A case series of 250 patients undergoing SDR (mean patient age of 5.9 years, follow up of at least 2 years in 49 patients) found that 58% (145/250) of patients suffered severe postoperative pain and 40 % (100/250) complained of dysesthesia [6]

Common bowel and bladder complications that were reported include constipation 20% (49/250)[6], and urinary retention in between 5% (13/250)[6] and 10% (20/208)[5] of patients. Other, less common but more serious complications reported include intra-operative bronchospasm in 5% (13/250)[6] of patients undergoing SDR, and postoperative aspiration pneumonia at a rate of about 1% (2/208)[5] and (3/250)[6].

Radiologically observed scoliosis was found in 6% (12/208) of patients followed up to 4.2 years although this was not considered to be functionally important[5]. Periods of increased spasticity during times of increased stress at months or years after surgery have been reported in 45 (10/250) of patients undergoing SDR in one case series[6]

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to selective dorsal rhizotomy for cerebral palsy. Searches were conducted via the following databases, covering the period from their commencement to 06/02/02; Medline, PreMedline, EMBASE, Cochrane Library and other

databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See Appendix C for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with cerebral palsy
Intervention/test	Selective dorsal rhizotomy
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on one meta anlaysis of 3 randomised controlled trials[1], two non randomised controlled trials [2,3]and 2 case series (3 publications[5,4,6].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (Table 2) have been listed in Appendix A. For case series studies, the sample size cut off for inclusion was 200 cases or more. All meta-analyses, RCT's other than those already included in the reviewed meta-analysis, and other controlled trials identified are described in Table 2.

Existing reviews on this procedure

There were no published reviews identified at the time of the literature search. A Cochrane protocol for selective dorsal rhizotomy in the management of children with spastic cerebral palsy has been published with the review expected to be published in the autumn of 2006 http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003360/frame.html

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

Interventional procedures:
None

Technology appraisals:
None

Clinical guidelines:
None

Public health:
None

Table 2 Summary of key efficacy and safety findings on selective dorsal rhizotomy for cerebral palsy

Abbreviations used: SDR – selective dorsal rhizotomy, CP – cerebral palsy, GMFM – Gross motor function measure,			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
McLaughlin J (2002)[1] **Meta analysis** USA and Canada **n=90 (number having SDR not stated)** Children with CP – inclusion criteria varied between study sites, SDR and physiotherapy vs. physiotherapy alone. Mean age = 5.5 years, Male =53%, gestational age =31.7 weeks, birth weight =1,849g, prenatal cause of CP = 87% (78/90), baseline GMFM score = 62.5, non-ambulatory = 57%. **Follow-up = all patients followed up to either 9 or 12 months** Disclosure of interest: Funding provided by a foundation	**Operative parameters** There was a statistically significant inverse correlation between the baseline GMFM-66 score and the percent of dorsal rootlets cut (p=0.0002). This was independent of study site. **Clinical outcomes** A weak inverse correlation was found between the percent of dorsal root tissue cut and change in Ashworth spasticity score (p=0.03) and GMFM score (p<0.001). A small but statistically significant benefit of SDR and physiotherapy over physiotherapy was found. GMFM scores improved by 4% in the control groups and 8% in the SDR groups (data read from figure) (p=0.008). It is not clear whether this benefit is clinically important.	No safety data from the primary studies is presented.	Primary researcher was also the author of one of the studies included, allowing for analysis of unpublished raw data, and ability to recalculate variables, but potential subjectivity. Follow-up limited to 12 months (2 studies) and 9 months (1 study) Medline, Cochrane and meeting abstracts searched for RCTs up to December 2000. No further details of search strategy provided. Multiple regression undertaken to assess factors of treatment group, study site, age, sex, birth weight, ambulatory status, and baseline clinical scores. In one study less dorsal root tissue was transected (25%) than at the other two studies (41% and 45%). Functional GFMF outcome scores were assessed blindly in all patients Method for data pooling used – blocked Wilcoxon's test. Completeness of follow-up is not reported

Abbreviations used: SDR – selective dorsal rhizotomy, CP – cerebral palsy, GMFM – Gross motor function measure,

Study details	Key efficacy findings	Key safety findings	Comments
Wong A M K (2005)[2] **Non-randomised controlled trial** Taiwan **n=61 (n=20 SDR,** Ambulatory children with spastic diplegia CP. Children with Ashworth spasticity scores 1 and 4 were excluded. Patients received regular rehabilitation therapy for 6 months before baseline. Patients were then entered into study arms of botulinum toxin type A (BTA) injection, SDR, or rehabilitation only, based on parent's choice of therapy. Mean age = 5 years, Male=59%, relying on walking aid = 51% No statistically significant difference between groups in terms of age, height, weight, sex, ambulation ability, or other baseline gait parameters. **Follow-up = 20 months** Disclosure of interest: Study supported by a national grant.	**Gait analysis** outcome / Baseline / 3 months / p= / 20 months / p= Velocity BTA 31.3 / 35.7 / N/S / 32.5 / N/S SDR 33.5 / 25.3 / <0.05 / 38.9 / N/S Rehab 35.5 / 36.6 / N/S / 40.3 / N/S Cadence BTA 92.0 / 100.8 / N/S / 92.8 / N/S SDR 88.5 / 76.4 / N/S / 94.9 / N/S Rehab 93.0 / 90.0 / N/S / 85.6 / N/S Step length BTA 26.0 / 26.2 / N/S / 24.7 / N/S SDR 21.4 / 16.0 / N/S / 278 / N/S Rehab 25.6 / 26.0 / N/S / 25.2 / N/S The BTA group showed a statistically significant improvement in walking velocity over baseline score at 6 months, 38.7 $\pm$ 12.4 % of body height per second and 31.3 $\pm$ 10.2% of body height per second ($p<0.05$) but the difference did not persist past 12 months. The SDR demonstrated a significant deterioration in velocity at 3 months 25.3 $\pm$ 12.0% of body height per second vs. 33.5 $\pm$ 12.8% of body height per second at baseline. However this score recovered at 6 months and was better than baseline at 12 and 20 months follow up (not a significant difference).	No safety data was presented in the study report	During the study period SDR treatment costs were paid for by insurance while BTA was not. No between groups analysis was performed (only within groups). Outcomes assessed by a computer assisted gait analysis system. Measuring gait velocity, cadence, and step length (corrected for patient height) Further study of SDR in children in whom repeated BTA injection produced a ceiling effect may be warranted. No details of blinding of outcomes assessors. Completeness of follow-up not reported

Abbreviations used: SDR – selective dorsal rhizotomy, CP – cerebral palsy, GMFM – Gross motor function measure,

Study details	Key efficacy findings	Key safety findings	Comments
Buckon C E (2004)[3] **Non-randomised controlled trial** USA **n=25 (n=18 SDR)** All children found by an MDT to be appropriate for SDR or orthopaedic soft tissue procedures. Parents chose the treatment therapy after discussions with clinicians. SDR vs. aponeurotomy / tenotomy with post surgical physiotherapy in both groups Mean age = 6 years and 1 month, Male = 76%, ambulatory = 92%. There were no significant differences between groups at baseline in any of the clinical outcomes measured. **Follow-up= 2 years** Disclosure of interest: No commercial party conferred a benefit on the author.	**Motor impairment** The gross motor performance measure (GMPM), was used to assess impairment at baseline 6 months, 12 months and 2 years. There were no significant differences between baseline and follow-up, or sub scores between the groups SDR baseline (n=18) / SDR 2 years / Ortho surgery baseline (n=7) / Ortho surgery 2 years / *p= GMPM total: 54.6 ± 7.0 / 63.4 ± 7.2 / 54.1 ± 7.8 / 60.7 ± 9.4 / 0.751 Within the SDR group GMPM scores improved by 8.13 points (95% CI 4.08 to 12.18) at two years follow up (p<0.001) **Functional limitation** Functional outcomes were evaluated by the GMFM (functional limitation dimension). There were no significant differences between baseline and follow-up scores or sub scores between the groups SDR baseline(n=18) / SDR 2 years / Ortho surgery baseline (n=7) / Ortho surgery 2 years / *p= GMFM total: 89.2 ± 13.2 / 89.5 ± 11.1 / 78.2 ± 13.0 / 85.7 ± 7.1 / 0.540 Within the SDR group GMFM scores improved by 6.32 points (95% CI 1.76 to 10.88) at two years follow up (p=0.011) **Disability** The paediatric evaluation of disability index SDR baseline(n=18) / SDR 2 years / Ortho-surgery baseline(n=7) / Ortho-surgery 2 years / *p= Functional skills Self care: 73.7 ± 13.1 / 84.1 ± 14.2 / 75.2 ± 12.7 / 83.4 ± 14.2 / 0.932 Mobility: 70.5 ±10.1 / 77.8 ± 10.4 / 69.3 ± 12.6 / 76.7 ± 16.1 / 0.511 social: 69.2 ± 8.8 / 75.0 ± 7.9 / 67.5 ± 6.9 / 75.1 ± 11.6 / 0.905	No safety data was presented in the study report	All 25 families asked to participate agreed to do so. All outcomes were evaluated by 2 investigators who were trained in using the scales The post surgical physiotherapy care was not standardised between the groups as it was focused to the remedial need, and may have influenced outcome Analysis shows some significant changes between different outcome measurement points, but not necessarily between baseline score and follow up. Completeness of follow-up not reported * p= describes differences between groups in change from baseline score to follow up.

Abbreviations used: SDR – selective dorsal rhizotomy, CP – cerebral palsy, GMFM – Gross motor function measure,

Study details	Key efficacy findings	Key safety findings	Comments
Abbott R (1992)[6] and (1993)[4] **Case series** USA **n=200 for efficacy outcome and 250 for safety** Cases from 1986 onwards. 600 cases were evaluated for SDR, and cases chosen that were likely to benefit from surgery Children with spastic diplegia and quadriplegia Sensory roots were stimulated and leg muscle activity monitored, if diffusion was present the rootlet was cut, up to a maximum of 50% of rootlets. Increased activity begun after discharge under supervision of a physical therapist. Age=5.9 years, **Follow-up = 12 moths for efficacy outcomes and up to 2+ years for safety** Disclosure of interest: not stated.	**Operative parameters** Mean length of stay was 10.7 weeks **Muscle tone** Median scores and range on the Ashworth scale Outcome / Baseline (n=250) / 12 months (n=49) / p= Walkers Abductors: 2 (1 to 3) / 0 (0 to 0.5) / 0.007 Hip flexors: 1 (0 to 2) / 0 (0) / 0.007 Quadriceps: 1.3 (0 to 2) / 0 (0) / 0.005 Hamstrings: 1.5 (0 to 2) / 0 (0 to 0.5) / 0.003 Plantar flexors: 3 (1 to 3) / 0 (0 to 0.5) / 0.001 Non locomotors Abductors: 2 (1 to 3) / 0 (0 to 2) / 0.001 Hip flexors: 1 (0 to 2) / 0 (0 to 2) / 0.001 Quadriceps: 2 (0.5 to 2) / 0.2 (0 to 1) / 0.001 Hamstrings: 2 (1 to 3) / 0 (0 to 1) / 0.001 Plantar flexors: 3 (1 to 3) / 0 (0 to 2) / 0.001 **Goniometry** Median and range as evaluated by movement analysis Outcome / Baseline (n=250) / 12 months (n=49) / p= Walkers Hip abduction: 45 (15 to 45) / 45 (37.5 to 45) / 0.02 Hip extension: 2.5 (-5 to 15) / 15 (-10 to 15) / N/S Knee extension: 145 (125 to 180) / 174 (160 to 180) / 0.005 Dorsiflexion: 7.5 (-5 to 20) / 13.7 (0 to 20) / N/S Non locomotors Hip abduction: 0 (12.5 to 45) / 45 (17.5 to 45) / 0.02 Hip extension: -1 (-12 to 15) / 15 (-5 to 15) / 0.044 Knee extension: 138 (133 to 170) / 156 (120 to 180) / N/S Dorsiflexion: 0 (-12.5 to 20) / 18.7 (7.5 to 20) / 0.044 Although the walking group did experience a deterioration in goniometric measurements of the plantar flexor range no child deteriorated past the neutral position at the ankles.	**Complications** Incidence **Pulmonary** Intraoperative bronchospasm: 5% (13/250) Aspiration pneumonia: 1% (3/250) **Bowel and bladder** Urinary retention: 5% (13/250) Constipation: 20% (49/250) Ileus: 1% (3/250) **Postoperative discomfort** Severe pain: 58% (145/250) Dysthesia: 40% (100/250) **Sensory** Proprioceptive loss: 1% (3/250) Pain / temperature loss: 1% (2/250) Two of the 3 patients with pneumonia required artificial ventilation. In addition 2 patients had lung segment or lobe collapse intraoperatively leading to the abandonment of the procedure. One patient with urinary retention remained on a catherarisation programme at 18 months follow up. Authors suggest that children with a history suggesting spastic bladder are at greatest risk of this complication Increased spasticity during periods of increased stress (illness anxiety) occurred in 4% (10/250) of patients months or years after surgery. All these patients were spastic quadriplegics at baseline 2% (6/250) of patients have undergone osteotomies of the femur for progressive hip dislocation. All these children were crawling at baseline. Children considered at risk are now placed in orthosis with single lateral upright bracing	Not stated whether this was a consecutive and exhaustive sample, or selected cohort. No details of blinding of outcome assessment Post operative physiotherapy programme (if any) not described. One investigator carried out all surgery. Change to preoperative medication during the series to reduce bronchospasm 50 patients followed up for more than 2 years at time of analysis of safety outcomes. Only 49 of 200 patients analysed for efficacy outcomes at 6 and 12 months Kappa score for reproducibility of Ashworth score was 0.55 for intra-observer retest and 0.64 for inter-observer analysis .

Abbreviations used: SDR – selective dorsal rhizotomy, CP – cerebral palsy, GMFM – Gross motor function measure,

Study details	Key efficacy findings	Key safety findings	Comments
Kim D-S (2001)[5] **Case series** South Korea **n=208 (198 Cerebral Palsy)** Selected patients meeting criteria for posterior rhizotomy. Spastic diplegia or quadriplegia with CP, spastic hemipleagia of cerebro-vascular cause, or spastic quadriparesis due to incomplete spinal cord. Access either by laminectomy or later in the cohort by laminoplasty. Posterior nerve root cut into 3 or 4 and stimulated, with 50 to 70% of abnormal rootlets cut. Procedure repeated from S2 to L2 and at L1 50% of the bilateral root cut without testing Mean age = 5.9 years, Spastic CP n=198, hemiplegia following cerebrovascular insult n=8, spastic quadraparesis after cervical cord injury n=2. **Mean follow-up = 4.2 years** Disclosure of interest: not stated	**Ability to walk** The ability to walk (Peacock grading) showed a improvement in gait quality from 4.2 points at baseline to 5.19 points at 1 year ($p<0.001$). 81.3% (169/208) of patients showed improvements in ambulatory function. **Muscle tone** As measured by the Ashworth scale mean and standard deviation. Baseline (n=208) / 1 year (n=208) / 4 years (n=132) Hip adductors: 2.9 ± 1.45 / 0.4 ± 0.72 / 0.4 ± 0.84 Hamstrings: 3.2 ± 1.32 / 0.2 ± 0.39 / 0.2 ± 0.53 Quadriceps: 2.4 ± 1.05 / 0.5 ± 0.69 / 0.6 ± 0.53 Gastrocnemius: 3.6 ± 0.77 / 0.4 ± 0.55 / 0.7 ± 0.51 Clonus: 0.8 ± 0.25 / 0.07 ± 0.21 / 0.15 ± 0.29 Significant improvement s in the spasticity of all tested muscles were noted at 1 and 4 years There was no statistically significant difference in results between the hemiplegic and diplegic groups. 50% (37/74) of patients with arm spasticity showed milder symptoms at the upper extremity after SDR **Range of motion** Changes in passive range of motion in degrees Baseline (n=208) / 1 year (n=208) / 4 years (n=132) Flexion contracture of the hips: -10.5 ± 12.23 / -3.3 ± 5.26 / -4.6 ± 6.33 Abduction of the hips: 37.5 ± 16.44 / 59.5 ± 17.56 / 62.5 ± 15.56 Popliteal angle of the knee: -31.7 ± 15.23 / -27.5 ± 14.25 / -27.9 ± 13.75 Dorsiflexion of the ankle: -1.3 ± 7.76 / 5 ± 6.76 / 4.8 ± 5.95 All patients showed an overall improvement (over 95%) in the range of abduction of the hips and dorsiflexion of the ankles, a decrease in the flexional contracture of the hips, and more normal popliteal angles.	**Complications** Incidence Hypotonia at final follow up: 3% (7/208) Urinary retention: 10% (20/208) 2 patients suffered long term incontinence Postoperative spinal deformity: 6% (12/208) Radiographic findings only and no functional findings, relating to excessive laminectomy Transient sensory changes: 7% (15/208) 5 patients had changes to final follow up Long standing back pain: 3% (7/208) Aspiration pneumonia: 1% (2/208) Involuntary arm movement: 1% (2/208) The majority of SDR patients suffered temporary hypotonia following the surgery but this resolved over 2 to 3 months for most. The most common postoperative discomfort was back pain that was experienced by all patients Radiologicaly observed scoliosis occurred in 9% (5/58) of patients who had laminectomy, and 2% (2/150) who had laminoplasty.	Retrospective study No value for degree of certainty of statistical results are given for most outcomes. Long standing spasticity in older children resulted in more severe musculoskeletal contracture which was more difficult to correct with SDR. Authors state that other causes other than spasticity can influence child ambulation Post operative physiotherapy regimen (if any) is not described.

Validity and generalisability of the studies

- Improvement in physiological outcome may be poor predictors of functional improvement. Conversely even a small improvement of a physiological measurement may impact disproportionally on disability or caring requirements.
- *Some studies do not report on ability to walk, which is probably the most important efficacy outcome.*
- There is no evidence about the quality of life impact of the operation, either on patients or carers / family members.
- Significant variation in operative procedure, including the extent of nerve testing before rhizotomy.
- Selection criteria for study entry varied between studies. It could be expected that patients with more severe spasticity at baseline are not going to report as favourable outcomes as less impaired children.
- The studies included in the overview do not allow for the effect of age on outcome to be considered.

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Dr G Cole, Dr A Roberts, Mr M Vloeberghs, Mr M Carter, Mr N Buxton, Dr M Clarke

- All but one of the advisors considered SDR to be an established procedure.
- The potential benefits of SDR are reductions in pain, improved functional outcomes through greater motor ability and reduced spasticity, and fewer corrective orthopaedic procedures.
- Adverse events that have been reported with this procedure include Bladder and bowel disturbances, limb weakness, joint subluxations, progressive scoliosis or kyphosis, and sensory disturbance.
- Additionally the following complications are theoretically possible; paralysis, dividing the wrong nerve rootlets, death, hypotonicity, and weight gain
- Standard outcome measures are lacking but audit criteria might include paediatric quality of life, gross motor function measurement, reduction in spasticity, perioperative morbidity, scoliosis, and sphincter function problems.
- A number of advisors commented that there is some controversy as to where SDR sits among other management options for spasticity in cerebral palsy.
- It has been commented that a reduction in spasticity does not always result in improved motor function.
- SDR is an irreversible procedure with long term outcomes not well researched.

- The most useful comparator would be continuous infusion with a baclofen pump, although this is not yet established for long term use.
- Few surgeons are currently experienced in this procedure in the UK, and the potential diffusion of SDR is likely to be to 10 or fewer specialist centres.
- Standard microsurgery facilities are required, and intraoperative spinal cord electrophysiology monitoring may be required, although there is some disagreement between advisors on the merits of this.
- Patient selection for this procedure is not well understood, and patient work up through a multidisciplinary team is seen as essential.

Issues for consideration by IPAC

- Many studies were available, and the majority were only detailed in appendix A.
- Many studies are 10-20 years old, suggesting the procedure may be established in other parts of the world.

References

1 McLaughlin J, Bjornson K, Temkin N et al. (2002) Selective dorsal rhizotomy: meta-analysis of three randomized controlled trials. *Developmental Medicine & Child Neurology* 44: 17-25.

2 Wong AM, Pei YC, Lui TN et al. (2005) Comparison between botulinum toxin type A injection and selective posterior rhizotomy in improving gait performance in children with cerebral palsy. *Journal of Neurosurgery* 102: 385-389.

3 Buckon CE, Thomas SS, Piatt JH, Jr. et al. (2004) Selective dorsal rhizotomy versus orthopedic surgery: a multidimensional assessment of outcome efficacy. *Archives of Physical Medicine & Rehabilitation* 85: 457-465.

4 Abbott R, Johann-Murphy M, Shiminski-Maher T et al. (1993) Selective dorsal rhizotomy: outcome and complications in treating spastic cerebral palsy. *Neurosurgery* 33: 851-857.

5 Kim DS, Choi JU, Yang KH et al. (2001) Selective posterior rhizotomy in children with cerebral palsy: a 10-year experience. *Childs Nervous System* 17: 556-562.

6 Abbott R. (1992) Complications with selective posterior rhizotomy. *Pediatric neurosurgery* 18: 43-47.

Appendix A: Additional papers on selective dorsal rhizotomy for cerebral palsy not included in summary Table 2

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Chicoine MR, Park TS, Kaufman BA. Selective dorsal rhizotomy and rates of orthopedic surgery in children with spastic cerebral palsy. Journal of Neurosurgery 1997; 86(1):34-39	Case series n=178 FU=44 months	Larger studies are included in table 2	Children treated later with SDR had a higher rate of subsequent orthopaedic surgery than those treated younger.
Graubert C, Song KM, McLaughlin JF, Bjornson KF. Changes in gait at 1 year post-selective dorsal rhizotomy: results of a prospective randomized study. Journal of pediatric orthopedics 2000; 20(4):496-500.	RCT n=32 FU=1 year	Same cases as those Included in McLaughlin (1998) study	Changes in ankle dorsiflexion, foot progression angle and hip and knee extension were greater with SDR than physiotherapy
McLaughlin JF, Bjornson KF, Astley SJ, Graubert C, Hays RM, Roberts TS et al. Selective dorsal rhizotomy: efficacy and safety in an investigator-masked randomized clinical trial. Developmental Medicine & Child Neurology 1998 Apr; 40(4):220-232	RCT n=38 FU=2 years	Included in McLaughlin (2002) meta analysis	SDR provided a greater reduction in spasticity than physiotherapy (p=0.02)
Maenpaa H, Salokorpi T, Jaakkola R, Blomstedt G, Sainio K, Merikanto J et al. Follow-up of children with cerebral palsy after selective posterior rhizotomy with intensive physiotherapy or physiotherapy alone. Neuropediatrics 2003; 34(2):67-71	Case series n=44 FU=to 5 years	Larger studies are included in table 2	A loss of spasticity was reported in both SDR and physiotherapy groups
O'Brien DF, Park TS, Puglisi JA, Collins DR, Leuthardt EC, Leonard JR. Orthopedic surgery after selective dorsal rhizotomy for spastic diplegia in relation to ambulatory status and age.[see comment]. Journal of Neurosurgery 2005; 103(1 Suppl):5-9.	Case series n=158 FU=7.5 years	Larger studies are included in table 2	Orthopaedic surgery is more likely in patients destined to be non-ambulators.
Peter JC, Arens LJ. Selective posterior lumbosacral rhizotomy for the management of cerebral palsy spasticity. A 10-year experience. South African Medical Journal 1993; Suid-Afrikaanse Tydskrif Vir Geneeskunde. 83(10):745-747.	Case series n=100 FU=to 10 years	Larger studies are included in table 2	Satisfactory tone reduction in 95% of cases
Salame K, Ouaknine GE, Rochkind S, Constantini S, Razon N. Surgical treatment of spasticity by selective posterior rhizotomy: 30 years experience. Israel Medical Association Journal: Imaj 2003; 5(8):543-546.	Case series n=154 FU=11 years	A mixed cohort of patients with spasticity only 60 had cerebral palsy. Data not analysed separately	Painful spasms alleviate in 80% of cases, and reduction of spasticity achieved in all cases

Steinbok P, Reiner AM, Beauchamp R, Armstrong RW, Cochrane DD, Kestle J. A randomized clinical trial to compare selective posterior rhizotomy plus physiotherapy with physiotherapy alone in children with spastic diplegic cerebral palsy. Developmental Medicine and Child Neurology 1997; 39(3):178-184	RCT n=30 FU=9 months	Included in McLaughlin (2002) meta analysis	Gross motor function measure improved significantly more in the SDR group (11.3%) than the physiotherapy group (5.2%)
Steinbok P, Schrag C. Complications after selective posterior rhizotomy for spasticity in children with cerebral palsy. Pediatric neurosurgery 1998; 28(6):300-313.	Case series n=158 FU=29 months	Larger studies are included in table 2	Aspiration pneumonia was the most common Intraoperative complication occurring in 2 patients
Steinbok P, Hicdonmez T, Sawatzky B, Beauchamp R, Wickenheiser D. Spinal deformities after selective dorsal rhizotomy for spastic cerebral palsy. Journal of Neurosurgery 2005; 102(4 Suppl):363-373	Case series n=105 FU=4.3 years	Larger studies are included in table 2	55% of children had scoliosis at last follow up with 25% having worsening of 10 degrees or more
Wright FV, Sheil EMH, Drake JM, Wedge JH, Naumann S. Evaluation of selective dorsal rhizotomy for the reduction of spasticity in cerebral palsy: A randomised controlled trial. Developmental Medicine and Child Neurology 1998; 40(4):239-247	RCT n=24 FU=1 year	Included in McLaughlin (2002) meta analysis	Gross motor function measure improved significantly more in the SDR group (12.1%) than the physiotherapy group (4.4%)

Appendix B: Related published NICE guidance for selective dorsal rhizotomy for cerebral palsy

Guidance programme	Recommendation
Interventional procedures	None applicable
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

Appendix C: Literature search for selective dorsal rhizotomy for cerebral palsy

Procedure number:	Procedure Name:	
Databases	**Version searched (if applicable)**	**Date searched**
The Cochrane Library	Issue 1: 2006	6.02.06
CRD	-	6.02.06
Embase	1980 – week 5 2006	6.02.06
Medline	1966 – Jan week 4 2006	6.02.06
Premedline	-	6.02.06
CINAHL	1982 – week 4 2006	7. 02.06
British Library Inside Conferences (limited to current year only)	-	7. 02.06
National Research Register	Issue 1: 2006	7. 02.06
Controlled Trials Registry	-	7. 02.06

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

1. Cerebral palsy/
2. cerebral pals$.tw
3. spasticit$.tw
4. spastic diplegia.tw
5. spastic quadriplegia.tw
6. Quadriplegia/
7. increase$ muscle tone.tw
8. rhizotomy/
9. sensory nerve root interruption.tw
10. ((function$ or posterior or dorsal) adj rhizot$).tw
11. sensory root rhizot$.tw
12. sensory nerve root rhizot$.tw
13. sensory nerve root interruption.tw
14. or/1-7
15. or/8-13
16. 14 and 15

NICE guidance

Selective dorsal rhizotomy for spasticity in cerebral palsy

Interventional procedures guidance
Published: 15 December 2010
nice.org.uk/guidance/ipg373

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG195.

1 Guidance

This document replaces previous guidance on selective dorsal rhizotomy for spasticity in cerebral palsy (interventional procedure guidance 195).

1.1 Current evidence on selective dorsal rhizotomy for spasticity in cerebral palsy shows that there is a risk of serious but well-recognised complications. The evidence on efficacy is adequate. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance and audit.

1.2 During the consent process parents or carers should be informed that selective dorsal rhizotomy for spasticity in cerebral palsy is irreversible, and that patients may experience deterioration in walking ability or bladder function, and later complications including spinal deformity. They should understand that prolonged physiotherapy and aftercare will be required and that additional surgery may be necessary.

1.3 Patient selection and treatment should be carried out by a multidisciplinary team with specialist training and expertise in the care of spasticity in patients with cerebral palsy, and with access to the full range of treatment options. This team would normally include a physiotherapist, a paediatrician and surgeons, all with specific training and expertise.

1.4 NICE encourages further research into this procedure. Long-term outcomes are encouraged. Outcome measures should include: the incidence of neurological impairment and spinal deformity; the need for additional operations; and assessments of disability, social inclusion, and quality of life.

2 The procedure

2.1 Indications and current treatments

2.1.1 Cerebral palsy encompasses different brain disorders originating during fetal development, birth or early childhood. It is associated with abnormalities of movement, balance and posture, language and vision. Lower limb spasticity affects 80% of people with cerebral palsy. This can impair walking and sitting, and can cause discomfort, cramps and spasms.

2.1.2 Current treatments include oral muscle relaxant medication, orthotic devices, physiotherapy, and repeated intramuscular injections of botulinum toxin. Surgical procedures include tendonotomy, tendon lengthening, peripheral neurotomy, osteotomy, electrical stimulation of the muscles or dorsal spinal cord, and continuous intrathecal baclofen infusion.

2.2 Outline of the procedure

2.2.1 The aim of selective dorsal rhizotomy is to achieve a long-term reduction in sensory input to the sensory–motor reflex arcs responsible for increased muscle tone, by dividing some of the lumbar sensory nerve roots.

2.2.2 With the patient under general anaesthesia, a laminectomy of one or more vertebrae is performed to expose the dural sac, which is opened to display the spinal conus with or without the cauda equina. Intraoperative neurophysiological assessment is commonly used to identify the sensory nerve rootlets judged to be most responsible for the excess motor tone. Selected sensory rootlets are divided, preserving some sensory supply and the motor roots responsible for voluntary movements.

2.2.3 Intensive physiotherapy and aftercare is usually given for several months after the procedure. Patients who were previously able to walk may have to learn different walking skills.

> Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 A non-randomised comparative study of 142 patients treated by the procedure (n = 71) or intrathecal baclofen pump (ITBP) (n = 71) reported improvements in Modified Ashworth Scale scores (measures muscle tone on a scale from 0 to 5; lower score indicates lower muscle tone) of −2.52 and −1.23 points respectively at 1-year follow-up ($p < 0.0001$).

2.3.2 A non-randomised comparative study of 108 patients treated by the procedure plus physiotherapy or physiotherapy alone reported mean improvements in

Gross Motor Function Measure (GMFM) score (higher score indicates better gross motor functioning) from baseline of 87 to 92 and 89 to 91 respectively at 20-month follow-up ($p < 0.05$ for both groups from baseline).

2.3.3 The non-randomised comparative study of 142 patients treated by the procedure or ITBP reported that 94% and 96% of parents respectively were satisfied at 1-year follow-up (absolute figures not stated) ($p = 0.71$).

2.3.4 The Specialist Advisers listed key efficacy outcomes as reduction in lower limb spasticity, reduction in number of subsequent orthopaedic procedures, improved gross motor function, improved gait and walking, improved level of independence and quality of life.

2.4 Safety

2.4.1 Radiologically observed scoliosis was reported in 9% (5/58) of patients who had laminectomy and 1% (2/150) of patients who had laminoplasty in the case series of 208 patients at a mean follow-up of 4.2 years. The percentage of patients with scoliosis pre-operatively was not stated. Case series of 105, 98 and 30 patients reported scoliosis of 10° or more in 55% at 4.3 years, in 43% at 5.8 years, and scoliosis of less than 35° in 50% at 21.4 years respectively.

2.4.2 In a case series of 61 patients, 4 patients developed spondylolysis and grade-I spondylolisthesis between 3 and 5 years after the procedure.

2.4.3 Urinary retention due to decreased bladder tone and hyporeflexia was reported in 10% (20/208) of patients in the case series of 208 patients. This resolved spontaneously within 4 weeks in 18 patients but 2 patients had long term urinary incontinence because of atonic bladder.

2.4.4 The Specialist Advisers considered theoretical adverse events to include death, worsening motor function and/or paraplegia, wound infection, meningitis, cerebrospinal fluid leakage, dislocation of the hip(s), back pain, constipation, weakness, chronic pain, and late arachnoiditis and/or syringomyelia.

2.5 Other comments

2.5.1 The Committee noted that most of the evidence for this procedure relates to children aged 4–10 years. The Committee also noted that this procedure and patient selection for it are still evolving. Several commentators recommend limited laminectomy to reduce the risk of late spinal deformity, and others question the need for intraoperative neurophysiology.

3 Further information

3.1 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 195.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

2 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation