

Health Evidence Review Commission's Value-based Benefits Subcommittee

August 11, 2022 8:00 AM - 1:00 PM

Online Meeting

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AGENDA VALUE-BASED BENEFITS SUBCOMMITTEE 8/11/2022 8:00am - 1:00pm

Virtual Meeting

All times are approximate

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

I.	Call to Order, Roll Call, Approval of Minutes – Kevin Olson	8:00 AM
Ш.	 Staff report – Ariel Smits, Jason Gingerich A. Errata B. Member updates C. Below the line review 	8:05 AM
III.	New Discussion items	8:10 AM
	A. Tympanostomy guideline (Update the ear tubes guideline)	
IV.	 Straightforward/Consent agenda – Ariel Smits A. Consent table B. Straightforward guideline note changes C. New codes of public health importance A. COVID-19 codes B. Monkeypox codes D. Updating preventive services guideline references E. Burst fractures of the spine (Serious injury to the backbone) F. Z code review G. Items not discussed in past 5 years with no changes recommended A. Brachial thermoplasty 	8:30 AM
V.	2023 ICD-10-CM Code ReviewA. Straightforward codesB. Codes requiring discussion	8:45 AM
VI.	2022 Biennial Review A. TMJ prioritization (<i>Disorders of the jaw joints associated with chron</i>	9:30 AM nic face pain)
VII.	 Reports for Review A. RHEA report (Legislature requested report published every 2 years reproductive health coverage changes) 	10:00 AM about
VIII.	Behavioral Health Advisory Panel report	10:15 AM

- A. Straightforward coding issues
- **B.** Drug induced movement disorder code cleanup
- **C.** Conduct disorder
- **D.** Insomnia

IX. **New Discussion Items**

- **A.** Autoimmune encephalitis (*Clarify coding related to a type of brain inflammation* where the body's immune system attacks healthy cells and tissues in the brain or spinal cord)
- B. Inflammatory skin disease guideline modifications (Guideline revision for conditions affecting skin)
- **C.** Microsatellite instability testing analysis for colon cancer (*Test done to help* decide on treatment for patients with colon cancer)
- **D.** Scoliosis guideline
- E. Canaloplasty for glaucoma

Х. **Coverage guidances**

A. High frequency chest wall oscillation (Coverage guidance to review effectiveness of high frequency chest wall oscillation devices for people with lung complications associated with neuromuscular conditions)

XI.	Other public comment	12:55 PM

XII. Adjournment – Kevin Olson

11:45 AM

1:00 PM

11:00 AM

Value-based Benefits Subcommittee Recommendations Summary For Presentation to: Health Evidence Review Commission on May 19, 2022

For specific coding recommendations and guideline wording, please see the text of the 5/19/2022 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 10/1/2022 Prioritized List unless otherwise noted)

- Add the procedure codes for visual field testing to the list of covered diagnostic tests
- Add the code for temporary urethral stents to a non-funded line
- Add the code for fecal lactoferrin quantitative testing to the list of covered diagnostic tests
- Add the codes for placements of gastric neurostimulators to a funded line with a new guideline
- Add the procedure codes for coronary CT angiography to the list of covered diagnostic tests
- Delete the procedure code for rhinophyma shaving from a currently-funded line and add to an unfunded line
- Add the procedure code for shoulder arthroplasty with subacromial spacers to an unfunded line
- Add the diagnosis codes for benign carcinoid tumors to several funded lines
- Make various straightforward guideline and coding changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

• Coverage for spinal cord stimulation for diabetic peripheral neuropathy was considered but not added

RECOMMENDED GUIDELINE CHANGES (changes to the 10/1/2022 Prioritized List unless otherwise noted)

- Edit the adenoidectomy guideline to allow adenoidectomy with the placement of the first set of tympanostomy tubes in certain situations
- Edit the guideline regarding bone anchored hearing aids (BAHAs) so that bilateral BAHAs are included on the relevant lines. Specify that maintenance and replacement of BAHAs in adulthood is also included
- Delete the guideline restricting the use of MRIs in multiple sclerosis
- Add the guideline for erythropoietin to a line with non-end stage chronic renal disease and add a requirement that the patient have sufficient iron stores in order to receive this treatment
- Edit the new orthodontia guideline to remove separate mention of qualifying criteria which are already encompassed in another tool, and add a requirement for a dental visit to ensure good oral health before beginning orthodontia treatment (*effective January 1, 2023*)

VALUE-BASED BENEFITS SUBCOMMITTEE Online meeting May 19, 2022 8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-chair; Cris Pinzon, MPH, BSN, BS, RN; Kathryn Schabel, MD (arrived 8:45); Brian Duty, MD (arrived 8:30); Mike Collins; Adriane Irwin, PharmD; David Saenger, MD.

Members Absent:

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

Also Attending: Dawn Mautner, MD, Kaz Rafia DMD, and Kristty Zamora-Polanco (Oregon Health Authority); Michael Yu (OHA Ombuds); Bethany Godlewski, Shauna Durbin, and Valerie King, MD, MPH (Center for Evidence Based Policy); Alison Christy, MD, PhD; Paria Zarrinnegar, MD; Michael Daines, MD; Julie Falardeau, MD; Peggy Kelley, MD; Leia Hughey, PhD; Monica Frederick, Robert Cuyler, PhD, and Joe Perekupka (Freespira); Sarah Lemley and Kym McCornack, Northwest PANDAS/PANS Network; Cristin Cronin-Vejar; Ivan Vejar; Deborah Miller; Dan Twibell (PACE Foundation); Laura McKeane; Kimberly Goddard (Rep Prusak's office); Cynthis Witcraft, Christian Moller-Andersen; Bob Cuyler; bhoveke_gobhi

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 March 10, 2022 VbBS meeting were reviewed and approved.

Gingerich introduced Amy Cantor as a new Medical Director for HERC. He also announced Daphne Peck's expanded role as Program and Outreach Coordinator for HERC, to sustain the efforts related to plain language summaries as well as other initiatives to improve public engagement and gather community input.

Gingerich mentioned that a new law (HB 2992) will allow a per diem reimbursement to members in certain situations, and more information is forthcoming. Smits announced that the congenital foot diagnosis review has been delayed until August to allow further expert input. She also reviewed the errata document and presented the summary of the HERC staff's below the funding line diagnosis review. Members of the subcommittee as well as the public were encouraged to suggest additional topics or research related to these decisions.

> Topic: Straightforward/Consent Agenda

Discussion: There was no discussion about the consent agenda items other than the "items discussed with leadership with no changes recommended" [see below].

The following members gave public testimony about topics which staff reviewed and discussed with leadership, but recommended no changes:

- 1) Freespira: Monica Frederick, an employee of Freespira, testified that Freespira is a digital therapeutic device with FDA approval. Freespira is for the treatment of panic disorder and post-traumatic stress disorder (PTSD), not opioid use. It is not a smartphone app. She said that HCPCS A9291 was published in April 2022: "Prescription digital behavioral therapy, FDA cleared, per course of treatment", and this code would be appropriate to use with Freespira. Bob Cuyler, PhD, Clinical Psychologist and Chief Clinical Officer of Freespira testified about how the device addresses respiratory dysfunction related to panic and PTSD. The device is used at home and monitored by a health coach at the company. The typical treatment protocol is twice daily use for 28 days. He noted that there is an extensive public literature on this intervention and multiple peer-reviewed studies find clinically significant symptom reduction in >70% of patients. Other studies have found a savings of 35% in medical spending in the one year period after treatment, mainly due to reduced medical visits. He noted the device has a high response rate in Medicaid populations. Joe Perekupka, CEO of Freespira, testified about how the device can help symptoms, address social determinants of health, and help patients gain access to care.
 - a. HERC staff noted that devices like Freespira are likely to be included in an upcoming MED report on digital therapeutics. If it is not included in the published MED report, staff will research this device for a future HERC meeting.
- 2) Equine therapy: Leia Hughey, a licensed clinical psychologist who owns an equine facility where she treats families/children with mental health issues, testified about one CCO discontinuing coverage for equine therapy, which she said is evidence-based practice. Children with better insurance can access this treatment, so it is discriminatory for OHP patients.
 - a. Subcommittee members encouraged Dr. Hughey to contact OHA's Health Systems Division regarding contracting. This is not an evidence question as psychotherapy is covered whether or not it is conducted in an equine setting.

Recommended Actions:

- 1) Remove 11960 (Insertion of tissue expander(s) for other than breast, including subsequent expansion) and 11971 (Removal of tissue expander without insertion of implant) from all current Prioritized List lines.
 - a. Advise HSD to add 11960 and 11971 to the Ancillary Procedures File
- 2) Advise HSD to add B4100 (Food thickener, administered orally, per ounce) to the Ancillary Procedure File
- 3) Remove 58559-58563 (Hysteroscopy with various surgical procedures) from line 1 PREGNANCY
- 4) Add 61538 and 61539 (Craniotomy with elevation of bone flap), and 61781 (Stereotactic computer-assisted (navigational) procedure; cranial, intradural) to line 174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS
- 5) Change the name of line 572 to OTHER MINOR COMPLICATIONS OF A PROCEDURE
- 6) Delete I86.1 (Scrotal varices) from line 548 SUBLINGUAL, SCROTAL, AND PELVIC VARICES
 a. Rename line 548 SUBLINGUAL, SCROTAL, AND PELVIC VARICES
- 7) Add 90759 (Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2), 10 mcg dosage, 3 dose schedule) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

- a. Advise HSD to remove 90759 from the Excluded File
- 8) Add 47562 and 47563 (Laparoscopy, surgical; cholecystectomy) to line 641 GALLSTONES WITHOUT CHOLECYSTITIS
- 9) Advise HSD to place the new COVID-related ICD-10-CM codes as shown below:

ICD-10	Code Description	Recommended
Code		Placement
Z28.310	Unvaccinated for COVID-19	Informational File
Z28.311	Partially vaccinated for COVID-19	Informational File
Z28.39	Other under-immunization status [non-COVID vaccines]	Informational File

10) Add the following HCPCS codes to the line/file as shown below:

HCPCS	Code Description	Recommended Placement
Code		
D1708	Pfizer-BioNTech Covid-19 vaccine administration – third dose	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS or line 399 INFLUENZA, COVID-19 AND OTHER NOVEL
D1700	Pfizer-BioNTech Covid-19 vaccine administration - booster	2
01709	dose	5
D1710	Moderna Covid-19 vaccine administration – third dose	3
D1711	Moderna Covid-19 vaccine administration – booster dose	3
D1712	Janssen Covid-19 vaccine administration - booster dose	3
D1713	Pfizer-BioNTech Covid-19 vaccine administration tris-	3
	sucrose pediatric – first dose	
D1714	Pfizer-BioNTech Covid-19 vaccine administration tris-	3
	sucrose pediatric – second dose	
M0220	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not recommended due to a history of severe adverse reaction to a covid-19 vaccine(s) and/or covid-19 vaccine component(s), includes injection and post administration monitoring	3
M0221	Injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known sars-cov-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available covid-19 vaccine is not	3

HCPCS	Code Description	Recommended Placement
Code		
	recommended due to a history of severe adverse reaction	
	to a covid-19 vaccine(s) and/or covid-19 vaccine	
	component(s), includes injection and post administration	
	monitoring in the home or residence; this includes a	
	beneficiary's home that has been made provider-based to	
	the hospital during the covid-19 public health emergency	
Q0220	Injection, tixagevimab and cilgavimab, for the pre-exposure	ANCILLARY PROCEDURES
	prophylaxis only, for certain adults and pediatric individuals	FILE
	(12 years of age and older weighing at least 40kg) with no	
	known sars-cov-2 exposure, who either have moderate to	
	severely compromised immune systems or for whom	
	vaccination with any available covid-19 vaccine is not	
	recommended due to a history of severe adverse reaction	
	to a covid-19 vaccine(s) and/or covid-19 vaccine	
	component(s), 600 mg.	
Q0221	Injection, tixagevimab and cilgavimab, for the pre-exposure	ANCILLARY PROCEDURES
	prophylaxis only, for certain adults and pediatric individuals	FILE
	(12 years of age and older weighing at least 40kg) with no	
	known sars-cov-2 exposure, who either have moderate to	
	severely compromised immune systems or for whom	
	vaccination with any available covid-19 vaccine is not	
	recommended due to a history of severe adverse reaction	
	to a covid-19 vaccine(s) and/or covid-19 vaccine	
	component(s), 300 mg.	
Q0222	Injection, bebtelovimab, 175 mg	ANCILLARY PROCEDURES
		FILE
M0222	Intravenous injection, bebtelovimab, includes injection and	399
	post administration monitoring	
M0223	Intravenous injection, bebtelovimab, includes injection and	399
	post administration monitoring in the home or residence;	
	this includes a beneficiary's home that has been made	
	provider-based to the hospital during the covid-19 public	
	health emergency	
Q0239	Injection, bamlanivimab, 700 mg	ANCILLARY PROCEDURES
		FILE
M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion	399
	and post administration monitoring	

11) Add the following CPT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

CPT Code	Code Description	Recommended Placement
91310	Severe acute respiratory syndrome coronavirus 2 (SARS-	3 PREVENTION SERVICES
	CoV-2) (coronavirus disease [COVID-19]) vaccine,	WITH EVIDENCE OF
	monovalent, preservative free, 5 mcg/0.5 mL dosage,	EFFECTIVENESS
	adjuvant AS03 emulsion, for intramuscular use	

CPT Code	Code Description	Recommended Placement
		Pending FDA approval/EUA
0104A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, monovalent, preservative free, 5 mcg/0.5 mL dosage, adjuvant AS03 emulsion, booster dose	3 Pending FDA approval/EUA
0074A	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, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; booster dose	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 6-0. (Absent: Duty, Schabel)

> Topic: Visual field testing

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

Public testimony

<u>Julie Falardeau, ophthalmologist, OHSU</u>: Dr. Falardeau testified that visual field testing is a diagnostic tool for a variety of conditions, such as tumor progression or localizing residual field deficits. The ability to objectively quantify visual deficits is very important and she relies very heavily on this tool to answer diagnostic questions.

Recommended Actions:

- 1) Remove visual field testing (CPT 92081-92083, 92133) from all current lines on the Prioritized List
 - a. Advise HSD to add CPT 92081-92083, 92133 to the Diagnostic Procedure File

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

(Absent: Duty, Schabel)

> Topic: Adenoidectomy update

Discussion: Smits presented the summary document. Hodges requested clarification of the wording around when symptoms were directly related to the adenoids. Dr. Kelley suggested "ear infections associated with rhinorrhea." Further subcommittee discussion also added "and/or upper respiratory infection."

Dr. Kelley also requested a review of the current guideline for tonsillectomy, specifically on the number of required strep infections needed for qualifying for surgery. HERC staff will review her materials and bring this topic in August for further discussion.

Recommended Actions:

1) Modify GN51 as shown in Appendix A

MOTION: To recommend the guideline note changes as amended. CARRIES 6-0. (*Absent: Duty, Schabel*)

> Topic: Bilateral bone anchored hearing aids

Discussion: Smits reviewed the summary document. Dr. Kelley recommended removing the proposed guideline criteria that a "patient is clinically unsuitable for other medical or surgical treatments" as a patient might be suitable for a surgery but is getting adequate hearing with a BAHA. Dr. Kelley also noted that some children older than age 5 use the headband-mounted BAHA devices and that if these work well, then the child should not be forced to undergo surgical implantation. The guideline was modified to allow headband use after age 5.

The subcommittee discussed coverage after age 20. The intent is that persons who had a BAHA inserted or a BAHA headband used prior to age 21 to continue to have these devices maintained after that age. Two sentences which reflect that intent were added to the guideline.

Recommended Actions:

1) Modify GN103 as shown in Appendix A

MOTION: To recommend the guideline note changes as amended. CARRIES 8-0.

> Topic: Temporary urethral stents 2022

Discussion: There was minimal discussion for this topic.

Recommended Actions:

- 1) Add HCPCS C9769 (Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts) to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
- 2) Modify GN173 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 8-0.

> Topic: Fecal lactoferrin

Discussion: There was minimal discussion for this topic.

Recommended Actions:

 Remove 83631 Lactoferrin, fecal; quantitative from Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

- a. Advise HSD to place CPT 83631 on the Diagnostic Procedures File
- 2) Delete the GN173 entry for CPT 83631

MOTION: To recommend the code and guideline note changes as presented. CARRIES 8-0.

> Topic: Gastric neurostimulators

Discussion: There was minimal discussion for this topic.

Recommended Actions:

- 1) Add the following codes to lines 8 TYPE 1 DIABETES MELLITUS, 27 TYPE 2 DIABETES MELLITUS and 529 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
 - a. CPT 43647 Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
 - b. CPT 43648 Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
 - c. CPT 43881 Implantation or replacement of gastric neurostimulator electrodes, antrum, open
 - d. CPT 43882 Revision or removal of gastric neurostimulator electrodes, antrum, open
 - e. HCPCS E0765 FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea
- 2) Advise HSD to remove the above codes from the Excluded File
- 3) Adopt a new guideline for lines 8, 27, and 529 as shown in Appendix B

MOTION: To recommend the code and guideline note changes as presented. CARRIES 8-0.

> Topic: Routine monitoring MRIs in multiple sclerosis

Discussion: There was minimal discussion for this topic. Hodges requested that the minutes reflect the intent is that MRI of both the brain and spine are covered for multiple sclerosis.

Recommended Actions:

1) Delete Diagnostic Guideline D10

MOTION: To recommend the guideline note changes as presented. CARRIES 8-0.

> Topic: Coronary CT angiography

Discussion: There was minimal discussion for this topic.

Recommended Actions:

- Remove CPT 75572 and 75574 (CT heart) from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
 - a. Advise HSD to add CPT 75572 and 75574 to the Diagnostic Procedures File
 - b. Remove the entries for CPT 75572 and 75574 from GN173
- 2) Advise HSD to add CPT 0501T-0504T (Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease) to the Diagnostic Procedures File

MOTION: To recommend the code and guideline note changes as presented. CARRIES 8-0.

> Topic: Rhinophyma shaving

Discussion: There was minimal discussion for this topic.

Recommended Actions:

- 1) Remove CPT 30120 (Excision or surgical planing of skin of nose for rhinophyma) from the following lines
 - a. 466 CHRONIC SINUSITIS
 - b. 506 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES
 - c. 525 BENIGN NEOPLASM OF NASAL CAVITIES, MIDDLE EAR AND ACCESSORY SINUSES
- 2) Add CPT 30120 to line 522 ROSACEA; MILD/MODERATE ACNE

MOTION: To recommend the code changes as presented. CARRIES 8-0.

> Topic: Spinal cord stimulators for diabetic peripheral neuropathy

Discussion: Smits presented the issue summary. There was concern regarding the small sample sizes in the studies presented. Olson noted that the best evidence regarding rates of adverse events was 6%, there was a signal for effectiveness of this therapy, but the lack of large sample sizes makes the effectiveness of the therapy in a larger population unknown. He noted that it was an invasive therapy. Pinzon noted that diabetics are at high risk of infection with any surgery. Hodges noted the high cost of the procedure, as well as the cost of treating complications. The decision was to make no change in the non-pairing of spinal cord stimulators with diabetic peripheral neuropathy.

> Topic: Shoulder arthroplasty with subacromial spacers

Discussion: There was minimal discussion for this topic

Recommended Actions:

1) Place HCPCS C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression,

acromioplasty, and biceps tenodesis when performed) on line 662/GN173 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 8-0.

> Topic: Erythropoietin in chronic renal disease

Discussion: Smits reviewed the issue summary. Olson requested that wording be added to the guideline to require that there be no iron deficiency prior to erythropoietin therapy.

Recommended Actions:

1) Modify GN7 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 8-0.

> Topic: Orthodontia guideline update

Discussion: There was minimal discussion for this topic.

Recommended Actions:

1) Modify Guideline Note 196 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 8-0.

> Topic: Benign gastrointestinal carcinoid tumors

Discussion: There was minimal discussion for this topic.

Recommended Actions:

- Add the ICD-10-CM D3A.0 family (benign GI carcinoid tumors) to line 157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS and remove from line 638 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
- Add ICD-10CM D3A.093 (Benign carcinoid tumor of the kidney) to line 214 CANCER OF KIDNEY AND OTHER URINARY ORGANS and remove from line 638 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM

MOTION: To recommend the code changes as presented. CARRIES 8-0.

> Topic: Coverage Guidance— PANDAS/PANS

Discussion: The Center for Evidence Based Policy (CEBP) and HERC staff presented the evidence review on PANDAS/PANS from EbGS. Smits reviewed the recommended changes to the Prioritized List that would correspond with the EbGS recommendations.

Staff noted that the Oregon pediatric infectious disease specialists requested that they not be included in this guideline. A friendly amendment was made to remove mention of this group from the proposed Prioritized List guideline.

Public testimony

- Sarah Lemley, Executive Director of the NW PANDAS/PANS Network and mother of a child with PANDAS: Ms. Lemley testified that there is a lack of expertise in these conditions in Oregon. She said the Commission needs to rely on the expertise of national experts. She listed Oregon and national experts who agreed with current recommendations, including psychiatrists and neurologists. Per Ms. Lemley, IVIG is approved for PANDAS by several commercial insurers. Bethany Godlewski, CEBP staff, clarified that that research reflected in the coverage guidance failed to find payer policies supporting coverage by commercial insurers.
- 2) <u>Cristina Cronin-Vejar, mother of a patient with PANDAS/PANS</u>: Ms. Cronin-Vejar testified of her daughter's symptoms, which were relieved partially by antibiotics, NSAIDs, tonsillectomy, SSRIs, and other treatments. However, she noted that her daughter has never returned to her baseline self after these therapies. Her daughter has difficultly with school. Not having access to IVIG is very distressing to her family.
- 3) <u>Deborah Miller, the mother of patient with PANDAS</u>: Ms. Miller urged adoption of proposed coverage, stating that her child needs IVIG therapy.
- 4) <u>Dan Twibell, PACE foundation and father of a PANDAS child</u>: Mr. Twibell testified that PACE is a non-profit organization dedicated to increasing awareness and treatment for PANDAS/PANS. PACE recommends that the EbGS recommendation be adopted by VbBS and HERC.

The subcommittee discussed their concerned with the lack of efficacy for these invasive and possibly harmful treatments. The experts were asked what percentage of PANDAS/PANS patients require IVIG. Daines replied that 10-15% of patients receive IVIG in his specialty clinic and that lessinvasive treatments are always tried first. Olson asked how the effectiveness of IVIG or other therapies are determined. Daines replied that his center uses neuropsychiatric testing, but he has many specialists in his clinic. OCD-related scores can be used. Olson asked what the timeframe is for when clinicians see a response to IVIG treatment. Daines replied that response is generally seen in the first 3 months of IVIG. He only continues IVIG past 3 months if there is a significant but partial response. Pinzon asked how long children require IVIG treatment. Daines replied that most children only require a few months of treatment, but about 5% require long-term IVIG treatment. Some children need repeat IVIG for recurrent symptoms after a subsequent infection. Multidisciplinary clinics that are readily available are the ideal setting for treatment; in the absence of such a center, a skilled provider can be sufficient for IVIG decisions. Hodges asked if this therapy is available in Oregon, as OHP rules require treatment in-state when available. Drs. Zarrinnegar and Christy both indicated that their health systems provide IVIG treatment. It was also noted that IVIG can be infused in the home.

Pinzon reflected that the testimony indicated that Oregon does not have the expertise for treatment of PANDAS/PANS. Zarrinnegar noted that she learned about PANDAS treatment through individual training/education and through reaching out to specialty centers in other states.

Olson reflected on the lack of evidence but the need to balance the vulnerability of the population. Pinzon also noted that the severity of the symptoms affects the decision around coverage. There was general concern with including coverage for plasmapheresis. The subcommittee recommended removing plasmapheresis from the proposed Prioritized List guideline as well as recommend that HERC strike coverage of plasmapheresis from the blue box of the coverage guidance report and amend the plasmapheresis evidence table.

Saenger expressed concern for how the end point of treatment is determined. He also expressed concern for the very small trial as the only evidence for this decision. He noted concern that assessment of effectiveness could be biased in these trials. Olson responded that the evidence base is very small, but the population is vulnerable and there is national expert consensus regarding treatment. Godlewski noted that Daines' IVIG trial data should be available in the next year or two. The subcommittee had concerns with waiting to provide coverage for sick, vulnerable children in the interim until the data from that study is available. Olson noted that if coverage of IVIG is adopted, it can be revisited once trial data from the study is available.

Saenger noted concern with publication bias, as negative trials tend to not get published. Hodges expressed concern about paying for an experimental treatment.

The final decision was to recommend the proposed guideline with the striking of plasmapheresis as a coverage therapy.

Recommended Actions:

- 1) Add ICD-10-CM D89.9 (Disorder involving the immune mechanism, unspecified) to line 313
- 2) Add a new guideline to line 313 DISORDERS INVOLVING THE IMMUNE SYSTEM as shown in Appendix B

A motion was made to approve the amended changes to the Prioritized List based on the draft coverage guidance scheduled for review by HERC at its May 19, 2022 meeting. **Motion approved 6-2** (*Opposed: Hodges, Saenger*).

> Public Comment:

No additional public comment was received.

Issues for next meeting: Review of the tonsillectomy guideline

> Next meeting:

August 11, 2022, virtual meeting.

> Adjournment:

The meeting adjourned at 12:30 PM.

Revised Guideline Notes

DIAGNOSTIC GUIDELINE D10, MRI IN MULTIPLE SCLEROSIS

MRI is a diagnostic test for multiple sclerosis and should not be used for routine monitoring of disease.

MRI may be considered in the following circumstances:

- A) Suspected drug failure in the setting of clinical relapse in patients with objective changes in neurological status or documented new clinical symptoms such as urinary urgency or cognitive changes
- B) Evaluation of a clear objective progression in clinical symptoms in patients with previously relapsing disease to rule out ongoing inflammatory disease when conversion to secondary progressive MS is suspected
- c) Patients who require enhanced pharmacovigilance, including
 - 1) Yearly monitoring for patients treated with natalizumab who are JCV seropositive
 - One MRI for patients who switch from natalizumab to other therapeutics (including fingolimod, alemtuzumab and dimethyl fumarate) one year after the switch from natalizumab

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,<u>339,</u>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 <u>disease</u> failure, with or without dialysis, <u>in the absence of iron deficiency</u>.
 - 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.

GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

Lines 311, 424, 446, 476

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) are not indicated for children with chronic otitis media with effusion (OME) (without another appropriate diagnosis).

Patients with specific higher risk conditions (including craniofacial anomalies, Down's syndrome, and cleft palate, or documented speech and language delay) along with hearing loss and chronic otitis media with effusion are intended to be included on Line 311 or Line 446 for children up to and including age 7. Otherwise hearing loss associated with chronic otitis media with effusion (without those specific higher risk conditions) is only included on Line 476.

For coverage to be considered on Line 311, Line 446 or Line 476, there should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented hearing loss is greater than or equal to 25dB in the better hearing ear, tympanostomy surgery may be indicated, given short- but not long- term improvement in hearing. Formal audiometry is indicated for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing upon diagnosis. Children with chronic OME who are not at risk for language delay (such as those with hearing loss <25dB in the better hearing ear) or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy is not indicated at the time of first pressure equalization tube insertion. It may be indicated in children aged 4 and older who are having their second set of tubes. included on these lines at the time of tympanostomy tube insertion for children under age 4 with symptoms directly related to the adenoids (for example, ear infection associated with rhinorrhea and/or upper respiratory infection) OR in children aged 4 years or older.

Removal of retained tympanostomy tubes requiring anesthesia (CPT code 69424) or as an office visit, is included on Line 424 as a complication, pairing with ICD-10-CM H74.8.

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

GUIDELINE NOTE 103, BONE ANCHORED HEARING AIDS

Lines 311,446

Bone anchored hearing aids (BAHA, CPT 69714, 69715; HCPCS L8690-L8694) are included on these lines when the following criteria are met:

- A) The patient is aged 5-20 years for <u>initial</u> implanted bone anchored hearing aids <u>or headband</u> mounted BAHA devices; headband mounted BAHA devices may be used for children under age 5; <u>AND</u>
- B) Treatment is for unilateral severe to profound hearing loss when the contralateral ear has normal hearing with or without a hearing aid

- c) Traditional air amplification hearing aids and contralateral routing of signal (CROS) hearing aid systems are not indicated or have been tried and are found to be not effective
- D) Implantation is unilateral.
- E) The patient has one of the following:
 - 1) <u>Permanent bilateral conductive or mixed hearing loss (for example, congenital malformation of the middle/external ear, microtia, or ossicular disease) unable to be aided by conventional air conducting devices; OR</u>
 - 2) <u>Unilateral conductive hearing loss with ear canal stenosis or ear canal atresia that is unlikely</u> to benefit from surgery; OR
 - 3) <u>Profound unilateral sensorineural hearing loss when the contralateral ear has normal hearing with or without a hearing aid; OR</u>
 - 4) <u>Temporary bilateral conductive hearing loss in patients with cleft palate and middle ear</u> <u>effusions until their palate is repaired and tympanostomy tubes can be placed (for BAHA</u> <u>headband only).</u>

Continuation and maintenance of these devices is included on these lines. This includes patients over the age of 20 who received these devices in childhood or adolescence.

Use of BAHA for treatment of tinnitus is not covered.

[see further wording changes made at the 5/19/22 HERC meeting]

GUIDELINE NOTE 169, ORTHODONTICS 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; AND
- 8) Free and clear of active decay and periodontal disease, verified by a dental exam in past 6 months

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
<u>C9781</u>	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon)	Insufficient evidence of effectiveness	<u>May 2022</u>
53855 <u>C9769</u>	Temporary prostatic stents	Insufficient evidence of effectiveness	October, 2015
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology	Insufficient evidence of effectiveness	December, 2009
75574	Computed tomography, heart	Insufficient evidence of benefit, unclear harms of radiation exposure	August, 2013 Coverage guidance
83631	Lactoferrin, fecal; quantitative	Insufficient evidence of effectiveness	January 2006

Appendix **B**

New Guideline Notes

GUIDELINE NOTE XXX GASTRIC ELECTRICAL STIMULATION

Line 8, 27,529

Gastric electrical stimulation (CPT 43657, 43648, 43881, 43882) is included on these lines only for pairing with diabetic gastroparesis (ICD-10-CM E10.43, E11.43) or idiopathic gastroparesis (ICD-10-CM K31.84) and only when ALL of the following criteria are met:

- 1) The patient has intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology; AND
- The patient is refractory or intolerant of prokinetic medications and antiemetic medications; AND
- 3) The patient is not on opioid medications; AND
- 4) The patient does not have abdominal pain as the predominant symptom.

GUIDELINE NOTE XXX PANDAS AND PANS

Line 313

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

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

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

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

Appendix B

Long term antibiotic therapy is not included on this line for treatment of PANDAS/PANS. <u>Therapeutic</u> plasma exchange (CPT 36514) does not pair with PANDAS or PANS (ICD-10-CM D89.89 or D89.9) on this line.

Section 2.0 Staff Report

Color Key	Topics under development
	Upcoming discussion topics
	Reviewed but no changes planned
	Already approved changes

			Planned	Summary of change (or recommended change, decision not
Request source	Topic Description	Meeting Date	Imp. Date	to change)
Staff review	Deformities of upper body and all limbs	tbd		Review with orthopedics expert
	Congenital anomalies of knee (Knee			
Staff review	problems since birth)	tbd		Review with orthopedics expert
	Genitourinary with minimal or no			
	treatment required (genital and urinary			
Staff review	organs)	tbd		Review with urology expert
				Only microotia (ICD10 17.2) might be considered to move to
				funded line and most treatment recommendations are only
				to repair for cosmetic reasons. Severe microotia (grade 3
	Congenital ear anomalies without			and 4) would have hearing impairment and the hearing
Dr. Hoffman	hearing impairment	tbd		issues are addressed on line 311
	Conduct disorder/impulse disorders (A			
Dr. Hoffman	type of behavior disorder)	8/11/2022		BHAP recommended adding to funded region
Staff review	Behavioral health coding	8/11/2022		Based on review of social emotional learning codes.
				Consider adding insomnia above the funding line for
	Sleep disorders other than sleep apnea			cognitive behavioral therapy for insomnia (CBTi). Consider
Staff review	(including insomnia)	8/11/2022		role of medication.
	Temporomandibular Joint Syndrome			
	(TMJ) (Pain and dysfunction in the jaw			
	joint and muscles controlling jaw			
Staff (Val King)	movement)	8/11/2022		Review evidence; no change recommended at this time
HSD nurse				Proposal to add to covered nerve lesion line with ulnar
reviewer	Median and radial nerve lesions	8/11/2022		nerve lesions

			Planned	Summary of change (or recommended change, decision not
Request source	Topic Description	Meeting Date	Imp. Date	to change)
				Under review with ortho and podiatry, likely October 2022
Staff review	Deformities of foot	October, 2022		review
	Somatic symptoms line (Extreme	October or		
	feelings and anxiety about physical	November		Review with BHAP for any need for reprioritization of one or
Staff review	symptoms)	(BHAP)		more diagnoses or of entire line
		October or		
Staff review	Broader Orthopedic review	November		Look through denied claims for candidates for review
	Benign neoplasm of the digestive			
	system (Surgery for an abnormal			
	growth found in the stomach or			
Staff review	intestines)	5/19/2022		Added benign carcinoid tumors to funded region
	Bilateral bone anchored hearing aids			
	(BAHA) (A specific type of hearing aid			
HSD	for children)	5/19/2022	10/1/2022	Proposal to expand coverage from unilateral to bilateral
	Scrotal varices (An enlargement of the			
	veins within the skin that holds the			Already on line 327 as well as line 548 with no guideline.
Staff review	testicles (scrotum))	5/19/2022	10/1/2022	Propose to remove from line 548 and change name of line
Staff review	Other complications of a procedure	5/19/2022	10/1/2022	Propose to rename line "Minor" as diagnoses are minor
	Anemias due to kidney diseases			
	(erythropoietin) (A drug to treat low			Recommend clarifying coverage of erythropoietin for non-
Staff review	blood count caused by kidney disease)	5/19/2022		end stage kidney disease
Staff review	Esophageal ulcer	3/10/2022	10/1/2022	Added to funded region
				Had already been addressed prior to the concern raised, but
Dr. Hoffman	Foreign body in digestive tract	3/10/2022	1/1/2022	implementation was pending
Staff review	Generalized muscle weakness	3/10/2022	10/1/2022	Added to funded region
				Working on implementation issues; addition to funded
HSD Staff	Handicapping malocclusion	11/18/2021	1/1/2023	region planned for 1/1/2023
ССО	Dorsal rhizotomy	3/10/2022	10/1/2022	Added to funded region
Staff review	Corneal abcess	3/10/2022	10/1/2022	Added to funded region

			Planned	Summary of change (or recommended change, decision not
Request source	Topic Description	Meeting Date	Imp. Date	to change)
				Change name of line to reflect mild/moderate; severe forms
Staff review	Lichen planus	3/12/2020	10/1/2022	on funded line as defined by Guideline Note 21
Staff review	Mastoiditis	3/12/2020	10/1/2022	Added to funded region
Dr. Hoffman	Nightmare disorder	11/18/2021	1/1/2022	Added to funded region
				Added to funded region for feeding problems in newborns
Dr. Hoffman	Oral candidiasis (thrush)	8/12/2021	10/1/2021	line
				Clarified coverage criteria for acquired vs congenital
	Phimosis (acquired penile			anomalies of the penis. Added to funded region for acquired
Dr. Hoffman	complications, circumcision etc)	10/7/2021	1/1/2022	anomalies.
Staff review	Polydactyly	3/12/2020	10/1/2022	Clarified earlier decision to confirm in funded region
				Created new criteria for septoplasty, clarified conditions for
	Rhinoplasty/septoplasty/ deviated			coverage. Some new coverage and new limitations for
Public	septum	8/12/2021	10/1/2022	services that would be cosmetic.
Advocates	Selective mutism	11/18/2021	1/1/2022	Moved to funded anxiety line
Staff review	Sjogren syndrome	3/10/2022	10/1/2022	Added to funded region
Staff review	Tendon and ligament injuries	3/10/2022	10/1/2022	Added to funded region for full tears
	Viral endocarditis, myocarditis,			
Staff review	pericarditis, cardiomyopathy	3/10/2022	10/1/2022	Added to funded region
				Added vitiligo as a funded condition. Affects children's social
Staff review	Vitiligo	10/7/2021	1/1/2022	function
Staff review	Acquired torsion of penis	3/10/2022	10/1/2022	Added to funded region
Staff review	Agenesis of lung	3/10/2022	10/1/2022	Added to funded region for supportive care
				Added path to coverage for treatments supporting growth,
EPSDT	Child growth and development	11/18/2021	1/1/2022	development and participation in school for children
Staff review	Chronic pancreatitis		1/1/2022	Already merged for 2022 before this review
Staff review	Vitiligo of eyelid	3/10/2022	10/1/2022	Added to funded region

			Planned	Summary of change (or recommended change, decision not
Request source	Topic Description	Meeting Date	Imp. Date	to change)
	Physical therapy for minor			
	musculoskeletal conditions (Injuries and			
	disorders that affect the human body's			
	movement or muscles, tendons,			
	ligaments, nerves, discs, blood vessels,			
Staff review	etc.)			Limited benefit; would be very difficult to implement
	Allergic rhinitis (Nasal allergies/Hay			No change; little impact on health except when comorbidity
Dr. Hoffman	fever)			or growth/development/school exceptions apply
	Angiodema (Swelling (edema) of the			
	lower layer of skin and tissue just under			Removed unfunded duplicate line (no substantive change,
Dr. Hoffman	the skin)	11/18/2021	1/1/2022	was already covered)
				No change made; serious benign neoplasms are on line 401;
Dr. Hoffman	Benign bone neoplasm			Guideline 137 clarifies which are covered.
	Congenital anomalies of female genital			No change: Diagnoses on this line have no treatment. Other
Dr. Hoffman	tract excluding vagina			anomalies that require repair are on funded line(s)
				No change; primary care and preferred medications should
Dr. Hoffman	Dermatophytoses (ringworm, etc.)			be sufficient for these conditions
				No change: Primary care and preferred medications
Dr. Hoffman	Diaper rash			(nystatin) should be sufficient
				No change; primary care and preferred medications
				(NSAIDS, birth control) should be sufficient for these
Dr. Hoffman	Dysmenorrhea			conditions
				No change; primary care and preferred meds should be
				sufficient for these conditions. Rare exceptions can be
Dr. Hoffman	Hodeolum/chalazeon			considered through existing processes
				No change; primary care and preferred medications should
Dr. Hoffman	Mild eczema			be sufficient for these conditions
				No change; primary care and preferred medications should
Dr. Hoffman	Mild psoriasis			be sufficient for these conditions

			Planned	Summary of change (or recommended change, decision not
Request source	Topic Description	Meeting Date	Imp. Date	to change)
				No change: Primary care and preferred medications should
Dr. Hoffman	Minor burns			be sufficient
	Pica (Persistent eating of non-food			No change: Removed ambiguity of coverage for pica in
	items (for example clay, wool, lead,			children (should have already been in funded region),
	wood) at an age when it is considered			renamed line to clarify that the unfunded line is "Pica in
Advocates	to be developmentally inappropriate)	3/10/2022	10/1/2022	adults"
				No change; primary care and preferred medications should
Dr. Hoffman	Symptomatic urticaria			be sufficient for these conditions
				Liver angiosarcoma has a very poor prognosis with any
	Angiosarcoma of liver; intrahepatic bile			treatment (6 months even with surgery). Per NIH, the only
Staff review	duct carcinoma			treatment of bile duct carcinoma is palliative care
Staff review	Central retinal artery occlusion			Reviewed; no effective treatment is available
				Cognitive behavioral therapy would be available with
	Conversion disorders F44.4-7, include			another underlying disorder such as depression. No other
Dr. Hoffman	non-epilectic seizures			treatment for actual disorder indicated
				N75.1 (Abscess of Bartholin's gland) is included on line 205.
				Cysts typically have no symptoms and do not need
Staff review	Cysts of Bartholin's gland and vulva			treatment
				Treatment is directed at underlying diseases, which appear
Staff review	Enophthalmos			in funded region
				Primary care should be sufficient; there is no treatment for
Dr. Hoffman	Infectious mononucleosis			this condition
	Miscellaneous rare congenital			
Staff review	anomalies			Individual consideration will be required
				and saline. Surgery indicated if causing chronic sinusitis due
				to blockage of sinus ostia (would be covered on chronic
Staff review	Nasal polyps			sinusitis line)
Staff review	Personality disorders			No effective treatment

			Planned	Summary of change (or recommended change, decision not
Request source	Topic Description	Meeting Date	Imp. Date	to change)
				Treatment should be targeted to primary cancer, which
Staff review	Secondary and ill-defined neoplasms			would be covered.
	Thrombosed and complicated			Generally treated with fiber and observation. Could be
Staff review	hemorrhoids			addressed based on individual review
Staff review	Tension headaches			Primary care and NSAIDs are effective treatments.

Errata August 2022

- 1) On August 2, 2022, the following corrections were made to the January 1, 2022 Prioritized List:
 - a. An incorrect ICD-10-CM code (Z91.020) was removed from Guideline Note 203 PEANUT ALLERGY TREATMENT and replaced with ICD-10-CM Z91.010, which is the correct code for allergy to peanuts.
 - b. Line 433 was removed from Guideline Note 73, PENILE ANOMALIES, and corrected to reference Line 434, HYPOSPADIAS AND EPISPADIAS.

Section 3.0 New Discussion Items

Plain Language Summary:

<u>Background</u>: The proposed changes would update the ear tubes guideline for recurrent ear infections to align with new national guidelines which 1) allows adenoidectomy at the time of ear tube placement, and 2) expands the definition of an at-risk child to include intellectual disability, learning disorders, autism spectrum disorder and other conditions.

<u>Should OHP cover this treatment?</u> Staff recommends covering this treatment for additional conditions because the national guidelines have changed.

Questions:

- 1) Should the tympanostomy guideline be updated based on the AAO-HNS 2022 guideline change?
- 2) Should adenoidectomy be added to the acute otitis media line with a guideline update allowing use with tympanostomy tube placement based on the AAO-HNS 2022 guideline change?

Question sources:

- 1) Dr. Peggy Kelley, pediatric ENT
- 2) Dr. Max Kaiser, CCO medical director

<u>Issue</u>: American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) has updated their tympanostomy guideline. One major change is in the definition of an "at risk" child. Currently, GN29 states "Patients with craniofacial anomalies, Down's syndrome, cleft palate, permanent hearing loss of 25dB or greater independent of otitis media with effusion, and patients with speech and language delay may be considered for tympanostomy if unresponsive to appropriate medical treatment or having recurring infections (without needing to meet the strict "recurrent" definition above)."

Dr. Kelley recommends that GN29 be modified to read: "Patient with suspected or confirmed speech and language delay, autism spectrum disorder, syndromes or craniofacial disorders that include cognitive, speech, or language delays, blindness or uncorrectable visual impairment, cleft palate, developmental delay, intellectual disability, learning disorder or attention-deficit/hyperactivity disorder may be considered for tympanostomy tube placement." Dr. Kelley also recommends the addition of atelectasis (collapsed eardrum) to the list of complications qualifying for ear tubes.

Of note, children over the age of 7 (post-language acquisition) are included in GN51 if they have chronic otitis media.

At the May 2022 meeting, the guideline for chronic otitis media was modified to allow adenoidectomy at the time of tympanostomy tube placement for children under age 4 with symptoms directly related to the adenoids. On staff review, the new AAO guideline for adenoidectomy with tympanostomy tubes appears to relate to tubes placed for either recurrent acute or chronic otitis media.

Current Prioritized List status

GUIDELINE NOTE 29, TYMPANOSTOMY TUBES IN ACUTE OTITIS MEDIA

Line 389

Tympanostomy tubes (CPT 69433, 69436) are only included on this line as treatment for:

A) recurrent acute otitis media (three or more well-documented and separate episodes in six months or four or more well-documented and separate episodes in the past 12 months with at

least one episode in the past six months) in patients who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy, or

B) patients with complicating conditions (immunocompromised host, meningitis by lumbar puncture, acute mastoiditis, sigmoid sinus/jugular vein thrombosis by CT/MRI/MRA, cranial nerve paralysis, sudden onset dizziness/vertigo, need for middle ear culture, labyrinthitis, or brain abscess).

Patients with craniofacial anomalies, Down's syndrome, cleft palate, permanent hearing loss of 25dB or greater independent of otitis media with effusion, and patients with speech and language delay may be considered for tympanostomy if unresponsive to appropriate medical treatment or having recurring infections (without needing to meet the strict "recurrent" definition above).

Removal of retained tympanostomy tubes requiring anesthesia (CPT code 69424) or as an office visit, is included on Line 424 as a complication, pairing with ICD-10-CM H74.8.

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

GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

Lines 311,424,446,476

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) are not indicated for children with chronic otitis media with effusion (OME) (without another appropriate diagnosis).

Patients with specific higher risk conditions (including craniofacial anomalies, Down's syndrome, and cleft palate, or documented speech and language delay) along with hearing loss and chronic otitis media with effusion are intended to be included on Line 311 or Line 446 for children up to and including age 7. Otherwise hearing loss associated with chronic otitis media with effusion (without those specific higher risk conditions) is only included on Line 476.

For coverage to be considered on Line 311, Line 446 or Line 476, there should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented hearing loss is greater than or equal to 25dB in the better hearing ear, tympanostomy surgery may be indicated, given short- but not long- term improvement in hearing. Formal audiometry is indicated for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing upon diagnosis. Children with chronic OME who are not at risk for language delay (such as those with hearing loss <25dB in the better hearing ear) or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy is included on these lines at the time of tympanostomy tube insertion for children under age 4 with symptoms directly related to the adenoids (for example, ear infection associated with rhinorrhea and/or upper respiratory infection) OR in children aged 4 years or older.

Removal of retained tympanostomy tubes requiring anesthesia (CPT code 69424) or as an office visit, is included on Line 424 as a complication, pairing with ICD-10-CM H74.8.

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

Expert guideline

- 1) Rosenfeld 2022, Clinical Practice Guideline: Tympanostomy Tubes in Children (Update)
 - a. New evidence from 6 clinical practice guidelines, 18 systematic reviews, and 27 randomized controlled trials (RCTs)
 - b. Addition of intellectual disability, learning disorder, or attention-deficit/hyperactivity disorder to the list of risk factors that place children who have otitis media with effusion (OME) at increased risk for developmental difficulties (at-risk child)
 - i. Aggregate evidence quality: Grade C, based on observational studies
 - ii. Level of confidence in evidence: High for children with Down syndrome, cleft palate, and/or permanent hearing loss; medium for other at-risk groups
 - c. Updates list of children at risk for developmental difficulties:
 - i. Permanent hearing loss independent of otitis media with effusion
 - ii. Suspected or confirmed speech and language delay or disorder
 - iii. Autism spectrum disorder
 - iv. Syndromes (eg, Down) or craniofacial disorders that include cognitive, speech, or language delays
 - v. Blindness or uncorrectable visual impairment
 - vi. Cleft palate, with or without associated syndrome
 - vii. Developmental delay
 - viii. Intellectual disability, learning disorder, or attention-deficit/ hyperactivity disorder [these are the only new conditions added in this update]
 - d. Adjuvant adenoidectomy:
 - i. Clinicians may perform adenoidectomy as an adjunct to tympanostomy tube insertion for children with symptoms directly related to the adenoids (adenoid infection or nasal obstruction) OR in children aged 4 years or older to potentially reduce future incidence of recurrent otitis media or the need for repeat tube insertion
 - ii. Strength of recommendation: <u>option</u> based on randomized controlled trials, meta-analyses, and population-level studies, with a balance of benefits and harms.
 - iii. Aggregate evidence quality: Grade B, based on RCTs for persistence of OME post-surgically, rate of repeat tube insertion, and hearing outcomes; observational studies regarding the rate of tube reinsertion and hearing outcomes; and meta-analyses on the benefit of adenoidectomy in patients greater than 4 years of age as compared with those younger than 4 years of age
 - iv. Level of confidence in evidence: High for symptoms related to adenoids and children over the age of 4 years; medium for role as primary treatment in select populations and role in second tube insertion procedures in patients younger than 4 years
 - v. Benefits: Optimize management of adenoid-related disease (nasal obstruction, bacterial infection, chronic rhinitis); reduce need for further surgery and anesthesia; optimize hearing outcomes; decreased persistence of MEE after surgery.
 - vi. Risks, harms, costs: Surgical risks of adenoidectomy, additional anesthetic risk related to need for intubation during procedure, bleeding, hypernasality, velopharyngeal insufficiency, nasopharyngeal scarring/stenosis, Grisel's syndrome, longer recovery
 - vii. Benefit-harm assessment: Equilibrium (balance) of benefits vs harms

HERC staff recommendation:

- 1) Add adenoidectomy codes to line 389 ACUTE OTITIS MEDIA
 - a. CPT 42830-42836 (Adenoidectomy primary or secondary)
- 2) Modify GN29 as shown below
 - a. Modify the list of conditions that make a child high risk
 - i. Note: AAO and Dr. Kelley recommend including "autism spectrum" as a condition for consideration for earlier tubes. HERC staff believe that one of the other conditions such as hearing loss or language delay should be met rather than just autism given the wide range of clinical presentations of that condition
 - b. Add wording about adenoidectomy mirroring language adopted for GN51

GUIDELINE NOTE 29, TYMPANOSTOMY TUBES IN ACUTE OTITIS MEDIA

Line 389

Tympanostomy tubes (CPT 69433, 69436) are only included on this line as treatment for:

- A) recurrent acute otitis media (three or more well-documented and separate episodes in six months or four or more well-documented and separate episodes in the past 12 months with at least one episode in the past six months) in patients who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy, or
- B) patients with complicating conditions (<u>atelectasis [collapsed eardrum]</u>, immunocompromised host, meningitis by lumbar puncture, acute mastoiditis, sigmoid sinus/jugular vein thrombosis by CT/MRI/MRA, cranial nerve paralysis, sudden onset dizziness/vertigo, need for middle ear culture, labyrinthitis, or brain abscess).

Patients with craniofacial anomalies<u>; syndromes</u>, Down's syndrome that include cognitive, speech, or language delays; cleft palate₇; permanent hearing loss of 25dB or greater independent of otitis media with effusion₇; developmental delay; intellectual disability₇; learning disorder₇; attentiondeficit/hyperactivity disorder₇; blindness or uncorrectable visual impairment₇; and patients with speech and language delay may be considered for tympanostomy if unresponsive to appropriate medical treatment or having recurring infections (without needing to meet the strict "recurrent" definition above).

Adenoidectomy is included on these lines at the time of tympanostomy tube insertion for children under age 4 with symptoms directly related to the adenoids (for example, ear infection associated with rhinorrhea and/or upper respiratory infection) OR in children aged 4 years or older.

Removal of retained tympanostomy tubes requiring anesthesia (CPT code 69424) or as an office visit, is included on Line 424 as a complication, pairing with ICD-10-CM H74.8.

The development of this guideline note was informed by a HERC <u>coverage guidance</u>. See <u>https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx</u>
Clinical Practice Guideline: Tympanostomy Tubes in Children (Update)

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. Insertion of tympanostomy tubes is the most common ambulatory surgery performed on children in the United States. Tympanostomy tubes are most often inserted because of persistent middle ear fluid, frequent ear infections, or ear infections that persist after antibiotic therapy. All these conditions are encompassed by the term otitis media (middle ear inflammation). This guideline update provides evidence-based recommendations for patient selection and surgical indications for managing tympanostomy tubes in children. The guideline is intended for any clinician involved in managing children aged 6 months to 12 years with tympanostomy tubes or children being considered for tympanostomy tubes in any care setting as an intervention for otitis media of any type. The target audience includes specialists, primary care clinicians, and allied health professionals.

Purpose. The purpose of this clinical practice guideline update is to reassess and update recommendations in the prior guideline from 2013 and to provide clinicians with trustworthy, evidence-based recommendations on patient selection and surgical indications for managing tympanostomy tubes in children. In planning the content of the updated guideline, the guideline update group (GUG) affirmed and included all the original key action statements (KASs), based on external review and GUG assessment of the original recommendations. The guideline update was supplemented with new research evidence and expanded profiles that addressed quality improvement and implementation issues. The group also discussed and prioritized the need for new recommendations based on gaps in the initial

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guideline or new evidence that would warrant and support KASs. The GUG further sought to bring greater coherence to the guideline recommendations by displaying relationships in a new flowchart to facilitate clinical decision making. Last, knowledge gaps were identified to guide future research.

Methods. In developing this update, the methods outlined in the American Academy of Otolaryngology-Head and Neck Surgery Foundation's "Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence Into Action" were followed explicitly. The GUG was convened with representation from the disciplines of otolaryngology-head and neck surgery, otology, pediatrics, audiology, anesthesiology, family medicine, advanced practice nursing, speech-language pathology, and consumer advocacy.

Action Statements. The GUG made strong recommendations for the following KASs: (14) clinicians should prescribe topical antibiotic ear drops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea; (16) the surgeon or designee should examine the ears of a child within 3 months of tympanostomy tube insertion AND should educate families regarding the need for routine, periodic follow-up to examine the ears until the tubes extrude.

The GUG made recommendations for the following KASs: (1) clinicians should not perform tympanostomy tube insertion in children with a single episode of otitis media with effusion (OME) of less than 3 months' duration, from the date of onset (if known) or from the date of diagnosis (if onset is unknown); (2) clinicians should obtain a hearing evaluation if OME persists for 3 months or longer OR prior to surgery when a child becomes a candidate for tympanostomy tube insertion; (3) clinicians should offer bilateral tympanostomy tube insertion to children with bilateral OME for 3 months or longer AND documented hearing difficulties; (5) clinicians should

reevaluate, at 3- to 6-month intervals, children with chronic OME who do not receive tympanostomy tubes, until the effusion is no longer present, significant hearing loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected; (6) clinicians should not perform tympanostomy tube insertion in children with recurrent acute otitis media who do not have middle ear effusion in either ear at the time of assessment for tube candidacy; (7) clinicians should offer bilateral tympanostomy tube insertion in children with recurrent acute otitis media who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy; (8) clinicians should determine if a child with recurrent acute otitis media or with OME of any duration is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors; (10) the clinician should not place longterm tubes as initial surgery for children who meet criteria for tube insertion unless there is a specific reason based on an anticipated need for prolonged middle ear ventilation beyond that of a short-term tube; (12) in the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications; (13) clinicians should not routinely prescribe postoperative antibiotic ear drops after tympanostomy tube placement; (15) clinicians should not encourage routine, prophylactic water precautions (use of earplugs or headbands, avoidance of swimming or water sports) for children with tympanostomy tubes.

The GUG offered the following KASs as options: (4) clinicians may perform tympanostomy tube insertion in children with unilateral or bilateral OME for 3 months or longer (chronic OME) AND symptoms that are likely attributable, all or in part, to OME that include, but are not limited to, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life; (9) clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is likely to persist as reflected by a type B (flat) tympanogram or a documented effusion for 3 months or longer; (11) clinicians may perform adenoidectomy as an adjunct to tympanostomy tube insertion for children with symptoms directly related to the adenoids (adenoid infection or nasal obstruction) OR in children aged 4 years or older to potentially reduce future incidence of recurrent otitis media or the need for repeat tube insertion.

Keywords

otitis media, tympanostomy tubes, grommets, otorrhea, middle ear effusion, pediatric otolaryngology, developmental delay disorders

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Update Rationale and Scope

This clinical practice guideline (CPG) is an update and replacement for the earlier guideline "Tympanostomy Tubes in Children," published in 2013 by the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF).¹ An update was necessitated by an >5-year lapse and by subsequent original research and systematic reviews that might modify existing recommendations or support new ones. Changes in content and methodology from the prior guideline include the following:

- New evidence from 6 CPGs, 18 systematic reviews, and 27 randomized controlled trials (RCTs)
- Emphasis on patient education and shared decision making with new tables of counseling opportunities and frequently asked questions
- Expanded key action statement (KAS) profiles to explicitly state quality improvement opportunities and implementation considerations
- New flowchart to clarify decision making and show the relationships among KAS recommendations
- A new strong recommendation that the surgeon or designee should examine the ears of a child within 3 months after tympanostomy tube insertion to assess outcomes and should educate families regarding the

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Section 4.0 Consent Agenda-Straightforward Items

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
46615	Anoscopy; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique	157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS	CPT 46615 is currently on lines 166,475,621. A CCO requested that it be added to line 157 to pair with ICD-10-CM D37.5 (Neoplasm of uncertain behavior of rectum)	Add 46615 to line 157
M50.121	Cervical disc disorder at C4-C5 level with radiculopathy	346 CONDITIONS OF THE BACK AND SPINE WITH URGENT	General cervical radiculopathy codes such as ICD-10-CM M54.12	Add M50.121, M50.122, M50.123,
10150.122	level with radiculopathy	SORGICAL INDICATIONS	on line 346. The codes shown are	
M50.123	Cervical disc disorder at C6-C7 level with radiculopathy		only on the medical back line (line 402) and the uncovered back	
M50.13	Cervical disc disorder with radiculopathy, cervicothoracic region		surgical line (line 530).	
43266	Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION	MMC case review found that CPT 43266 should pair with ICD-10-CM K56.6X (Intestinal obstruction), which is on line 41. CPT 43266 is currently on lines 215,314,378,593,638	Add 43266 to line 41
G96.198	Other disorders of meninges, not elsewhere classified	424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT	MMC case review found that CPT 63709 (Repair of dural/ cerebrospinal fluid leak or pseudomeningocele, with laminectomy) should pair with ICD- 10 G96.198. One subdiagnosis of G96.198 is "acquired pseudomeningocele". 63709 is currently on lines 33,285,424	Add G96.198 to line 424

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
K80.20	Calculus of gallbladder without cholecystitis without obstruction	55 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS	Coverage was added for uncomplicated gallstones when there are certain conditions met in	Add K80.20, K80.50, K80.70 to line 55
K80.50	Calculus of bile duct without cholangitis or cholecystitis without obstruction		GN167. However, the 3 ICD-10-CM codes for these conditions remain only on line 641 GALLSTONES	
K80.70	Calculus of gallbladder and bile duct without cholecystitis without obstruction		WITHOUT CHOLECYSTITIS. These codes should be added to line 55 and stay on line 641, with GN167 determining when they are covered	
G56.1X family	Other lesions of median nerve	416 PERIPHERAL NERVE ENTRAPMENT	HSD nurse reviewer question. Ulnar nerve lesions (ICD-10-CM G56.2X) are on line 416. However, median nerve lesions other than carpal tunnel syndrome and radial nerve	Add G56.1X family and G56.3X family to 416 PERIPHERAL NERVE ENTRAPMENT
G56.3X family	Lesion of radial nerve	509 and 537 PERIPHERAL NERVE DISORDERS	lesions are only on lines 509 and 537. (Medical and Surgical treatment respectively). Compressions of the median and radial nerves can cause issues with use of the hand and/or arm. Similar nerve lesions for the nerves innervating the foot are on line 416.	Remove G56.1X family and G56.3X family from lines 509 and 537
96450	Chemotherapy administration, into CNS (eg, intrathecal), requiring and including spinal puncture	292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS	Spinal muscular atrophy (ICD-10- CM G12.9) is on lines 71,292,345, 377. This condition can be treated with the drug nusinersen (Spinraza) which is administered with CPT code 96450. CPT 62323 can also be used, which is on line 292.	Add CPT 96450 to line 292

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
K76.7	Hepatorenal syndrome	307 CIRRHOSIS OF LIVER OR	There is no treatment for	Add K76.7 to line 307
		BILIARY TRACT; BUDD-CHIARI	hepatorenal syndrome other than a	and keep on line 493
		SYNDROME; HEPATIC VEIN	liver transplant, which corrects	
		THROMBOSIS; INTRAHEPATIC	both the liver disease and	
		VASCULAR MALFORMATIONS;	associated impaired renal function.	
		CAROLI'S DISEASE Treatment:	Even after successful liver	
		LIVER TRANSPLANT, LIVER-	transplantation, patients who had	
		KIDNEY TRANSPLANT	hepatorenal syndrome beforehand	
			may not fully recover their kidney	
		493 HEPATORENAL SYNDROME	function. A small percentage may	
		Treatment: MEDICAL THERAPY	go on to permanent damage	
			requiring dialysis. This diagnosis	
			was found on denied inpatient	
			claims review	
G61 family	Inflammatory polyneuropathy	165 PREVENTIVE FOOT CARE IN	Line 165 PREVENTIVE FOOT CARE	Add the G61 and G62
		HIGH-RISK PATIENTS	IN HIGH-RISK PATIENTS is intended	ICD-10-CM families to
G62 family	Other and unspecified		to include diagnoses that place a	line 165
	polyneuropathies		patient at higher risk of foot ulcers	
			and other complications. Such	
			diagnoses include lower extremity	
			neuropathies. HERC staff have	
			found multiple peripheral	
			neuropathy diagnosis codes that	
			are missing from this line.	
90584	Dengue vaccine, quadrivalent,	Excluded File	The AMA released a new vaccine	Add 90584 to the
	live, 2 dose schedule, for		code for Dengue vaccine effective	Excluded File
	subcutaneous use		July 1, 2022. This is a travel	
			vaccine.	

<u>Issue 1:</u> GN9 is currently attached to two lines, line 29 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE and line 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE. However, capsule endoscopy is used for diagnosis of conditions such as iron deficiency anemia, GI bleeding, or abdominal pain. These diagnoses are on the Diagnostic File. The two lines attached to GN9 have established diagnoses. GN9 needs to be converted to a Diagnostic Guideline and the CPT code for capsule endoscopy (CPT 91110) be placed on the Diagnostic Procedures File.

HERC staff recommendation:

- Remove CPT 91110 (Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report) from lines 29 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE and line 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE.
 - a. Advise HSD to add CPT 91110 to the Diagnostic Procedures File
- 2) Modify GN9 as shown below

GUIDELINE NOTE 9 DIAGNOSTIC GUIDELINE DX, WIRELESS CAPSULE ENDOSCOPY

Lines 29,56

- A) Wireless capsule endoscopy is included on these lines for diagnosis of:
 - 1) Obscure GI bleeding suspected to be of small bowel origin with iron deficiency anemia or documented GI blood loss
 - 2) Suspected Crohn's disease with prior negative work up
- B) Wireless capsule endoscopy is not included on these lines for:
 - 1) Colorectal cancer screening
 - 2) Confirmation of lesions of pathology normally within the reach of upper or lower endoscopes (lesions proximal to the ligament of Treitz or distal to the ileum)
- C) Wireless capsule endoscopy is only included on these lines when the following conditions have been met:
 - 1) Prior studies must have been performed and been non-diagnostic
 - a) GI bleeding: upper and lower endoscopy
 - b) Suspected Crohn's disease: upper and lower endoscopy, small bowel follow through
 - 2) Radiological evidence of lack of stricture
 - 3) Only covered once during any episode of illness
 - 4) FDA approved devices must be used
 - 5) Patency capsule should not be used prior to procedure

Straightforward Guideline Note Changes

<u>Issue 2</u>: The genetic testing guidelines were updated recently. A reference to the non-prenatal genetic testing guideline in the high risk breast cancer guideline was not updated to reflect this. The older version of Diagnostic Guideline D1 discussed genetic testing in section A2. The updated guideline discusses genetic testing in section B:

- 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.
 - "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

HERC staff recommendation:

1) Modify GN3 as shown below

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) <u>www.nccn.org</u>). Prior to surgery, women without a personal history of breast cancer must have a genetics consultation as defined in section A2 B of the DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE.

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

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

COVID-19 Related Codes August 2022

Issues:

- 1) New COVID vaccine codes were released for pediatric Moderna vaccination
- 2) A new COVID vaccine administration code was added for the 3rd dose of the tris-sucrose vaccine formulation

HERC staff recommendations:

1) Add the following CPT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

СРТ	Code Description	Recommended Placement
Code		
0091A	Moderna Covid-19 vaccine administration – children	3 PREVENTION SERVICES WITH
	ages 6-11 – first dose	EVIDENCE OF EFFECTIVENESS
0092A	Moderna Covid-19 vaccine administration – –	3
	children ages 6-11 – second dose	
0093A	Moderna Covid-19 vaccine administration – –	3
	children ages 6-11 – third dose	
91311	Moderna Covid-19 vaccine administration – children	3
	ages 6 months to 5 years	
0111A	Moderna Covid-19 vaccine administration – children	3
	ages 6 months to 5 years – first dose	
0112A	Moderna Covid-19 vaccine administration – –	3
	children ages 6 months to 5 years – second dose	
0113A	Moderna Covid-19 vaccine administration – –	3
	children ages 6 months to 5 years – third dose	
0083A	IMM ADMN SARSCOV2 3MCG/0.2ML TRIS-SUCROSE	3
	3 RD dose	

<u>Issue:</u> New CPT codes were released in late July for the two vaccines with FDA authorization or EUA for prevention and pre-exposure prophylaxis for monkeypox. Monkeypox is a rare disease caused by infection with the monkeypox virus. Monkeypox virus is part of the same family of viruses as variola virus, the virus that causes smallpox.

There is currently an outbreak of monkeypox in the US, with multiple cases in Oregon. CDC recommends vaccination for people who have been exposed to monkeypox and people who are at higher risk of being exposed to monkeypox. There are two vaccines available for monkeypox: Jynneos is specific for monkeypox and ACAM2000 was initially developed for smallpox, but has activity against monkeypox.

A new CPT code was also released for the testing for monkeypox and related orthopoxviruses

HERC staff recommendations:

- 1) Add the following CPT codes for monkeypox vaccines to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
 - CPT 90611 Jynneos vaccine (Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous injection)
 - b. CPT 90622 ACAM2000 vaccine (Vaccinia (smallpox) virus vaccine, live, lyophilized, 0.3 mL dosage, for percutaneous use)
- Advise HSD to add CPT 87593 (Infectious agent detection by nucleic acid (DNA or RNA); orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each) to the DIAGNOSTIC PROCEDURES FILE

Preventive Services Guideline References Update

Issue: The preventive services guideline needs several updates:

- 1) The current link to the USPSTF recommendations is incorrect
- 2) Bright Futures was updated in July 2022 and the link needs to be updated
- 3) The dates of USPSTF and HRSA covered services need to be updated

HERC staff recommendations:

- 1) Update GN106 as shown below
 - a. Update the link for the USPSTF A and B recommendations

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

- A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2021 2022.
 - http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-brecommendations/ https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-aand-b-recommendation
 - a) Treatment of falls prevention with exercise interventions is included on Line 292.
 - 2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.
- B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
 - <u>http://brightfutures.aap.org.</u> Periodicity schedule available at <u>http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity Schedule_FINAL.pdf.</u> <u>https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf</u>
 - a) Bright Futures is the periodicity schedule for screening for EPSDT for the Oregon Health Plan.
 - 2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.
- C) Health Resources and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines (revised January, 2022)as updated by HRSA in December 2019. Available at <u>https://www.hrsa.gov/womens-guidelines-2019</u> retrieved as of on September 4, 2020July 28, 2022.
- D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): <u>http://www.cdc.gov/vaccines/schedules/hcp/index.html</u> or approved for the Oregon Immunization Program: <u>https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProv</u> iderResources/Documents/DMAPvactable.pdf
 - COVID-19 vaccines are intended to be included on this line even if the specific administration code(s) do not yet appear on the line when the vaccine has both 1) FDA approval or FDA emergency use authorization (EUA) and 2) ACIP recommendation.

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

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

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

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

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

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

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

American Academy of Pediatrics DEDICATED TO THE HEALTH OF ALL CHILDREN®



Recommendations for Preventive Pediatric Health Care

Bright Futures/American Academy of Pediatrics

Each child and family is unique: therefore, these Recommendations for Preventive Pediatric Health Care are designed for the care of children who are receiving nurturing parenting, have no manifestations of any important health problems, and are growing and developing in a satisfactory fashion. Developmental, psychosocial, and chronic disease issues for children and adolescents may require more frequent counseling and treatment visits separate from preventive care visits. Additional visits also may become necessary if circumstances suggest concerns.

These recommendations represent a consensus by the American Academy of Pediatrics (AAP) and Bright Futures. The AAP continues to emphasize the great importance of continuity of care in comprehensive health supervision and the need to avoid fragmentation of care.

Refer to the specific guidance by age as listed in the Bright Futures Guidelines (Hagan JF, Shaw JS, Duncan PM, eds. Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents. 4th ed. American Academy of Pediatrics; 2017).

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The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

The Bright Futures/American Academy of Pediatrics Recommendations for Preventive Pediatric Health Care are updated annually

				INFANCY							EARLY	CHILDHOOD)					MIDDLE CH	HILDHOOI	D						AD	OLESCENCE					
AGE ¹	Prenatal ²	Newborn ³	3-5 d⁴	By 1 mo	2 mo	4 mo	6 mo	9 mo	12 mo	15 mo	18 mo	24 mo	30 mo	3 y	4 y	5 y	б у	7 y	8 y	9 y	10 y	11 y	12 y	13 y	14 y	15 y	16 y	17 y	18 y	19 y	20 y	21 y
HISTORY Initial/Interval	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
MEASUREMENTS						1																										
Length/Height and Weight		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Head Circumference	1	•	•	٠	•	•			•	•	٠	•				_																
Weight for Length		•	•	•	•	•	•		•	•	•																					
Body Mass Index ⁵												•	•	•	•	•	•	•	•	•	•	•	•	•	٠	•	•	•	•		•	•
Blood Pressure ⁶		*	*	*	*	*	*	*	*	*	*	*	*	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•
SENSORY SCREENING		1																														
Vision ⁷		*	*	*	*	*	*	*	*	*	*	*	*	•		•	•	*	•	*	•	*	•	*	*	•	*	*	*	*	*	*
Hearing		•8	• ⁹ -		->	*	*	*	*	*	*	*	*	*		•	•	*	•	*	•	-		●10		-	— • —	→	-	<u> </u>		
DEVELOPMENTAL/SOCIAL/BEHAVIORAL/MENTAL HEALTH	1												1							1												
Maternal Depression Screening ¹¹				•	•	•	•																									
Developmental Screening ¹²	1										٠		•																			
Autism Spectrum Disorder Screening ¹³											٠	•				-																
Developmental Surveillance		•	•	•	•	•	•		•	•		•		•		•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	
Behavioral/Social/Emotional Screening ¹⁴		•	•	•	•	•	•		•	•	٠	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•
Tobacco, Alcohol, or Drug Use Assessment ¹⁵																						*	*	*	*	*	*	*	*	*	*	*
Depression and Suicide Risk Screening ¹⁶																-							•	•	•	•	•	•	•		•	
PHYSICAL EXAMINATION ¹⁷		•	•	•	•	•	•		•	•	٠	•	•	•	•	•	•	•	•	•	•	٠	•	•	٠	•	•	•	٠		•	
PROCEDURES ¹⁸		1																														
Newborn Blood		●19	•20-		->																											
Newborn Bilirubin ²¹		•																														
Critical Congenital Heart Defect ²²		•																														
Immunization ²³		•	•	•	•				•	•	•	•	•			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•
Anemia ²⁴						*			•	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Lead ²⁵							*	*	● or ★ ²⁶		*	● or ★ ²⁶		*	*	*	*															
Tuberculosis ²⁷				*			*		*			*		*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Dyslipidemia ²⁸												*			*		*		*	-	•	▲	*	*	*	*	*	┥		<u> </u>		→
Sexually Transmitted Infections ²⁹																						*	*	*	*	*	*	*	*	*	*	*
HIV ³⁰																						*	*	*	*	-		— • —		*	*	*
Hepatitis B Virus Infection ³¹		*																												—		-
Hepatitis C Virus Infection ³²																													•—	—		\rightarrow
Sudden Cardiac Arrest/Death ³³																						*								—		-
Cervical Dysplasia ³⁴																																•
ORAL HEALTH ³⁵							●36	●36	*	Ì	*	*	*	*	*	*	*															
Fluoride Varnish ³⁷							-				—• —					-																
Fluoride Supplementation ³⁸							*	*	*		*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*					
ANTICIPATORY GUIDANCE	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	٠	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•

1. If a child comes under care for the first time at any point on the schedule, or if any items are not accomplished at the suggested 5. Screen, per "Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and age, the schedule should be brought up to date at the earliest possible time.

2. A prenatal visit is recommended for parents who are at high risk, for first-time parents, and for those who request a conference. 6. The prenatal visit should include anticipatory guidance, pertinent medical history, and a discussion of benefits of breastfeeding and planned method of feeding, per "The Prenatal Visit" (https://doi.org/10.1542/peds.2018-1218)

3. Newborns should have an evaluation after birth, and breastfeeding should be encouraged (and instruction and support should be offered).

4. Newborns should have an evaluation within 3 to 5 days of birth and within 48 to 72 hours after discharge from the hospital to include evaluation for feeding and jaundice. Breastfeeding newborns should receive formal breastfeeding evaluation, and their mothers should receive encouragement and instruction, as recommended in "Breastfeeding and the Use of Human Milk" (https://doi.org/10.1542/peds.2011-3552). Newborns discharged less than 48 hours after delivery must be examined within 48 hours of discharge, per "Hospital Stay for Healthy Term Newborn Infants" (https://doi.org/10.1542/peds.2015-0699).

Adolescent Overweight and Obesity: Summary Report" (https://doi.org/10.1542/peds.2007-2329C).

Screening should occur per "Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents" (https://doi.org/10.1542/peds.2017-1904). Blood pressure measurement in infants and children with specific risk conditions should be performed at visits before age 3 years.

7. A visual acuity screen is recommended at ages 4 and 5 years, as well as in cooperative 3-year-olds. Instrument-based screening may be used to assess risk at ages 12 and 24 months, in addition to the well visits at 3 through 5 years of age. See "Visual System Assessment in Infants, Children, and Young Adults by Pediatricians" (<u>https://doi.org/10.1542/peds.2015-3596</u>) and "Procedures for the Evaluation of the Visual System by Pediatricians" (https://doi.org/10.1542/peds.2015-3597).

Confirm initial screen was completed, verify results, and follow up, as appropriate. Newborns should be screened, 8 per "Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs" (https://doi.org/10.1542/peds.2007-2333).

9. Verify results as soon as possible, and follow up, as appropriate.

10. Screen with audiometry including 6,000 and 8,000 Hz high frequencies once between 11 and 14 years, once between 15 and 17 years, and once between 18 and 21 years. See "The Sensitivity of Adolescent Hearing Screens Significantly Improves by Adding High Frequencies" (https://www.sciencedirect.com/science/article/abs/pii/S1054139X16000483)

11. Screening should occur per "Incorporating Recognition and Management of Perinatal Depression Into Pediatric Practice" (https://doi.org/10.1542/peds.2018-3259).

(https://doi.org/10.1542/peds.2019-3447).



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Screening should occur per "Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening" (https://doi.org/10.1542/peds.2019-3449). 13. Screening should occur per "Identification, Evaluation, and Management of Children With Autism Spectrum Disorder

(continued)

(continued)

- 14. Screen for behavioral and social-emotional problems per "Promoting Optimal Development: Screening for Behavioral and Emotional Problems (https://doi.org/10.1542/peds.2014-3716), "Mental Health Competencies for Pediatric Practice" (https://doi.org/10.1542/peds.2019-2757), "Clinical Practice Guideline for the Assessment and Treatment of Children and Adolescents With Anxiety Disorders" (https://pubmed.ncbi.nlm.nih.gov/32439401), and "Screening for Anxiety in Adolescent and Adult Women: A Recommendation From the Women's Preventive Services Initiative" (https://pubmed.ncbi.nlm.nih.gov/32510990). The screening should be family centered and may include asking about caregiver emotional and mental health concerns and social determinants of health, racism, poverty, and relational health. See "Poverty and Child Health in the United States" (https://doi.org/10.1542/peds.2016-0339), "The Impact of Racism on Child and Adolescent Health" (https://doi.org/10.1542/peds.2019-1765), and "Preventing Childhood Toxic Stress: Partnering With Families and Communities to Promote Relational Health" (https://doi.org/10.1542/peds.2021-052582).
- 15. A recommended assessment tool is available at http://crafft.org.
- 16. Screen adolescents for depression and suicide risk, making every effort to preserve confidentiality of the adolescent. See "Guidelines for Adolescent Depression in Primary Care (GLAD-PC): Part I. Practice Preparation, Identification, Assessment, and Initial Management" (https://doi.org/10.1542/peds.2017-4081), "Mental Health Competencies for Pediatric Practice" (https://doi.org/10.1542/peds.2019-2757), "Suicide and Suicide Attempts in Adolescents" (https://doi.org/10.1542/peds.2016-1420), and "The 21st Century Cures Act & Adolescent Confidentiality" (https://www.adolescenthealth.org/ Advocacy/Advocacy-Activities/2019-(1)/NASPAG-SAHM-Statement.aspx).
- 17. At each visit, age-appropriate physical examination is essential, with infant totally unclothed and older children undressed and suitably draped. See "Use of Chaperones During the Physical Examination of the Pediatric Patient" (https://doi.org/10.1542/peds.2011-0322).
- 18. These may be modified, depending on entry point into schedule and individual need. 19. Confirm initial screen was accomplished, verify results, and follow up, as
- appropriate. The Recommended Uniform Screening Panel (https://www.hrsa.gov/ advisory-committees/heritable-disorders/rusp/index.html), as determined by Children The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, and state newborn screening laws/regulations (https://www.babysfirsttest.org/) establish the criteria for and coverage of newborn screening procedures and programs 20. Verify results as soon as possible, and follow up, as appropriate
- 21. Confirm initial screening was accomplished, verify results, and follow up, as appropriate. See "Hyperbilirubinemia in the Newborn Infant ≥35 Weeks' Gestation: An Update With Clarifications" (https://doi.org/10.1542/peds.2009-0329).
- 22. Screening for critical congenital heart disease using pulse oximetry should be performed in newborns, after 24 hours of age, before discharge from the hospital, per "Endorsement of Health and Human Services Recommendation for Pulse Oximetry Screening for Critical Congenital Heart Disease" (https://doi.org/10.1542/peds.2011-3211).
- 23. Schedules, per the AAP Committee on Infectious Diseases, are available at https://publications.aap.org/redbook/pages/immunization-schedules. Every visit should be an opportunity to update and complete a child's immunizations.
- 24. Perform risk assessment or screening, as appropriate, per recommendations in the current edition of the AAP Pediatric Nutrition: Policy of the American Academy of Pediatrics (Iron chapter)
- 25. For children at risk of lead exposure, see "Prevention of Childhood Lead Toxicity" (https://doi.org/10.1542/peds.2016-1493) and "Low Level Lead Exposure Harms" Children: A Renewed Call for Primary Prevention" (https://www.cdc.gov/nceh/lead/ docs/final document 030712.pdf).
- 26. Perform risk assessments or screenings as appropriate, based on universal screening requirements for patients with Medicaid or in high prevalence areas.

- 27. Tuberculosis testing per recommendations of the AAP Committee on Infectious Diseases, published in the current edition of the AAP Red Book: Report of the Committee on Infectious Diseases. Testing should be performed on recognition of high-risk factors.
- 28. See "Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents" (http://www.nhlbi.nih.gov/guidelines/cvd_ped/index.htm).
- 29. Adolescents should be screened for sexually transmitted infections (STIs) per recommendations in the current edition of the AAP Red Book: Report of the Committee on Infectious Diseases.
- 30. Adolescents should be screened for HIV according to the US Preventive Services Task Force (USPSTF) recommendations (https://www.uspreventiveservicestaskforce.org/ uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening once between the ages of 15 and 18, making every effort to preserve confidentiality of the adolescent. Those at increased risk of HIV infection, including those who are sexually active, participate in injection drug use, or are being tested for other STIs, should be tested for HIV and reassessed annually.
- 31. Perform a risk assessment for hepatitis B virus (HBV) infection according to recommendations per the USPSTF (https://www.uspreventiveservicestaskforce.org/ uspstf/recommendation/hepatitis-b-virus-infection-screening) and in the 2021–2024 edition of the AAP Red Book: Report of the Committee on Infectious Diseases, making every effort to preserve confidentiality of the patient.
- 32. All individuals should be screened for hepatitis C virus (HCV) infection according to the USPSTF (https://www.uspreventiveservicestaskforce.org/uspstf/ recommendation/hepatitis-c-screening) and Centers for Disease Control and Prevention (CDC) recommendations (https://www.cdc.gov/mmwr/volumes/69/rr/rr6902a1.htm) at least once between the ages of 18 and 79. Those at increased risk of HCV infection, including those who are persons with past or current injection drug use, should be tested for HCV infection and reassessed annually.
- 33. Perform a risk assessment, as appropriate, per "Sudden Death in the Young: Information for the Primary Care Provider" (https://doi.org/10.1542/peds.2021-052044)
- 34. See USPSTF recommendations (https://www.uspreventiveservicestaskforce.org/uspstf/ recommendation/cervical-cancer-screening). Indications for pelvic examinations prior to age 21 are noted in "Gynecologic Examination for Adolescents in the Pediatric Office Setting" (https://doi.org/10.1542/peds.2010-1564).
- 35. Assess whether the child has a dental home. If no dental home is identified, perform a risk assessment (https://www.aap.org/en/patient-care/oral-health/oral-health practice-tools/) and refer to a dental home. Recommend brushing with fluoride toothpaste in the proper dosage for age. See "Maintaining and Improving the Oral Health of Young Children" (https://doi.org/10.1542/peds.2014-2984)
- 36. Perform a risk assessment (https://www.aap.org/en/patient-care/oral-health/oralhealth-practice-tools/). See "Maintaining and Improving the Oral Health of Young Children" (https://doi.org/10.1542/peds.2014-2984).
- 37. The USPSTF recommends that primary care clinicians apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption (https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/preventionof-dental-caries-in-children-younger-than-age-5-years-screening-and-interventions1). Once teeth are present, apply fluoride varnish to all children every 3 to 6 months in the primary care or dental office based on caries risk. Indications for fluoride use are noted in "Fluoride Use in Caries Prevention in the Primary Care Setting" (https://doi.org/10.1542/ peds 2020-034637)
- 38. If primary water source is deficient in fluoride, consider oral fluoride supplementation. See "Fluoride Use in Caries Prevention in the Primary Care Setting" (https://doi.org/10.1542/peds.2020-034637).

Summary of Changes Made to the Bright Futures/AAP Recommendations for Preventive Pediatric Health Care (Periodicity Schedule)

This schedule reflects changes approved in November 2021 and published in July 2022. For updates and a list of previous changes made, visit www.aap.org/periodicityschedule.

CHANGES MADE IN NOVEMBER 2021

HEPATITIS B VIRUS INFECTION

Assessing risk for HBV infection has been added to occur from newborn to 21 years (to account for the range in which the risk assessment can take place) to be consistent with recommendations of the USPSTF and the 2021–2024 edition of the AAP Red Book: Report of the Committee on Infectious Diseases.

Footnote 31 has been added to read as follows: "Perform a risk assessment for hepatitis B virus (HBV) infection according to recommendations per the USPSTF (https://www.uspreventiveservicestaskforce.org/uspstf/ recommendation/hepatitis-b-virus-infection-screening) and in the 2021-2024 edition of the AAP Red Book: Report of the Committee on Infectious Diseases, making every effort to preserve confidentiality of the patient."

SUDDEN CARDIAC ARREST AND SUDDEN CARDIAC DEATH

Assessing risk for sudden cardiac arrest and sudden cardiac death has been added to occur from 11 to 21 years (to account for the range in which the risk assessment can take place) to be consistent with AAP policy ("Sudden Death in the Young: Information for the Primary Care Provider").

Footnote 33 has been added to read as follows: "Perform a risk assessment, **FLUORIDE SUPPLEMENTATION** as appropriate, per 'Sudden Death in the Young: Information for the • Footnote 38 has been updated to read as follows: "If primary water Primary Care Provider' (https://doi.org/10.1542/peds.2021-052044)." source is deficient in fluoride, consider oral fluoride supplementation. See 'Fluoride Use in Caries Prevention in the Primary Care Setting' (https://doi. **DEPRESSION AND SUICIDE RISK** org/10.1542/peds.2020-034637)."

Screening for suicide risk has been added to the existing depression screening recommendation to be consistent with the GLAD-PC and AAP policy.

Footnote 16 has been updated to read as follows: "Screen adolescents for DEVELOPMENTAL depression and suicide risk, making every effort to preserve confidentiality · Footnote 12 has been updated to read as follows: "Screening should of the adolescent. See 'Guidelines for Adolescent Depression in Primary occur per 'Promoting Optimal Development: Identifying Infant and Care (GLAD-PC): Part I. Practice Preparation, Identification, Assessment, and Young Children With Developmental Disorders Through Initial Management' (https://doi.org/10.1542/peds.2017-4081), 'Mental Health Developmental Surveillance and Screening' (https://doi.org/10.1542/ Competencies for Pediatric Practice' (https://doi.org/10.1542/peds.2019-2757), peds.2019-3449)." 'Suicide and Suicide Attempts in Adolescents' (https://doi.org/10.1542/ peds.2016-1420), and 'The 21st Century Cures Act & Adolescent AUTISM SPECTRUM DISORDER Confidentiality' (https://www.adolescenthealth.org/Advocacy/Advocacy-• Footnote 13 has been updated to read as follows: "Screening should Activities/2019-(1)/NASPAG-SAHM-Statement.aspx)." occur per 'Identification, Evaluation, and Management of Children With Autism Spectrum Disorder' (https://doi.org/10.1542/peds.2019-3447)."

BEHAVIORAL/SOCIAL/EMOTIONAL

The Psychosocial/Behavioral Assessment recommendation has been updated to Behavioral/Social/Emotional Screening (annually from newborn to 21 years) to align with AAP policy, the American College of Obstetricians and Gynecologists (Women's Preventive Services Initiative) recommendations and the American Academy of Child & Adolescent Psychiatry guidelines.

Footnote 14 has been updated to read as follows: "Screen for behavioral and social-emotional problems per 'Promoting Optimal Development: Screening for Behavioral and Emotional Problems' (https://doi.org/10.1542/ peds.2014-3716), 'Mental Health Competencies for Pediatric Practice' (https://doi.org/10.1542/peds.2019-2757), 'Clinical Practice Guideline for the Assessment and Treatment of Children and Adolescents With Anxiety Disorders' (https://pubmed.ncbi.nlm.nih.gov/32439401), and 'Screening for Anxiety in Adolescent and Adult Women: A Recommendation From the Women's Preventive Services Initiative' (https://pubmed.ncbi.nlm.nih. gov/32510990/). The screening should be family centered and may include asking about caregiver emotional and mental health concerns and social



determinants of health, racism, poverty, and relational health. See 'Poverty and Child Health in the United States' (https://doi.org/10.1542/peds.2016-0339), 'The Impact of Racism on Child and Adolescent Health' (https://doi. org/10.1542/peds.2019-1765), and 'Preventing Childhood Toxic Stress: Partnering With Families and Communities to Promote Relational Health' (https://doi.org/10.1542/peds.2021-052582)."

FLUORIDE VARNISH

- Footnote 37 has been updated to read as follows: "The USPSTF recommends that primary care clinicians apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption (https://www.uspreventiveservicestaskforce.org/uspstf/ recommendation/prevention-of-dental-caries-in-children-younger-than-age-5-years-screening-and-interventions1). Once teeth are present, apply fluoride varnish to all children every 3 to 6 months in the primary care or dental office based on caries risk. Indications for fluoride use are noted in 'Fluoride Use in Caries Prevention in the Primary Care Setting' (https://doi. ora/10.1542/peds.2020-034637)."
- **CHANGES MADE IN NOVEMBER 2020**

HEPATITIS C VIRUS INFECTION

- Screening for HCV infection has been added to occur at least once between the ages of 18 and 79 years (to be consistent with recommendations of the USPSTF and CDC).
- Footnote 32 has been added to read as follows: "All individuals should be screened for hepatitis C virus (HCV) infection according to the USPSTF (https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/ hepatitis-c-screening) and Centers for Disease Control and Prevention (CDC) recommendations (https://www.cdc.gov/mmwr/volumes/69/rr/ rr6902a1.htm) at least once between the ages of 18 and 79. Those at increased risk of HCV infection, including those who are persons with past or current injection drug use, should be tested for HCV infection and reassessed annually."



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Plain Language Summary:

<u>Background</u>: Serious injury to the bones of the spine requiring immediate medical attention to prevent or minimize injury to the spinal cord.

<u>Should OHP cover this treatment?</u> Staff recommends cover this treatment because similar diagnosis codes are already placed in the funded region of the Prioritized List.

Question: Should burst fractures of the spine be moved to covered lines?

<u>Question source</u>: Denied inpatient claims review

<u>Issue</u>: There are multiple ICD-10-CM codes for stable and unstable burst fractures of vertebra. Some of these codes are on covered lines and some are on uncovered lines.

In general, a burst fracture is serious injury resulting from the vertebral body shattering with enough force to separate the bone fragments and compromise the vertebra's ability to support the spine. Bone fragments can also be displaced into the spinal canal or foramen, leading to pressure on the nerves and compromised function. Potential for a spinal cord injury is high. Burst fractures require immediate attention and treatment to prevent or minimize injury to the spinal cord and typically requires immediate hospitalization and treatment. If the burst fracture is not severe, i.e., has not led to neurological and/or structural compromise, a nonoperative approach can be considered. However, surgery is required if the burst fracture has significantly impaired the mechanical strength of the spine or causes compression of the spinal cord or nerves, leading to neurological deficits.

Multiple denied hospital claims for patients with spinal burst fractures were found on claims review.

ICD-10 Code	Code Description	Current Line(s)
S12.[1-6]	Fractures of cervical vertebrae, all	150 CERVICAL VERTEBRAL
	types, open or closed	DISLOCATIONS/FRACTURES, OPEN OR
		CLOSED; OTHER VERTEBRAL
		DISLOCATIONS/FRACTURES, OPEN OR
		UNSTABLE; SPINAL CORD INJURIES WITH OR
		WITHOUT EVIDENCE OF VERTEBRAL INJURY
S12.[xxx]K	Fractures of cervical vertebrae, all	443 MALUNION AND NONUNION OF
	types, subsequent encounter for	FRACTURE
	fracture with nonunion	
S22.0[x][1-2]	Stable or unstable burst fracture of	478 CLOSED DISLOCATIONS/FRACTURES OF
	thoracic vertebrae, closed	NON-CERVICAL VERTEBRAL COLUMN
		WITHOUT NEUROLOGIC INJURY OR
		STRUCTURAL INSTABILITY
S22.0[x][1-2]	Stable or unstable burst fracture of	150
	thoracic vertebrae, open	
S32.0[x][1-2]	Stable or unstable burst fracture of	478 CLOSED DISLOCATIONS/FRACTURES OF
	lumbar vertebrae, closed	NON-CERVICAL VERTEBRAL COLUMN
		WITHOUT NEUROLOGIC INJURY OR
		STRUCTURAL INSTABILITY

S32.0[x][1-2]	Stable or unstable burst fracture of	150
	lumbar vertebrae, open	

HERC staff recommendation:

 Move the S22.0[x][1-2] family and the S32.0[x][1-2] family (stable or unstable burst fractures of thoracic or lumbar spine) to line 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 <u>Issue</u>: HERC staff have reviewed the current ICD-10-CM "Z" codes that are currently listed as being on the Informational Diagnosis file. "Z" codes include a variety of types of codes, and currently appear on lines, on the INFORMATIONAL DIAGNOSES file, or on the DIAGNOSTIC WORKUP FILE. Several of these codes appear to be appropriate for a clinical encounter. HERC staff proposes moving these codes as shown below.

HERC staff recommendation

1) Advise HSD to move the codes below to the Diagnostic Work Up File and remove from the Informational Diagnosis File

ICD-10	Code Description	Current Placement	Recommended	Comment
Code			Placement	
Z71.2	Person consulting for explanation of examination	INFORMATIONAL DIAGNOSES	DIAGNOSTIC WORKUP FILE	
Z72.51	High risk heterosexual behavior	INFORMATIONAL DIAGNOSES	DIAGNOSTIC WORKUP FILE	Appropriate for STI screening or for PrEP
Z72.52	High risk homosexual behavior	INFORMATIONAL DIAGNOSES	DIAGNOSTIC WORKUP FILE	See above
Z72.53	High risk bisexual behavior	INFORMATIONAL DIAGNOSES	DIAGNOSTIC WORKUP FILE	See above

Plain Language Summary:

Background: Treatment for severe asthma by using heat to widen the bronchial tubes in the lungs.

<u>Should OHP cover this treatment?</u> Staff recommends that OHP not cover this treatment because the evidence shows little benefit and the procedure may increase short-term asthma flareups.

Question: Should bronchial thermoplasty be moved to a covered line?

Question source: Dr. Mark Buchholz, medical director, PacificSource

<u>Issue</u>: Bronchial thermoplasty was last reviewed in 2012 as a new 2013 CPT code. It was found to be investigational and placed on the Excluded List, and then later to line 662/GN173. Dr. Buchholtz is requesting an updated review. Bronchial thermoplasty is an interventional treatment option for severe asthma that involves the delivery of controlled radiofrequency thermal energy to the walls of accessible proximal airways with the intent of reducing excess airway smooth muscle tissue in the airways and reducing the frequency of severe asthma exacerbations on a long-term basis. It was approved by the FDA in 2010.

Updated evidence review

- 1) **D'Anci 2017**, AHRQ evidence review on the effectiveness and safety of bronchial thermoplasty is management of asthma
 - a. N=15 studies (3 RCTs with 432 patients)
 - i. Impact of bronchial thermoplasty (BT)in addition to standard care in patients with asthma
 - b. BT and standard care improved asthma control (defined by the Asthma Control Questionnaire [ACQ] change from baseline to 12 months) and Asthma Quality of Life Questionnaire (AQLQ) scores more than standard care alone to a degree that was statistically significant but not clinically important (low strength of evidence [SOE]).
 - c. However, BT and standard care, compared with a sham bronchoscopic procedure and standard care, did not improve asthma control (defined as ACQ change from baseline to 12 months), hospitalizations for respiratory symptoms, use of rescue medications, pulmonary physiology measures, or AQLQ scores (in the intention-to-treat analysis) (low SOE)
 - d. In the RCTs comparing BT and standard care to standard care alone, evidence was insufficient to assess if BT reduced rates of severe exacerbations
 - e. Common adverse events following BT during the 12-week treatment period in the RCTs included bronchial irritation, chest discomfort, cough, discolored sputum, dyspnea, night awakenings, and wheezing. Hospitalizations were more common in patients undergoing BT than with either standard care alone or sham bronchoscopy during the 12-week treatment period, as were upper respiratory tract infections, wheezing, dyspnea, lower respiratory tract infections, anxiety, and segmental atelectasis, but the events were too infrequent to achieve statistical significance. Severe adverse events (including post-procedure segmental atelectasis due to mucus plugging, hemoptysis, chest infections requiring hospitalization, and bronchial artery pseudoaneurysm) were also reported in six case reports and two small case series

Bronchial Thermoplasty

- f. Conclusions. While asthma control and quality of life measures modestly improved in patients undergoing BT compared to medical management alone in two controlled but nonblinded studies, these measures did not improve in the sham-controlled study. The sham-controlled, blinded study found modest improvements in severe exacerbations and significantly fewer emergency department visits following BT compared to the sham bronchoscopic procedure, but serious adverse events and post-procedure hospitalizations were more common during the 12- week treatment period in patients undergoing BT than in patients undergoing sham treatment. The available body of literature on BT is small and uncertainty remains about appropriate patient selection criteria and the effects of the treatment beyond 5 years.
- 2) NICE 2018, bronchial thermoplasty for severe asthma

https://www.nice.org.uk/guidance/ipg635/evidence/overview-final-pdf-6651284509

- a. N=14 studies (2 SRs with meta-analysis, 1 RCT, 3 case series, 1 non-randomized comparative study, 1 registry and 5 case reports
- b. Quality of life: In a systematic review (SR) of 3 randomized control trials (RCTs, n=429), quality of life assessed by the Asthma Quality of Life Questionnaire (AQLQ) was statistically significantly better in patients who had bronchial thermoplasty (BT) compared with standard medical care (SMC) or sham (mean difference [MD] 0.28, 95% confidence interval [CI] 0.07 to 0.5, p=0.0099; I2=0%), at 12-month follow-up. Mean AQLQ score was 0.28 (0.07 to 0.5) higher in the BT group compared with controls (5.1 to 5.7)
- c. In the SR of 3 RCTs (n=429) asthma control measured using the Asthma Control Questionnaire (ACQ) was not statistically significantly different between patients who had BT and SMC or sham controls (MD -0.15, 95% CI -0.40 to 0.10, p=0.23; I 2=32%) at 12-month follow-up
- d. In 1 RCT (n=112) reported in the SR of 3 RCTs, the mean reduction in mild asthma exacerbations was statistically significantly higher from baseline in patients who had BT (-0.16 ± 0.37 per week) compared with SMC (0.04 ± 0.29 per week, p0.05). In another RCT (n=288) reported in the same SR, the number of severe exacerbations was statistically significantly lower in patients who had BT (0.48 ± 0.067) than sham (0.70 ± 0.122, p<0.05) at 12-month follow-up</p>
- e. In an RCT (n=34) in the SR of 3 RCTs, complete wean from regular corticosteroids was not statistically significantly different in patients who had BT (50% [4/8]) compared with SMC (14% [1/7], p>0.05). In the same RCT, mean reduction in regular oral corticosteroid (OCS) doses was also not statistically significantly different between patients who had BT (63.5 ± 45.4%) and controls (26.21 ± 40.70%, p>0.05) at 12-month follow-up. The SR of 3 RCTs reported that the mean use of rescue medication was not statistically significantly different between patients who had BT (68.95% CI 3.63 to 2.28), p=0.65; I2=0%) at 12-month follow-up
- f. In the SR of 3 RCTs (n=429) admissions to hospital in the post-treatment period were not statistically significantly different between patients who had BT compared with sham or SMC (risk ratio [RR] 1.12, 95% CI 0.44 to 2.85, p=0.82; I 2=0%) at 12-month follow-up. This resulted in 6% (6/100) of patients who had BT needing hospitalization because of a respiratory adverse event (95% CI 1 to 21) compared with 5% (5/100) in the control group. In the SR of 6 studies, the frequency of hospital admissions for respiratory events was not statistically significantly different between 1-year and 5-year follow-up (RR 1.47, 95% CI 0.69 to 3.12, p=0.32; I2=36%) in patients who had BT

- g. In the SR of 6 studies, the frequency of visits to the emergency department (ED) because of respiratory events was not statistically significantly different between 1-year and 5-year follow-up (RR 1.06, 95% CI 0.77 to 1.46, p=0.71; I2=0%) in patients who had BT
- h. Admission to hospital during the treatment period was statistically significantly higher in patients who had BT compared with SMC or sham (RR 3.5, 95% CI 1.26 to 9.68, p=0.016; I2=0%, n=429) in a pooled analysis reported in the SR of 3 RCTs
- i. Respiratory adverse events during the treatment period were more frequent in patients who had BT (407 events) compared with SMC or sham (106 events) in the RCT of 112 patients reported in the SR of 3 RCTs. This was similar in the RCT of 32 patients (136 events in the BT group, 57 events in controls) and in the RCT of 288 patients (85% patients BT group, 76% patients in control group) included in the same SR. Most adverse events happened within 1 day after bronchoscopy and were resolved within 7 days. The frequency of respiratory adverse events was not statistically significantly different at 1-year and 5-year follow-up (RR 3.41, 95%CI 2.96 to 3.93, p<0.00001; I2=70%) in the pooled analysis of patients who had BT, reported in the SR of 6 studies
- j. Conclusions
 - i. There is uncertainty about which patients may benefit from the procedure
 - ii. The procedure should only be used for severe asthma that is not controlled despite optimal drug treatment
- k. Recommendations:
 - i. Current evidence on the safety and efficacy of bronchial thermoplasty for severe asthma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
 - ii. The procedure should only be done by a multidisciplinary team in specialist centers with on-site access to intensive care. It should only be done by clinicians with training in the procedure and experience in managing severe asthma.
 - iii. Clinicians should enter details of all patients who have the procedure onto the UK Severe Asthma Registry.
 - iv. Further research should report details of patient selection and long-term safety and efficacy outcomes

HERC staff summary

Since the 2012 HERC review on this topic, AHRQ and NICE have both conducted evidence reviews. Both evidence-based organizations found that bronchial thermoplasty provides little benefit in addition to optimal medical management, and may cause increases in short term exacerbations. Both reviews found asthma control and quality of life measures to be modestly improved in patients undergoing bronchial thermoplasty, and possible modest improvements in asthma exacerbations. NICE reported no difference in hospital admission or use of steroid inhalers with bronchial thermoplasty. AHRQ concludes that "The available body of literature on BT is small and uncertainty remains about appropriate patient selection criteria and the effects of the treatment beyond 5 years." NICE concludes that bronchial thermoplasty may be considered for use in specialized settings as part of research studies.

HERC staff recommendation:

1) Update the date of last review in GN173 as shown below

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

Line 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
31660-31661	Bronchial thermoplasty	Insufficient evidence of effectiveness	<u>January, 2014</u> August 2022

Comparative Effectiveness Review Number 202

Effectiveness and Safety of Bronchial Thermoplasty in Management of Asthma





Effectiveness and Safety of Bronchial Thermoplasty in Management of Asthma

Structured Abstract

Objective. This review assesses the effectiveness and safety of bronchial thermoplasty (BT) in adults with asthma.

Data sources. We systematically searched the gray literature and five bibliographic databases, MEDLINE[®], Embase[®], PubMed[®], CINAHL[®], and the Cochrane Library, through April 20, 2017.

Review methods. Eligible studies included systematic reviews, meta-analyses, randomized controlled trials (RCTs), and nonrandomized interventional studies with concurrent controls. Case reports and series were also considered for describing adverse events. Studies were evaluated for risk of bias using the Cochrane Risk of Bias instrument, and the evidence base was assessed using the methods guidance established by the Evidence-based Practice Center program.

Results. Fifteen studies, including three RCTs with 5-year single-arm followup in BT-treated patients (n=432 for the RCTs), examined the impact of BT in addition to standard care (continued medical management) on patients with asthma. BT and standard care improved asthma control (defined by the Asthma Control Questionnaire [ACQ] change from baseline to 12 months) and Asthma Quality of Life Questionnaire (AQLQ) scores more than standard care alone to a degree that was statistically significant but not clinically important (low strength of evidence [SOE]). However, BT and standard care, compared with a sham bronchoscopic procedure and standard care, did not improve asthma control (defined as ACO change from baseline to 12 months), hospitalizations for respiratory symptoms, use of rescue medications, pulmonary physiology measures, or AQLQ scores (in the intention-to-treat analysis) (low SOE). In the same sham-controlled trial, BT reduced severe exacerbations after the 12-week treatment period to a statistically but not clinically important degree (low SOE), and patients undergoing BT had fewer emergency department visits than patients who had the sham bronchoscopic procedure (moderate SOE). In the RCTs comparing BT and standard care to standard care alone, evidence was insufficient to assess if BT reduced rates of severe exacerbations. Common adverse events following BT during the 12-week treatment period in the RCTs included bronchial irritation, chest discomfort, cough, discolored sputum, dyspnea, night awakenings, and wheezing. Hospitalizations were more common in patients undergoing BT than with either standard care alone or sham bronchoscopy during the 12-week treatment period, as were upper respiratory tract infections, wheezing, dyspnea, lower respiratory tract infections, anxiety, and segmental atelectasis, but the events were too infrequent to achieve statistical significance. Severe adverse events (including post-procedure segmental atelectasis due to mucus plugging, hemoptysis, chest infections requiring hospitalization, and bronchial artery pseudoaneurysm) were also reported in six case reports and two small case series. Following the 12-week treatment period, rates of respiratory-related hospitalizations were not significantly different between groups for up to 5 years of followup. No deaths were attributed to BT.

Conclusions. While asthma control and quality of life measures modestly improved in patients undergoing BT compared to medical management alone in two controlled but nonblinded studies, these measures did not improve in the sham-controlled study. The sham-controlled, blinded study found modest improvements in severe exacerbations and significantly fewer

emergency department visits following BT compared to the sham bronchoscopic procedure, but serious adverse events and post-procedure hospitalizations were more common during the 12-week treatment period in patients undergoing BT than in patients undergoing sham treatment. The available body of literature on BT is small and uncertainty remains about appropriate patient selection criteria and the effects of the treatment beyond 5 years.

Bronchial thermoplasty for severe asthma

Interventional procedures guidance Published: 19 December 2018 www.nice.org.uk/guidance/ipg635

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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG419.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of bronchial thermoplasty for severe asthma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 1.2 The procedure should only be done by a multidisciplinary team in specialist centres with on-site access to intensive care. It should only be done by clinicians with training in the procedure and experience in managing severe asthma.
- 1.3 Clinicians should enter details of all patients who have the procedure onto the <u>UK Severe Asthma Registry</u>.
- 1.4 Further research should report details of patient selection and long-term safety and efficacy outcomes.

2 The condition, current treatments and procedure

The condition

- 2.1 Asthma is a long-term condition of the airways in the lungs that affects children, young people and adults. It consists of inflammation and constriction of the smooth muscle in the airway walls (bronchoconstriction). This is triggered by increased responsiveness of the airways to various allergic stimuli, leading to airflow obstruction. Symptoms include recurring episodes of wheezing, breathlessness, chest-tightness and coughing.
- 2.2 Asthma is diagnosed and its severity assessed on the basis of symptoms and objective tests of lung function.

Current treatments

2.3 Treatment, including advice about lifestyle changes, aims to reduce the frequency and severity of attacks, allowing the person to lead a normal and

active life. In the UK, treatment for asthma follows <u>NICE's guideline on asthma</u> and <u>guidelines from the Global Initiative for Asthma</u>.

The procedure

- 2.4 The aim of bronchial thermoplasty for severe asthma is to reduce the smooth muscle mass lining the airways, decreasing their ability to constrict.
- 2.5 The procedure is usually done using sedation or general anaesthesia. A catheter is introduced into the bronchial tree. Short pulses of radiofrequency energy are applied circumferentially to sequential portions of the airway wall, moving from the distal to the proximal bronchi. Treatment is usually delivered in 3 sessions with an interval of at least 3 weeks between each session. After the first session, treated airways are evaluated by bronchoscopy before proceeding with further treatment.

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 14 sources, which was discussed by the committee. The evidence included 2 systematic reviews with meta-analysis, 1 randomised controlled trial, 3 case series (2 of which were extensions of randomised trials; evidence from 1 was extracted from 2 published sources), 1 non-randomised comparative study, 1 registry and 5 case reports, and is presented in <u>table 2 of the interventional procedures overview</u>. Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life, reduced exacerbations and hospital admissions, and improved respiratory function.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: pneumothorax, bleeding, admissions to intensive care and, in the longer term, airway stenosis and lung fibrosis.

3.4 Two commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Committee comments

- 3.5 There is uncertainty about which patients may benefit from the procedure.
- 3.6 The committee noted that the device used in this procedure does not have a CE mark for use in people younger than 18 years.
- 3.7 The committee noted that there is some evidence to suggest this procedure may not be suitable for people with bronchiectasis.
- 3.8 The procedure should only be used for severe asthma that is not controlled despite optimal drug treatment.
- 3.9 The committee was informed that bronchial thermoplasty could complement the use of biological treatment in the future.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.

Accreditation



Section 5.0 New Codes

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
B37.31	Acute candidiasis of vulva and vagina	Parent code B37.3 (Candidiasis of vulva and	428 VAGINITIS AND CERVICITIS	
		vagina) was on line 428		
B37.32	Chronic candidiasis of vulva and vagina	See above	428 VAGINITIS AND CERVICITIS	
D59.30	Hemolytic-uremic syndrome, unspecified	Parent code D59.3 (Hemolytic-uremic syndrome)	99 END STAGE RENAL DISEASE	
		was on line 99,148	148 ACQUIRED HEMOLYTIC ANEMIAS	
D59.31	Infection-associated hemolytic-uremic	See above	99 END STAGE RENAL DISEASE	
	syndrome		148 ACQUIRED HEMOLYTIC ANEMIAS	
D59.32	Hereditary hemolytic-uremic syndrome	See above	99 END STAGE RENAL DISEASE	
			148 ACQUIRED HEMOLYTIC ANEMIAS	
D59.39	Other hemolytic-uremic syndrome	See above	99 END STAGE RENAL DISEASE	
			148 ACQUIRED HEMOLYTIC ANEMIAS	
D68.00	Von Willebrand disease, unspecified	Parent code D68.0 (Von Willebrand's disease) was	109 COAGULATION DEFECTS	
		on line 109		
D68.01	Von Willebrand disease, type 1	See above	109 COAGULATION DEFECTS	
D68.020	Von Willebrand disease, type 2A	See above	109 COAGULATION DEFECTS	
D68.021	Von Willebrand disease, type 2B	See above	109 COAGULATION DEFECTS	
D68.022	Von Willebrand disease, type 2M	See above	109 COAGULATION DEFECTS	
D68.023	Von Willebrand disease, type 2N	See above	109 COAGULATION DEFECTS	
D68.029	Von Willebrand disease, type 2, unspecified	See above	109 COAGULATION DEFECTS	
D68.03	Von Willebrand disease. type 3	See above	109 COAGULATION DEFECTS	
D68.04	Acquired von Willebrand disease	See above	109 COAGULATION DEFECTS	
D68.09	Other von Willebrand disease	See above	109 COAGULATION DEFECTS	
D75.821	Non-immune heparin-induced	Parent code D75.82 (Heparin induced	303 THROMBOCYTOPENIA	
	thrombocytopenia	thrombocytopenia (HIT)) was on line 303		
D75.822	Immune-mediated heparin-induced	See above	303 THROMBOCYTOPENIA	
	thrombocytopenia			
D75.828	Other heparin-induced thrombocytopenia	See above	303 THROMBOCYTOPENIA	
	syndrome			
D75.829	Heparin-induced thrombocytopenia, unspecified	See above	303 THROMBOCYTOPENIA	
D75.84	Other platelet-activating anti-PF4 disorders		303 THROMBOCYTOPENIA	Causes thrombocytopenia

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
D81.82	Activated Phosphoinositide 3-kinase Delta		313 DISORDERS INVOLVING THE	APDS is a primary
	Syndrome [APDS]		IMMUNE SYSTEM	immunodeficiency disease
				caused by activating gain of
				function mutations in
				the PIK3CD gene. APDS and APDS-
				2 affected individuals present
				with similar symptoms, which
				include increased susceptibility to
				airway
				infections, bronchiectasis and
				lymphoproliferation
E34.30	Short stature due to endocrine disorder.	Parent code E34.3 (Short stature due to endocrine	652 ENDOCRINE AND METABOLIC	
	unspecified	disorder) was on line 652	CONDITIONS WITH NO OR MINIMALLY	
		,	EFFECTIVE TREATMENTS OR NO	
			TREATMENT NECESSARY	
E34.31	Constitutional short stature	Parent code E34.3 (Short stature due to endocrine	652 ENDOCRINE AND METABOLIC	
		disorder) was on line 652	CONDITIONS WITH NO OR MINIMALLY	
			EFFECTIVE TREATMENTS OR NO	
			TREATMENT NECESSARY	
E34.321	Primary insulin-like growth factor-1 (IGF-1)	Parent code E34.3 (Short stature due to endocrine	652 ENDOCRINE AND METABOLIC	Genetic condition which results
	deficiency	disorder) was on line 652	CONDITIONS WITH NO OR MINIMALLY	in inability to respond to human
			EFFECTIVE TREATMENTS OR NO	growth hormone
			TREATMENT NECESSARY	
E34.322	Insulin-like growth factor-1 (IGF-1) resistance	Parent code E34.3 (Short stature due to endocrine	652 ENDOCRINE AND METABOLIC	Genetic condition which results
		disorder) was on line 652	CONDITIONS WITH NO OR MINIMALLY	in inability to respond to human
			EFFECTIVE TREATMENTS OR NO	growth hormone
			TREATMENT NECESSARY	
E34.328	Other genetic causes of short stature	Parent code E34.3 (Short stature due to endocrine	652 ENDOCRINE AND METABOLIC	
		disorder) was on line 652	CONDITIONS WITH NO OR MINIMALLY	
			EFFECTIVE TREATMENTS OR NO	
			TREATMENT NECESSARY	
E34.329	Unspecified genetic causes of short stature	Parent code E34.3 (Short stature due to endocrine	652 ENDOCRINE AND METABOLIC	
		disorder) was on line 652	CONDITIONS WITH NO OR MINIMALLY	
			EFFECTIVE TREATMENTS OR NO	
			TREATMENT NECESSARY	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
E34.39	Other short stature due to endocrine disorder	Parent code E34.3 (Short stature due to endocrine disorder) was on line 652	652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY	
			EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	
E87.20	Acidosis, unspecified	Parent code E87.2 (Acidosis) was on line 221	221 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE	
E87.21	Acute metabolic acidosis	Parent code E87.2 (Acidosis) was on line 221	221 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE	
E87.22	Chronic metabolic acidosis	Parent code E87.2 (Acidosis) was on line 221	221 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE	
E87.29	Other acidosis	Parent code E87.2 (Acidosis) was on line 221	221 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE	
F01.511	Vascular dementia, unspecified severity, with agitation	Parent code F01.51 (Vascular dementia with behavioral disturbance) was on lines 71,201,292,345,377	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	Discussed and approved by BHAP
F01.518	Vascular dementia, unspecified severity, with other behavioral disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
F01.52	Vascular dementia, unspecified severity, with psychotic disturbance	Previously coded with F03.91 (Unspecified dementia with behavioral disturbance) was is on lines 71,201,292,345,377	71,201,292,345,377	Discussed and approved by BHAP
F01.53	Vascular dementia, unspecified severity, with mood disturbance	See F01.511	71,201,292,345,377	Discussed and approved by BHAP
F01.54	Vascular dementia, unspecified severity, with anxiety	See F01.511	71,201,292,345,377	Discussed and approved by BHAP
F01.A0	Vascular dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	New code family. Other dementia codes on lines 71,201,292,345,377	71,201,292,345,377	Discussed and approved by BHAP
F01.A11	Vascular dementia, mild, with agitation	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.A18	Vascular dementia, mild, with other behavioral disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.A2	Vascular dementia, mild, with psychotic disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.A3	Vascular dementia, mild, with mood disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.A4	Vascular dementia, mild, with anxiety	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.B0	Vascular dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.B11	Vascular dementia, moderate, with agitation	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.B18	Vascular dementia, moderate, with other behavioral disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.B2	Vascular dementia, moderate, with psychotic disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.B3	Vascular dementia, moderate, with mood disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.B4	Vascular dementia, moderate, with anxiety	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.C0	Vascular dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	See above	71,201,292,345,377	Discussed and approved by BHAP

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
F01.C11	Vascular dementia, severe, with agitation	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.C18	Vascular dementia, severe, with other behavioral disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.C2	Vascular dementia, severe, with psychotic disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.C3	Vascular dementia, severe, with mood disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F01.C4	Vascular dementia, severe, with anxiety	See above	71,201,292,345,377	Discussed and approved by BHAP
F02.811	Dementia in other diseases classified elsewhere, unspecified severity, with agitation	Parent code F02.81 (Dementia in other diseases classified elsewhere with behavioral disturbance) was on line 201 only	71,201,292,345,377	Discussed and approved by BHAP
F02.818	Dementia in other diseases classified elsewhere, unspecified severity, with other behavioral disturbance	Parent code F02.81 (Dementia in other diseases classified elsewhere with behavioral disturbance) was on line 201 only	71,201,292,345,377	Discussed and approved by BHAP
F02.82	Dementia in other diseases classified elsewhere, unspecified severity, with psychotic disturbance	Parent code F02.81 (Dementia in other diseases classified elsewhere with behavioral disturbance) was on line 201 only	71,201,292,345,377	Discussed and approved by BHAP
F02.83	Dementia in other diseases classified elsewhere, unspecified severity, with mood disturbance	Parent code F02.81 (Dementia in other diseases classified elsewhere with behavioral disturbance) was on line 201 only	71,201,292,345,377	Discussed and approved by BHAP
F02.84	Dementia in other diseases classified elsewhere, unspecified severity, with anxiety	Parent code F02.81 (Dementia in other diseases classified elsewhere with behavioral disturbance) was on line 201 only	71,201,292,345,377	Discussed and approved by BHAP
F02.A0	Dementia in other diseases classified elsewhere, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.A11	Dementia in other diseases classified elsewhere, mild, with agitation	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.A18	Dementia in other diseases classified elsewhere, mild, with other behavioral disturbance	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
F02.A2	Dementia in other diseases classified elsewhere, mild, with psychotic disturbance	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.A3	Dementia in other diseases classified elsewhere, mild, with mood disturbance	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.A4	Dementia in other diseases classified elsewhere, mild, with anxiety	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.B0	Dementia in other diseases classified elsewhere, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.B11	Dementia in other diseases classified elsewhere, moderate, with agitation	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.B18	Dementia in other diseases classified elsewhere, moderate, with other behavioral disturbance	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.B2	Dementia in other diseases classified elsewhere, moderate, with psychotic disturbance	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.B3	Dementia in other diseases classified elsewhere, moderate, with mood disturbance	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.B4	Dementia in other diseases classified elsewhere, moderate, with anxiety	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.C0	Dementia in other diseases classified elsewhere, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.C11	Dementia in other diseases classified elsewhere, severe, with agitation	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.C18	Dementia in other diseases classified elsewhere, severe, with other behavioral disturbance	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.C2	Dementia in other diseases classified elsewhere, severe, with psychotic disturbance	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F02.C3	Dementia in other diseases classified elsewhere, severe, with mood disturbance	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
F02.C4	Dementia in other diseases classified elsewhere, severe, with anxiety	Similar to F02.811	71,201,292,345,377	Discussed and approved by BHAP
F03.911	Unspecified dementia, unspecified severity, with agitation	Parent code F03.91 (Unspecified dementia with behavioral disturbance) was on lines 71,201,292,345,377	71,201,292,345,377	Discussed and approved by BHAP
F03.918	Unspecified dementia, unspecified severity, with other behavioral disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.92	Unspecified dementia, unspecified severity, with psychotic disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F03.93	Unspecified dementia, unspecified severity, with mood disturbance	See above	71,201,292,345,377	Discussed and approved by BHAP
F03.94	Unspecified dementia, unspecified severity, with anxiety	See above	71,201,292,345,377	Discussed and approved by BHAP
F03.A0	Unspecified dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.A11	Unspecified dementia, mild, with agitation	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.A18	Unspecified dementia, mild, with other behavioral disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.A2	Unspecified dementia, mild, with psychotic disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.A3	Unspecified dementia, mild, with mood disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.A4	Unspecified dementia, mild, with anxiety	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.B0	Unspecified dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.B11	Unspecified dementia, moderate, with agitation	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.B18	Unspecified dementia, moderate, with other behavioral disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.B2	Unspecified dementia, moderate, with psychotic disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
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F03.B3	Unspecified dementia, moderate, with mood disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.B4	Unspecified dementia, moderate, with anxiety	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.C0	Unspecified dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.C11	Unspecified dementia, severe, with agitation	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.C18	Unspecified dementia, severe, with other behavioral disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.C2	Unspecified dementia, severe, with psychotic disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.C3	Unspecified dementia, severe, with mood disturbance	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F03.C4	Unspecified dementia, severe, with anxiety	Similar to F03.911	71,201,292,345,377	Discussed and approved by BHAP
F06.70	Mild neurocognitive disorder due to known physiological condition without behavioral disturbance	Previously coded with F06.8 (Other specified mental disorders due to known physiological condition) which is on lines 71,201,292,345,377	71,201,292,345,377	Discussed and approved by BHAP
F06.71	Mild neurocognitive disorder due to known physiological condition with behavioral disturbance	See F06.70	71,201,292,345,377	Discussed and approved by BHAP
F10.90	Alcohol use, unspecified, uncomplicated	F11.90 (Opioid use, unspecified, uncomplicated) is on line 649	649 MENTAL DISORDERS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	Discussed and approved by BHAP
F10.91	Alcohol use, unspecified, in remission	Other "in remission codes" are on line 4	4 SUBSTANCE USE DISORDER	Discussed and approved by BHAP
F11.91	Opioid use, unspecified, in remission	See above	4 SUBSTANCE USE DISORDER	Discussed and approved by BHAP
F12.91	Cannabis use, unspecified, in remission	See above	4 SUBSTANCE USE DISORDER	Discussed and approved by BHAP
F13.91	Sedative, hypnotic or anxiolytic use, unspecified, in remission	See above	4 SUBSTANCE USE DISORDER	Discussed and approved by BHAP
F14.91	Cocaine use, unspecified, in remission	See above	4 SUBSTANCE USE DISORDER	Discussed and approved by BHAP

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
F15.91	Other stimulant use, unspecified, in remission		4 SUBSTANCE USE DISORDER	Discussed and approved by BHAP
		See above		
F16.91	Hallucinogen use, unspecified, in remission		4 SUBSTANCE USE DISORDER	Discussed and approved by BHAP
		See above		
F18.91	Inhalant use, unspecified, in remission		4 SUBSTANCE USE DISORDER	Discussed and approved by BHAP
		See above		
F19.91	Other psychoactive substance use, unspecified,		4 SUBSTANCE USE DISORDER	Discussed and approved by BHAP
	in remission	See above		
F43.81	Prolonged grief disorder	Parent code F43.8 (Other reactions to severe	445 ADJUSTMENT DISORDERS	Discussed and approved by BHAP
		stress) was on line 445		
F43.89	Other reactions to severe stress	Parent code F43.8 (Other reactions to severe	445 ADJUSTMENT DISORDERS	Discussed and approved by BHAP
		stress) was on line 445		
G71.031	Autosomal dominant limb girdle muscular	Other muscular dystrophy codes are on the	71 NEUROLOGICAL DYSFUNCTION IN	
	dystrophy	dysfunction lines	BREATHING, EATING, SWALLOWING,	
			BOWEL, OR BLADDER CONTROL CAUSED	
			BY CHRONIC CONDITIONS; ATTENTION	
			TO OSTOMIES	
			292 NEUROLOGICAL DYSFUNCTION IN	
			POSTURE AND MOVEMENT CAUSED BY	
			CHRONIC CONDITIONS	
			345 NEUROLOGICAL DYSEUNCTION IN	
			CONDITIONS	
			377 DYSELINCTION RESULTING IN LOSS	
			INDEPENDENCE IN SELE-DIRECTED CARE	
			CAUSE NEOROLOGICAE DISI UNCTION	
G71.032	Autosomal recessive limb girdle muscular	See above	71,292,345,377	
	dystrophy due to calpain-3 dysfunction			
G71.033	Limb girdle muscular dystrophy due to dysferlin	See above	71.292.345.377	
	dysfunction		, - ,, -	
G71.0340	Limb girdle muscular dystrophy due to	See above	71,292,345,377	
	sarcoglycan dysfunction, unspecified			
G71.0341	Limb girdle muscular dystrophy due to alpha	See above	71,292,345,377	
	sarcoglycan dysfunction			
G71.0342	Limb girdle muscular dystrophy due to beta	See above	71,292,345,377	
	sarcoglycan dysfunction			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
G71.0349	Limb girdle muscular dystrophy due to other	See above	71,292,345,377	
	sarcoglycan dysfunction			
G71.035	Limb girdle muscular dystrophy due to	See above	71,292,345,377	
	anoctamin-5 dysfunction			
G71.038	Other limb girdle muscular dystrophy	See above	71,292,345,377	
G71.039	Limb girdle muscular dystrophy, unspecified	See above	71,292,345,377	
G90.A	Postural orthostatic tachycardia syndrome [POTS]		71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	See Issues
G93.31	Postviral fatigue syndrome		531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS	See issues
G93.32	Myalgic encephalomyelitis/chronic fatigue syndrome		531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS	See issues
G93.39	Other post infection and related fatigue syndromes		531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS	See issues
120.2	Refractory angina pectoris		189 CHRONIC ISCHEMIC HEART DISEASE	See issues
125.112	Atherosclerosic heart disease of native coronary artery with refractory angina pectoris		189 CHRONIC ISCHEMIC HEART DISEASE	See issues

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
125.702	Atherosclerosis of coronary artery bypass		189 CHRONIC ISCHEMIC HEART DISEASE	See issues
	graft(s), unspecified, with refractory angina			
	pectoris			
125.712	Atherosclerosis of autologous vein coronary		189 CHRONIC ISCHEMIC HEART DISEASE	See issues
	artery bypass graft(s) with refractory angina			
	pectoris			
125.722	Atherosclerosis of autologous artery coronary		189 CHRONIC ISCHEMIC HEART DISEASE	See issues
	artery bypass graft(s) with refractory angina			
	pectoris			
125.732	Atherosclerosis of nonautologous biological		189 CHRONIC ISCHEMIC HEART DISEASE	See issues
	coronary artery bypass graft(s) with refractory			
	angina pectoris			
125.752	Atherosclerosis of native coronary artery of		189 CHRONIC ISCHEMIC HEART DISEASE	See issues
	transplanted heart with refractory angina			
	pectoris			
125.762	Atherosclerosis of bypass graft of coronary		189 CHRONIC ISCHEMIC HEART DISEASE	See issues
	artery of transplanted heart with refractory			
	angina pectoris			
125.792	Atherosclerosis of other coronary artery bypass		189 CHRONIC ISCHEMIC HEART DISEASE	See issues
	graft(s) with refractory angina pectoris			
131.31	Malignant pericardial effusion in diseases	Parent code I31.3 (Pericardial effusion	81 MYOCARDITIS, PERICARDITIS, AND	
	classified elsewhere	(noninflammatory)) was on line 81	ENDOCARDITIS	
131.39	Other pericardial effusion (noninflammatory)	Parent code I31.3 (Pericardial effusion	81 MYOCARDITIS, PERICARDITIS, AND	
		(noninflammatory)) was on line 81	ENDOCARDITIS	
134.81	Nonrheumatic mitral (valve) annulus	Parent code I34.8 (Other nonrheumatic mitral	257 DISEASES OF MITRAL, TRICUSPID,	
	calcification	valve disorders) was on line 257	AND PULMONARY VALVES	
134.89	Other nonrheumatic mitral valve disorders	Parent code I34.8 (Other nonrheumatic mitral	257 DISEASES OF MITRAL, TRICUSPID,	
		valve disorders) was on line 257	AND PULMONARY VALVES	
			_	
147.20	Ventricular tachycardia, unspecified	Parent code l47.2 () was on lines 264 and 281	264 CONGESTIVE HEART FAILURE,	
			CARDIOMYOPATHY, MALIGNANT	
			ARRHYTHMIAS, AND COMPLEX	
			CONGENITAL HEART DISEASE	
			281 LIFE-THREATENING CARDIAC	
			ARRHYTHMIAS	
147.04				
147.21	Torsades de pointes	See above	264,281	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
147.29	Other ventricular tachycardia	See above	264,281	
171.010	Dissection of ascending aorta	I71.0 family (dissection of aorta) is on line 284	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.011	Dissection of aortic arch	I71.0 family (dissection of aorta) is on line 284	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.012	Dissection of descending thoracic aorta	I71.0 family (dissection of aorta) is on line 284	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.019	Dissection of thoracic aorta, unspecified	I71.0 family (dissection of aorta) is on line 284	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.10	Thoracic aortic aneurysm, ruptured, unspecified	See I71.20	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.11	Aneurysm of the ascending aorta, ruptured	See I71.10	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.12	Aneurysm of the aortic arch, ruptured	See I71.10	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.13	Aneurysm of the descending thoracic aorta,	See I71.10	284 DISSECTING OR RUPTURED AORTIC	
	ruptured		ANEURYSM	
171.20	Thoracic aortic aneurysm, without rupture,	Parent code I71.1 (Thoracic aortic aneurysm,	325 NON-DISSECTING ANEURYSM	
	unspecified	without rupture) was on line 325	WITHOUT RUPTURE	
171.21	Aneurysm of the ascending aorta, without	See I71.20	325 NON-DISSECTING ANEURYSM	
	rupture		WITHOUT RUPTURE	
171.22	Aneurysm of the aortic arch, without rupture	See I71.20	325 NON-DISSECTING ANEURYSM	
			WITHOUT RUPTURE	
171.23	Aneurysm of the descending thoracic aorta,	See I71.20	325 NON-DISSECTING ANEURYSM	
	without rupture		WITHOUT RUPTURE	
171.30	Abdominal aortic aneurysm, ruptured,	Parent code I71.3 (Abdominal aortic aneurysm,	284 DISSECTING OR RUPTURED AORTIC	
	unspecified	ruptured) was on line 284	ANEURYSM	
171.31	Pararenal abdominal aortic aneurysm, ruptured	See I71.30	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.32	Juxtarenal abdominal aortic aneurysm, ruptured	See 171.30	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.33	Infrarenal abdominal aortic aneurysm, ruptured	See 171.30	284 DISSECTING OR RUPTURED AORTIC	
			ANEURYSM	
171.40	Abdominal aortic aneurysm, without rupture,	Parent code I71.4 (Abdominal aortic aneurysm,	325 NON-DISSECTING ANEURYSM	
	unspecified	without rupture) was on line 325	WITHOUT RUPTURE	
171.41	Pararenal abdominal aortic aneurysm, without	See I71.40	325 NON-DISSECTING ANEURYSM	
	rupture		WITHOUT RUPTURE	<u> </u>
171.42	Juxtarenal abdominal aortic aneurysm, without	See 171.40	325 NON-DISSECTING ANEURYSM	
	rupture		WITHOUT RUPTURE	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
171.43	Infrarenal abdominal aortic aneurysm, without	See 171.40	325 NON-DISSECTING ANEURYSM	
	rupture		WITHOUT RUPTURE	
171.50	Thoracoabdominal aortic aneurysm, ruptured,	Parent code I71.5 (Thoracoabdominal aortic	284 DISSECTING OR RUPTURED AORTIC	
	unspecified	aneurysm, ruptured) was on line 284	ANEURYSM	
171.51	Supraceliac aneurysm of the abdominal aorta,	See 171.50	284 DISSECTING OR RUPTURED AORTIC	
	ruptured		ANEURYSM	
171.52	Paravisceral aneurysm of the abdominal aorta,	See 171.50	284 DISSECTING OR RUPTURED AORTIC	
	ruptured		ANEURYSM	
171.60	Thoracoabdominal aortic aneurysm, without	Parent code I71.6 (Thoracoabdominal aortic	325 NON-DISSECTING ANEURYSM	
	rupture, unspecified	aneurysm, without rupture) was on line 325	WITHOUT RUPTURE	
171.61	Supraceliac aneurysm of the abdominal aorta,	See I71.60	325 NON-DISSECTING ANEURYSM	
	without rupture		WITHOUT RUPTURE	
171.62	Paravisceral aneurysm of the abdominal aorta,	See 171.60	325 NON-DISSECTING ANEURYSM	
	without rupture		WITHOUT RUPTURE	
177.82	Antineutrophilic cytoplasmic antibody [ANCA]		99 END STAGE RENAL DISEASE	See Issues
	vasculitis		129 GRANULOMATOSIS WITH	
			POLYANGIITIS	
			219 PULMONARY FIBROSIS	
J95.87	Transfusion-associated dyspnea (TAD)			See Issues
			285 COMPLICATIONS OF A PROCEDURE	
			ALWAYS REQUIRING TREATMENT	
K76.82	Hepatic encephalopathy	Previously coded with K72.9X (Hepatic failure)	334 ALCOHOLIC FATTY LIVER OR	
		which is on line 334	ALCOHOLIC HEPATITIS, CIRRHOSIS OF	
			LIVER	
M51.A0	Intervertebral annulus fibrosus defect, lumbar	Previously coded with M51.86 (Other	402 CONDITIONS OF THE BACK AND	
	region, unspecified size	intervertebral disc disorders, lumbar region)	SPINE	
		which is on lines 402 and 530	530 CONDITIONS OF THE BACK AND	
			SPINE WITHOUT URGENT SURGICAL	
			INDICATIONS	
M51.A1	Intervertebral annulus fibrosus defect, small,	See M51.A0	402,530	
	lumbar region			
M51.A2	Intervertebral annulus fibrosus defect, large,	See M51.A0	402,530	
	lumbar region			
M51.A3	Intervertebral annulus fibrosus defect,	Previously coded with M51.87 (Other	402 CONDITIONS OF THE BACK AND	
	lumbosacral region, unspecified size	intervertebral disc disorders, lumbosacral region)	SPINE	
		which is on lines 402 and 530	530 CONDITIONS OF THE BACK AND	
			SPINE WITHOUT URGENT SURGICAL	
			INDICATIONS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
M51.A4	Intervertebral annulus fibrosus defect, small,	See M51.A3	402,530	
	lumbosacral region			
M51.A5	Intervertebral annulus fibrosus defect, large,	See M51.A3	402,530	
	lumbosacral region			
M62.5A0	Muscle wasting and atrophy, not elsewhere	Other muscle wasting and atrophy diagnosis	292 NEUROLOGICAL DYSFUNCTION IN	
	classified, back, cervical	codes are on lines 292 and 377	POSTURE AND MOVEMENT CAUSED BY	
			CHRONIC CONDITIONS	
			377 DYSFUNCTION RESULTING IN LOSS	
			OF ABILITY TO MAXIMIZE LEVEL OF	
			INDEPENDENCE IN SELF-DIRECTED CARE	
			CAUSED BY CHRONIC CONDITIONS THAT	
			CAUSE NEUROLOGICAL DYSFUNCTION	
M62.5A1	Muscle wasting and atrophy, not elsewhere	See M62.5A0	292.377	
11102.0712	classified, back, thoracic			
M62.5A2	Muscle wasting and atrophy, not elsewhere	See M62.5A0	292,377	
	classified, back, lumbosacral			
M62.5A9	Muscle wasting and atrophy, not elsewhere	See M62.5A0	292,377	
	classified, back, unspecified level			
M93.004	Unspecified slipped upper femoral epiphysis	Similar slipped upper femoral epiphysis codes are	355 CLOSED FRACTURE OF EXTREMITIES	
	(nontraumatic), bilateral hips	on line 355	(EXCEPT MINOR TOES)	
M93.014	Acute slipped upper femoral epiphysis, stable	See M93.004	355	
	(nontraumatic), bilateral hips			
M93.024	Chronic slipped upper femoral epiphysis, stable	See M93.004	355	
	(nontraumatic), bilateral hips			
M93.034	Acute on chronic slipped upper femoral	See M93.004	355	
	epiphysis, stable (nontraumatic), bilateral hips			
M93.041	Acute slipped upper femoral epiphysis, unstable	See M93.004	355	
	(nontraumatic), right hip			
M93.042	Acute slipped upper femoral epiphysis, unstable	See M93.004	355	
	(nontraumatic), left hip			
M93.043	Acute slipped upper femoral epiphysis, unstable	See M93.004	355	
	(nontraumatic), unspecified hip			ł
M93.044	Acute slipped upper femoral epiphysis, unstable	See M93.004	355	
	(nontraumatic), bilateral hips			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
M93.051	Acute on chronic slipped upper femoral	See M93.004	355	
	epiphysis, unstable (nontraumatic), right hip			
M93.052	Acute on chronic slipped upper femoral	See M93.004	355	
	epiphysis, unstable (nontraumatic), left hip			
M93.053	Acute on chronic slipped upper femoral	See M93.004	355	
	epiphysis, unstable (nontraumatic), unspecified hip			
M93.054	Acute on chronic slipped upper femoral	See M93.004	355	
	epiphysis, unstable (nontraumatic), bilateral hips			
M93.061	Acute slipped upper femoral epiphysis,	See M93.004	355	
	unspecified stability (nontraumatic), right hip			
M93.062	Acute slipped upper femoral epiphysis,	See M93.004	355	
	unspecified stability (nontraumatic), left hip			
M93.063	Acute slipped upper femoral epiphysis,	See M93.004	355	
	unspecified stability (nontraumatic), unspecified			
	hip			
M93.064	Acute slipped upper femoral epiphysis,	See M93.004	355	
	hips			
M93.071	Acute on chronic slipped upper femoral	See M93.004	355	
	epiphysis, unspecified stability (nontraumatic),			
	right hip			
M93.072	Acute on chronic slipped upper femoral	See M93.004	355	
	epiphysis, unspecified stability (nontraumatic),			
	left hip			
M93.073	Acute on chronic slipped upper femoral	See M93.004	355	
	epipinysis, unspecified stability (nontraumatic),			
M93.074	Acute on chronic slipped upper femoral	See M93.004	355	
	epiphysis, unspecified stability (nontraumatic),			
	bilateral hips			
M96.A1	Fracture of sternum associated with chest	S22.20XA (Unspecified fracture of sternum, initial	490 CLOSED FRACTURES OF RIBS,	
	compression and cardiopulmonary resuscitation	encounter for closed fracture) is on line 490	STERNUM AND COCCYX	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
M96.A2	Fracture of one rib associated with chest	Rib fractures are on line 490	490	
	compression and cardiopulmonary resuscitation			
M96.A3	Multiple fractures of ribs associated with chest	Rib fractures are on line 490	490	
	compression and cardiopulmonary resuscitation			
M96.A4	Flail chest associated with chest compression	S22.5 (Flail chest) is on line 490	490	
	and cardiopulmonary resuscitation			
M96.A9	Other fracture associated with chest	see series above	490	
	compression and cardiopulmonary resuscitation			
N14.11	Contrast-induced nephropathy	Parent code N14.1 (Nephropathy induced by	99 END STAGE RENAL DISEASE	
		other drugs, medicaments and biological	339 CHRONIC KIDNEY DISEASE	
		substances) was on lines 99 and 339		
N14.19	Nephropathy induced by other drugs,	See above	99,339	
	medicaments and biological substances			
N76.82	Fournier disease of vagina and vulva	Other Fournier's gangrene diagnoses (N49.3) are	47 DEEP ABSCESSES, INCLUDING	
		on line 47	APPENDICITIS AND	
N80.00	Endometriosis of the uterus, unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.01	Superficial endometriosis of the uterus	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.02	Deep endometriosis of the uterus	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.03	Adenomyosis of the uterus	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.101	Endometriosis of right ovary, unspecified depth	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.102	Endometriosis of left ovary, unspecified depth	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.103	Endometriosis of bilateral ovaries, unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	depth	395	ADENOMYOSIS	
N80.109	Endometriosis of ovary, unspecified side,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.111	Superficial endometriosis of right ovary	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.112	Superficial endometriosis of left ovary	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
N80.113	Superficial endometriosis of bilateral ovaries	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.119	Superficial endometriosis of ovary, unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	ovary	395	ADENOMYOSIS	
N80.121	Deep endometriosis of right ovary	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.122	Deep endometriosis of left ovary	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.123	Deep endometriosis of bilateral ovaries	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.129	Deep endometriosis of ovary, unspecified ovary	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.201	Endometriosis of right fallopian tube,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.202	Endometriosis of left fallopian tube, unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	depth	395	ADENOMYOSIS	
N80.203	Endometriosis of bilateral fallopian tubes,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.209	Endometriosis of unspecified fallopian tube,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.211	Superficial endometriosis of right fallopian tube	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.212	Superficial endometriosis of left fallopian tube	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.213	Superficial endometriosis of bilateral fallopian	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	tubes	395	ADENOMYOSIS	
N80.219	Superficial endometriosis of unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	fallopian tube	395	ADENOMYOSIS	
N80.221	Deep endometriosis of right fallopian tube	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.222	Deep endometriosis of left fallopian tube	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.223	Deep endometriosis of bilateral fallopian tubes	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.229	Deep endometriosis of unspecified fallopian	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	tube	395	ADENOMYOSIS	
N80.30	Endometriosis of pelvic peritoneum, unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
N80.311	Superficial endometriosis of the anterior cul-de-	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	sac	395	ADENOMYOSIS	
N80.312	Deep endometriosis of the anterior cul-de-sac	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.319	Endometriosis of the anterior cul-de-sac,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.321	Superficial endometriosis of the posterior cul-de-	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	sac	395	ADENOMYOSIS	
N80.322	Deep endometriosis of the posterior cul-de-sac	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.329	Endometriosis of the posterior cul-de-sac,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.331	Superficial endometriosis of the right pelvic	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	sidewall	395	ADENOMYOSIS	
N80.332	Superficial endometriosis of the left pelvic	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	sidewall	395	ADENOMYOSIS	
N80.333	Superficial endometriosis of bilateral pelvic	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	sidewall	395	ADENOMYOSIS	
N80.339	Superficial endometriosis of pelvic sidewall,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified side	395	ADENOMYOSIS	
N80.341	Deep endometriosis of the right pelvic sidewall	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.342	Deep endometriosis of the left pelvic sidewall	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.343	Deep endometriosis of the bilateral pelvic	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	sidewall	395	ADENOMYOSIS	
N80.349	Deep endometriosis of the pelvic sidewall,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified side	395	ADENOMYOSIS	
N80.351	Endometriosis of the right pelvic sidewall,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.352	Endometriosis of the left pelvic sidewall,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.353	Endometriosis of bilateral pelvic sidewall,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.359	Endometriosis of pelvic sidewall, unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	side, unspecified depth	395	ADENOMYOSIS	
N80.361	Superficial endometriosis of the right pelvic brim	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
N80.362	Superficial endometriosis of the left pelvic brim	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.363	Superficial endometriosis of bilateral pelvic brim	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.369	Superficial endometriosis of the pelvic brim,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified side	395	ADENOMYOSIS	
N80.371	Deep endometriosis of the right pelvic brim	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.372	Deep endometriosis of the left pelvic brim	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.373	Deep endometriosis of bilateral pelvic brim	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.379	Deep endometriosis of the pelvic brim,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified side	395	ADENOMYOSIS	
N80.381	Endometriosis of the right pelvic brim,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.382	Endometriosis of the left pelvic brim,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.383	Endometriosis of bilateral pelvic brim,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.389	Endometriosis of the pelvic brim, unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	side, unspecified depth	395	ADENOMYOSIS	
N80.391	Superficial endometriosis of the pelvic	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	peritoneum, other specified sites	395	ADENOMYOSIS	
N80.392	Deep endometriosis of the pelvic peritoneum,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	other specified sites	395	ADENOMYOSIS	
N80.399	Endometriosis of the pelvic peritoneum, other	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	specified sites, unspecified depth	395	ADENOMYOSIS	
N80.3A1	Superficial endometriosis of the right	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	uterosacral ligament	395	ADENOMYOSIS	
N80.3A2	Superficial endometriosis of the left uterosacral	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	ligament	395	ADENOMYOSIS	
N80.3A3	Superficial endometriosis of the bilateral	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	uterosacral ligament(s)	395	ADENOMYOSIS	
N80.3A9	Superficial endometriosis of the uterosacral	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	ligament(s), unspecified side	395	ADENOMYOSIS	
N80.3B1	Deep endometriosis of the right uterosacral	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	ligament	395	ADENOMYOSIS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
N80.3B2	Deep endometriosis of the left uterosacral	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	ligament	395	ADENOMYOSIS	
N80.3B3	Deep endometriosis of bilateral uterosacral	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	ligament(s)	395	ADENOMYOSIS	
N80.3B9	Deep endometriosis of the uterosacral	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	ligament(s), unspecified side	395	ADENOMYOSIS	
N80.3C1	Endometriosis of the right uterosacral ligament,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.3C2	Endometriosis of the left uterosacral ligament,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.3C3	Endometriosis of bilateral uterosacral	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	ligament(s), unspecified depth	395	ADENOMYOSIS	
N80.3C9	Endometriosis of the uterosacral ligament(s),	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified side, unspecified depth	395	ADENOMYOSIS	
N80.40	Endometriosis of rectovaginal septum,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified involvement of vagina	395	ADENOMYOSIS	
N80.41	Endometriosis of rectovaginal septum without	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	involvement of vagina	395	ADENOMYOSIS	
N80.42	Endometriosis of rectovaginal septum with	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	involvement of vagina	395	ADENOMYOSIS	
N80.50	Endometriosis of intestine, unspecified		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.511	Superficial endometriosis of the rectum		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.512	Deep endometriosis of the rectum		41 INTUSSCEPTION, VOLVULUS,	See issues
			INTESTINAL OBSTRUCTION, HAZARDOUS	
			FOREIGN BODY IN GI TRACT WITH RISK	
			OF PERFORATION OR OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.519	Endometriosis of the rectum, unspecified depth		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.521	Superficial endometriosis of the sigmoid colon		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
N80.522	Deep endometriosis of the sigmoid colon		41 INTUSSCEPTION, VOLVULUS,	See issues
			INTESTINAL OBSTRUCTION, HAZARDOUS	
			FOREIGN BODY IN GI TRACT WITH RISK	
			OF PERFORATION OR OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.529	Endometriosis of the sigmoid colon, unspecified		395 ENDOMETRIOSIS AND	See issues
	depth		ADENOMYOSIS	
N80.531	Superficial endometriosis of the cecum		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.532	Deep endometriosis of the cecum		41 INTUSSCEPTION, VOLVULUS,	See issues
			INTESTINAL OBSTRUCTION, HAZARDOUS	
			FOREIGN BODY IN GI TRACT WITH RISK	
			OF PERFORATION OR OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.539	Endometriosis of the cecum, unspecified depth		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.541	Superficial endometriosis of the appendix		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.542	Deep endometriosis of the appendix		41 INTUSSCEPTION, VOLVULUS,	See issues
			INTESTINAL OBSTRUCTION, HAZARDOUS	
			FOREIGN BODY IN GI TRACT WITH RISK	
			OF PERFORATION OR OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.549	Endometriosis of the appendix, unspecified		395 ENDOMETRIOSIS AND	See issues
	depth		ADENOMYOSIS	
N80.551	Superficial endometriosis of other parts of the		395 ENDOMETRIOSIS AND	See issues
	colon		ADENOMYOSIS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
N80.552	Deep endometriosis of other parts of the colon		41 INTUSSCEPTION, VOLVULUS,	See issues
			INTESTINAL OBSTRUCTION, HAZARDOUS	
			FOREIGN BODY IN GI TRACT WITH RISK	
			OF PERFORATION OR OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.559	Endometriosis of other parts of the colon,		395 ENDOMETRIOSIS AND	See issues
	unspecified depth		ADENOMYOSIS	
N80.561	Superficial endometriosis of the small intestine		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.562	Deep endometriosis of the small intestine		41 INTUSSCEPTION, VOLVULUS,	See issues
			INTESTINAL OBSTRUCTION, HAZARDOUS	
			FOREIGN BODY IN GI TRACT WITH RISK	
			OF PERFORATION OR OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.569	Endometriosis of the small intestine, unspecified		395 ENDOMETRIOSIS AND	See issues
	depth		ADENOMYOSIS	
N80.A0	Endometriosis of bladder, unspecified depth		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.A1	Superficial endometriosis of bladder		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.A2	Deep endometriosis of bladder		327 FUNCTIONAL AND MECHANICAL	See issues
			DISORDERS OF THE GENITOURINARY	
			SYSTEM INCLUDING BLADDER OUTLET	
			OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.A41	Superficial endometriosis of right ureter		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.A42	Superficial endometriosis of left ureter		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.A43	Superficial endometriosis of bilateral ureters		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.A49	Superficial endometriosis of unspecified ureter		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
N80.A51	Deep endometriosis of right ureter		327 FUNCTIONAL AND MECHANICAL	See issues
			DISORDERS OF THE GENITOURINARY	
			SYSTEM INCLUDING BLADDER OUTLET	
			OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.A52	Deep endometriosis of left ureter		327 FUNCTIONAL AND MECHANICAL	See issues
			DISORDERS OF THE GENITOURINARY	
			SYSTEM INCLUDING BLADDER OUTLET	
			OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.A53	Deep endometriosis of bilateral ureters		327 FUNCTIONAL AND MECHANICAL	See issues
			DISORDERS OF THE GENITOURINARY	
			SYSTEM INCLUDING BLADDER OUTLET	
			OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.A59	Deep endometriosis of unspecified ureter		327 FUNCTIONAL AND MECHANICAL	See issues
			DISORDERS OF THE GENITOURINARY	
			SYSTEM INCLUDING BLADDER OUTLET	
			OBSTRUCTION	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.A61	Endometriosis of right ureter, unspecified depth		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.A62	Endometriosis of left ureter, unspecified depth		395 ENDOMETRIOSIS AND	See issues
			ADENOMYOSIS	
N80.A63	Endometriosis of bilateral ureters, unspecified		395 ENDOMETRIOSIS AND	See issues
	depth		ADENOMYOSIS	
N80.A69	Endometriosis of unspecified ureter, unspecified	ł	395 ENDOMETRIOSIS AND	See issues
	depth		ADENOMYOSIS	
N80.B1	Endometriosis of pleura			See issues
			372 BENIGN NEOPLASM OF RESPIRATORY	,
			AND INTRATHORACIC ORGANS	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
N80.B2	Endometriosis of lung			See issues
			372 BENIGN NEOPLASM OF RESPIRATORY	
			AND INTRATHORACIC ORGANS	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.B31	Superficial endometriosis of diaphragm			See issues
			372 BENIGN NEOPLASM OF RESPIRATORY	
			AND INTRATHORACIC ORGANS	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.B32	Deep endometriosis of diaphragm			See issues
			372 BENIGN NEOPLASM OF RESPIRATORY	
			AND INTRATHORACIC ORGANS	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.B39	Endometriosis of diaphragm, unspecified depth			See issues
			372 BENIGN NEOPLASM OF RESPIRATORY	
			AND INTRATHORACIC ORGANS	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.B4	Endometriosis of the pericardial space			See issues
			372 BENIGN NEOPLASM OF RESPIRATORY	
			AND INTRATHORACIC ORGANS	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.B5	Endometriosis of the mediastinal space			See issues
			372 BENIGN NEOPLASM OF RESPIRATORY	
			AND INTRATHORACIC ORGANS	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.B6	Endometriosis of cardiothoracic space			See issues
			372 BENIGN NEOPLASM OF RESPIRATORY	
			AND INTRATHORACIC ORGANS	
			395 ENDOMETRIOSIS AND	
			ADENOMYOSIS	
N80.C0	Endometriosis of the abdomen, unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.C10	Endometriosis of the anterior abdominal wall,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	subcutaneous tissue	395	ADENOMYOSIS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
N80.C11	Endometriosis of the anterior abdominal wall,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	fascia and muscular layers	395	ADENOMYOSIS	
N80.C19	Endometriosis of the anterior abdominal wall,	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	unspecified depth	395	ADENOMYOSIS	
N80.C2	Endometriosis of the umbilicus	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.C3	Endometriosis of the inguinal canal	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.C4	Endometriosis of extra-pelvic abdominal	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
	peritoneum	395	ADENOMYOSIS	
N80.C9	Endometriosis of other site of abdomen	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.D0	Endometriosis of the pelvic nerves, unspecified	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.D1	Endometriosis of the sacral splanchnic nerves	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.D2	Endometriosis of the sacral nerve roots	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.D3	Endometriosis of the obturator nerve	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.D4	Endometriosis of the sciatic nerve	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.D5	Endometriosis of the pudendal nerve	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.D6	Endometriosis of the femoral nerve	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N80.D9	Endometriosis of other pelvic nerve	Endometrosis in the abdominal cavity is on line	395 ENDOMETRIOSIS AND	
		395	ADENOMYOSIS	
N85.A	Isthmocele		423 MENSTRUAL BLEEDING DISORDERS	See issues document
O35.00X0	Maternal care for (suspected) central nervous	All pregnancy related codes are on line 1	1 PREGNANCY	
	system malformation or damage in fetus,			
	unspecified, not applicable or unspecified			
O35.00X1	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	unspecified, fetus 1			
O35.00X2	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	unspecified, fetus 2			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.00X3	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	unspecified, fetus 3			
O35.00X4	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	unspecified, fetus 4			
O35.00X5	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	unspecified, fetus 5			
O35.00X9	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	unspecified, other fetus			
O35.01X0	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	agenesis of the corpus callosum, not applicable			
	or unspecified			
O35.01X1	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	agenesis of the corpus callosum, fetus 1			
O35.01X2	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	agenesis of the corpus callosum, fetus 2			
O35.01X3	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	agenesis of the corpus callosum, fetus 3			
025 0174	Maternal care for (curnected) control pervous			
055.0174	system malformation or damage in fotus		IFREGNANCE	
	agonosis of the corpus collosum fotus A			
O35.01X5	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	agenesis of the corpus callosum, fetus 5			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.01X9	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	agenesis of the corpus callosum, other fetus			
O35.02X0	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	anencephaly, not applicable or unspecified			
O35.02X1	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	anencephaly, fetus 1			
O35.02X2	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	anencephaly, fetus 2			
O35.02X3	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	anencephaly, fetus 3			
O35.02X4	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	anencephaly, fetus 4			
O35.02X5	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	anencephaly, fetus 5			
O35.02X9	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	anencephaly, other fetus			
O35.03X0	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	choroid plexus cysts, not applicable or			
	unspecified			
O35.03X1	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	choroid plexus cysts, fetus 1			
O35.03X2	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	choroid plexus cysts, fetus 2			
O35.03X3	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	choroid plexus cysts, fetus 3			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.03X4	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	choroid plexus cysts, fetus 4			
O35.03X5	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	choroid plexus cysts, fetus 5			
O35.03X9	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	choroid plexus cysts, other fetus			
O35.04X0	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	encephalocele, not applicable or unspecified			
O35.04X1	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	encephalocele, fetus 1			
O35.04X2	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	encephalocele, fetus 2			
O35.04X3	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	encephalocele, fetus 3			
O35.04X4	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	encephalocele, fetus 4			
O35.04X5	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	encephalocele, fetus 5			
O35.04X9	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	encephalocele, other fetus			
O35.05X0	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	holoprosencephaly, not applicable or			
	unspecified			
O35.05X1	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	holoprosencephaly, fetus 1			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.05X2	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	holoprosencephaly, fetus 2			
O35.05X3	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	holoprosencephaly, fetus 3			
O35.05X4	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	holoprosencephaly, fetus 4			
O35.05X5	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	holoprosencephaly, fetus 5			
O35.05X9	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	holoprosencephaly, other fetus			
O35.06X0	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	hydrocephaly, not applicable or unspecified			
O35.06X1	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	hydrocephaly, fetus 1			
O35.06X2	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	hydrocephaly, fetus 2			
O35.06X3	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	hydrocephaly, fetus 3			
O35.06X4	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	hydrocephaly, fetus 4			
O35.06X5	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	hydrocephaly, fetus 5			
O35.06X9	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	hydrocephaly, other fetus			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.07X0	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	microcephaly, not applicable or unspecified			
O35.07X1	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	microcephaly, fetus 1			
O35.07X2	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	microcephaly, fetus 2			
O35.07X3	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	microcephaly, fetus 3			
O35.07X4	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	microcephaly, fetus 4			
O35.07X5	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	microcephaly, fetus 5			
O35.07X9	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus,			
	microcephaly, other fetus			
O35.08X0	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus, spina			
	bifida, not applicable or unspecified			
O35.08X1	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus, spina			
	bifida, fetus 1			
O35.08X2	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus, spina			
	bifida, fetus 2			
O35.08X3	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus, spina			
	bifida, fetus 3			
O35.08X4	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus, spina			
	bifida, fetus 4			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.08X5	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus, spina			
	bifida, fetus 5			
O35.08X9	Maternal care for (suspected) central nervous		1 PREGNANCY	
	system malformation or damage in fetus, spina			
	bifida, other fetus			
O35.09X0	Maternal care for (suspected) other central		1 PREGNANCY	
	nervous system malformation or damage in			
	fetus, not applicable or unspecified			
O35.09X1	Maternal care for (suspected) other central		1 PREGNANCY	
	nervous system malformation or damage in			
	fetus, fetus 1			
O35.09X2	Maternal care for (suspected) other central		1 PREGNANCY	
	nervous system malformation or damage in			
	fetus, fetus 2			
O35.09X3	Maternal care for (suspected) other central		1 PREGNANCY	
	nervous system malformation or damage in			
	fetus, fetus 3			
O35.09X4	Maternal care for (suspected) other central		1 PREGNANCY	
	nervous system malformation or damage in			
	fetus, fetus 4			
O35.09X5	Maternal care for (suspected) other central		1 PREGNANCY	
	nervous system malformation or damage in			
	fetus, fetus 5			
O35.09X9	Maternal care for (suspected) other central		1 PREGNANCY	
	nervous system malformation or damage in			
	fetus, other fetus			
O35.10X0	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, unspecified, not applicable			
	or unspecified			
O35.10X1	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, unspecified, fetus 1			
O35.10X2	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, unspecified, fetus 2			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.10X3	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, unspecified, fetus 3			
O35.10X4	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, unspecified, fetus 4			
O35.10X5	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, unspecified, fetus 5			
O35.10X9	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, unspecified, other fetus			
O35.11X0	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 13, not applicable or unspecified			
O35.11X1	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 13, fetus 1			
O35.11X2	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 13, fetus 2			
O35.11X3	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 13, fetus 3			
O35.11X4	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 13, fetus 4			
O35.11X5	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 13, fetus 5			
O35.11X9	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 13, other fetus			
O35.12X0	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 18, not applicable or unspecified			
O35.12X1	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 18, fetus 1			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.12X2	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 18, fetus 2			
025 421/2				
035.1283	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 18, fetus 3			
O35.12X4	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 18, fetus 4			
O35.12X5	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 18, fetus 5			
O35.12X9	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 18, other fetus			
O35.13X0	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 21, not applicable			
	or unspecified			
O35.13X1	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 21, fetus 1			
O35.13X2	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 21, fetus 2			
O35.13X3	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 21, fetus 3			
035 1384	Maternal care for (suspected) chromosomal		1 PREGNANCY	
000.10/(1	abnormality in fetus, Trisomy 21, fetus 4			
O35.13X5	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 21, fetus 5			
O35.13X9	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Trisomy 21, other fetus			
O35.14X0	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Turner Syndrome, not			
	applicable or unspecified			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.14X1	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Turner Syndrome, fetus 1			
O35.14X2	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Turner Syndrome, fetus 2			
O35.14X3	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Turner Syndrome, fetus 3			
O35.14X4	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Turner Syndrome, fetus 4			
O35.14X5	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Turner Syndrome, fetus 5			
O35.14X9	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, Turner Syndrome, other			
	fetus			
O35.15X0	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, sex chromosome			
	abnormality, not applicable or unspecified			
025 15V1	Maternal care for (suspected) chromosomal			
035.1571	abnormality in fotus, soy chromosomo		IFREGNANCI	
	abnormality fetus 1			
035 1582	Maternal care for (suspected) chromosomal		1 PREGNANCY	
000110/12	abnormality in fetus, sex chromosome			
	abnormality, fetus 2			
O35.15X3	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, sex chromosome			
	abnormality, fetus 3			
O35.15X4	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, sex chromosome			
	abnormality, fetus 4			
O35.15X5	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, sex chromosome			
	abnormality, fetus 5			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.15X9	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, sex chromosome			
	abnormality, other fetus			
O35.19X0	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, other chromosomal			
	abnormality, not applicable or unspecified			
O35.19X1	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, other chromosomal			
	abnormality, fetus 1			
O35.19X2	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, other chromosomal			
	abnormality, fetus 2			
O35.19X3	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, other chromosomal			
	abnormality, fetus 3			
O35.19X4	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, other chromosomal			
	abnormality, fetus 4			
O35.19X5	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, other chromosomal			
	abnormality, fetus 5			
O35.19X9	Maternal care for (suspected) chromosomal		1 PREGNANCY	
	abnormality in fetus, other chromosomal			
	abnormality, other fetus			
O35.AXX0	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal facial anomalies,			
	not applicable or unspecified			
O35.AXX1	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal facial anomalies,			
	fetus 1			
O35.AXX2	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal facial anomalies,			
	fetus 2			
O35.AXX3	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal facial anomalies,			
	fetus 3			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.AXX4	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal facial anomalies,			
	fetus 4			
O35.AXX5	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal facial anomalies,			
	fetus 5			
O35.AXX9	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal facial anomalies,			
	other fetus			
O35.BXX0	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal cardiac			
	anomalies, not applicable or unspecified			
O35.BXX1	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal cardiac			
	anomalies, fetus 1			
O35.BXX2	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal cardiac			
	anomalies, fetus 2			
O35.BXX3	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal cardiac			
	anomalies, fetus 3			
O35.BXX4	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal cardiac			
	anomalies, fetus 4			
O35.BXX5	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal cardiac			
	anomalies, fetus 5			
O35.BXX9	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal cardiac			
	anomalies, other fetus			
O35.CXX0	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal pulmonary			
	anomalies, not applicable or unspecified			
O35.CXX1	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal pulmonary			
	anomalies, fetus 1			
O35.CXX2	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal pulmonary			
	anomalies, fetus 2			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.CXX3	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal pulmonary			
	anomalies, fetus 3			
O35.CXX4	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal pulmonary			
	anomalies, fetus 4			
O35.CXX5	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal pulmonary			
	anomalies, fetus 5			
O35.CXX9	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal pulmonary			
	anomalies, other fetus			
O35.DXX0	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal gastrointestinal			
	anomalies, not applicable or unspecified			
O35.DXX1	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal gastrointestinal			
	anomalies, fetus 1			
O35.DXX2	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal gastrointestinal			
	anomalies, fetus 2			
O35.DXX3	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal gastrointestinal			
	anomalies, fetus 3			
O35.DXX4	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal gastrointestinal			
	anomalies, fetus 4			
O35.DXX5	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal gastrointestinal			
	anomalies, fetus 5			
O35.DXX9	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal gastrointestinal			
	anomalies, other fetus			
O35.EXX0	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal genitourinary			
	anomalies, not applicable or unspecified			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.EXX1	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal genitourinary			
	anomalies, fetus 1			
O35.EXX2	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal genitourinary			
	anomalies, fetus 2			
O35.EXX3	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal genitourinary			
	anomalies, fetus 3			
O35.EXX4	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal genitourinary			
	anomalies, fetus 4			
O35.EXX5	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal genitourinary			
	anomalies, fetus 5			
O35.EXX9	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal genitourinary			
	anomalies, other fetus			
O35.FXX0	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal musculoskeletal			
	anomalies of trunk, not applicable or			
	unspecified			
O35.FXX1	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal musculoskeletal			
	anomalies of trunk, fetus 1			
O35.FXX2	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal musculoskeletal			
	anomalies of trunk, fetus 2			
O35.FXX3	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal musculoskeletal			
	anomalies of trunk, fetus 3			
O35.FXX4	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal musculoskeletal			
	anomalies of trunk, fetus 4			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.FXX5	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal musculoskeletal			
	anomalies of trunk, fetus 5			
O35.FXX9	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal musculoskeletal			
	anomalies of trunk, other fetus			
035.GXX0	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal upper			
	extremities anomalies, not applicable or			
025 CVV1	Unspecified			
035.6771	shoermality and damage fetal upper		IPREGNANCY	
	abhormanty and damage, fetal upper			
035 6882	Maternal care for other (suspected) fetal		1 PREGNANCY	
033.0772	abnormality and damage fetal upper		TREGRATET	
	extremities anomalies fetus 2			
O35.GXX3	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal upper			
	extremities anomalies, fetus 3			
O35.GXX4	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal upper			
	extremities anomalies, fetus 4			
O35.GXX5	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal upper			
	extremities anomalies, fetus 5			
O35.GXX9	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal upper			
	extremities anomalies, other fetus			
O35.HXX0	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal lower			
	extremities anomalies, not applicable or			
	unspecified			
O35.HXX1	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal lower			
	extremities anomalies, fetus 1			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
O35.HXX2	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal lower			
	extremities anomalies, fetus 2			
O35.HXX3	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal lower			
	extremities anomalies, fetus 3			
O35.HXX4	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal lower			
	extremities anomalies, fetus 4			
O35.HXX5	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal lower			
	extremities anomalies, fetus 5			
O35.HXX9	Maternal care for other (suspected) fetal		1 PREGNANCY	
	abnormality and damage, fetal lower			
	extremities anomalies, other fetus			
P28.30	Primary sleep apnea of newborn, unspecified	Parent code P28.3 (Primary sleep apnea of	11 RESPIRATORY CONDITIONS OF FETUS	
		newborn) was on line 11	AND NEWBORN	
P28.31	Primary central sleep apnea of newborn	See P28.30	11 RESPIRATORY CONDITIONS OF FETUS	
			AND NEWBORN	
P28.32	Primary obstructive sleep apnea of newborn	See P28.30	11 RESPIRATORY CONDITIONS OF FETUS	
			AND NEWBORN	
P28.33	Primary mixed sleep apnea of newborn	See P28.30	11 RESPIRATORY CONDITIONS OF FETUS	
			AND NEWBORN	
P28.39	Other primary sleep apnea of newborn	See P28.30	11 RESPIRATORY CONDITIONS OF FETUS	
			AND NEWBORN	
P28.40	Unspecified apnea of newborn	Parent code P28.4 (Other apnea of newborn) was	11 RESPIRATORY CONDITIONS OF FETUS	
		on line 11	AND NEWBORN	
P28.41	Central neonatal apnea of newborn	See P28.40	11 RESPIRATORY CONDITIONS OF FETUS	
			AND NEWBORN	
P28.42	Obstructive apnea of newborn	See P28.40	11 RESPIRATORY CONDITIONS OF FETUS	
			AND NEWBORN	
P28.43	Mixed neonatal apnea of newborn	See P28.40	11 RESPIRATORY CONDITIONS OF FETUS	
			AND NEWBORN	
P28.49	Other apnea of newborn	See P28.40	11 RESPIRATORY CONDITIONS OF FETUS	
			AND NEWBORN	
Q21.10	Atrial septal defect, unspecified	Parent code Q21.1 (Atrial septal defect) was on	118 ATRIAL SEPTAL DEFECT, SECUNDUM	
		line 118		
Q21.11	Secundum atrial septal defect	See Q21.10	118 ATRIAL SEPTAL DEFECT, SECUNDUM	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
Q21.12	Patent foramen ovale	See Q21.10	118 ATRIAL SEPTAL DEFECT, SECUNDUM	
Q21.13	Coronary sinus atrial septal defect	See Q21.10	118 ATRIAL SEPTAL DEFECT, SECUNDUM	
Q21.14	Superior sinus venosus atrial septal defect	See Q21.10	118 ATRIAL SEPTAL DEFECT, SECUNDUM	
Q21.15	Inferior sinus venosus atrial septal defect	See Q21.10	118 ATRIAL SEPTAL DEFECT, SECUNDUM	
Q21.16	Sinus venosus atrial septal defect, unspecified	See Q21.10	118 ATRIAL SEPTAL DEFECT, SECUNDUM	
Q21.19	Other specified atrial septal defect	See Q21.10	118 ATRIAL SEPTAL DEFECT, SECUNDUM	
Q21.20	Atrioventricular septal defect, unspecified as to partial or complete	Parent code Q21.2 (Atrioventricular septal defect) was on line 84	84 ENDOCARDIAL CUSHION DEFECTS	
Q21.21	Partial atrioventricular septal defect	See Q21.20	84 ENDOCARDIAL CUSHION DEFECTS	
Q21.22	Transitional atrioventricular septal defect	See Q21.20	84 ENDOCARDIAL CUSHION DEFECTS	
Q21.23	Complete atrioventricular septal defect	See Q21.20	84 ENDOCARDIAL CUSHION DEFECTS	
Q85.81	PTEN tumor syndrome		191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	See issues document
Q85.82	Other Cowden syndrome		191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER	See issues document
Q85.83	Von Hippel-Lindau syndrome		125 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD	See issues document
Q85.89	Other phakomatoses, not elsewhere classified		125 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD	See issues document
S06.0XAA	Concussion with loss of consciousness status unknown, initial encounter	Similar code S06.0X1A (Concussion with loss of consciousness of 30 minutes or less, initial encounter) is on line 91	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS	
S06.0XAD	Concussion with loss of consciousness status unknown, subsequent encounter	See above	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS	
SO6.0XAS	Concussion with loss of consciousness status unknown, sequela	See above	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS	
S06.1XAA	Traumatic cerebral edema with loss of consciousness status unknown, initial encounter	Similar codes for traumatic cerebral edema with loss of conciousness (i.e. S06.1X1A) are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
S06.1XAD	Traumatic cerebral edema with loss of	See above	196 SUBARACHNOID AND	
	consciousness status unknown, subsequent		INTRACEREBRAL	
	encounter		HEMORRHAGE/HEMATOMA; CEREBRAL	
			ANEURYSM; COMPRESSION OF BRAIN	
S06.1XAS	Traumatic cerebral edema with loss of	See above	196 SUBARACHNOID AND	
	consciousness status unknown, sequela		INTRACEREBRAL	
			HEMORRHAGE/HEMATOMA; CEREBRAL	
			ANEURYSM; COMPRESSION OF BRAIN	
S06.2XAA	Diffuse traumatic brain injury with loss of	Similar code S06.2X1A (Diffuse traumatic brain	91 SEVERE/MODERATE HEAD INJURY:	
	consciousness status unknown, initial encounter	injury with loss of consciousness of 30 minutes or	HEMATOMA/EDEMA WITH PERSISTENT	
		less, initial encounter) is on line 91	SYMPTOMS	
S06.2XAD	Diffuse traumatic brain injury with loss of	See above	91 SEVERE/MODERATE HEAD INJURY:	
	consciousness status unknown, subsequent		HEMATOMA/EDEMA WITH PERSISTENT	
	encounter		SYMPTOMS	
S06.2XAS	Diffuse traumatic brain injury with loss of	See above	91 SEVERE/MODERATE HEAD INJURY:	
	consciousness status unknown, sequela		HEMATOMA/EDEMA WITH PERSISTENT	
			SYMPTOMS	
S06.30AA	Unspecified focal traumatic brain injury with	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	loss of consciousness status unknown, initial		HEMATOMA/EDEMA WITH PERSISTENT	
	encounter		SYMPTOMS	
S06.30AD	Unspecified focal traumatic brain injury with	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	loss of consciousness status unknown,		HEMATOMA/EDEMA WITH PERSISTENT	
	subsequent encounter		SYMPTOMS	
S06.30AS	Unspecified focal traumatic brain injury with	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	loss of consciousness status unknown, sequela		HEMATOMA/EDEMA WITH PERSISTENT	
			SYMPTOMS	
S06.31AA	Contusion and laceration of right cerebrum with	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	loss of consciousness status unknown, initial		HEMATOMA/EDEMA WITH PERSISTENT	
	encounter		SYMPTOMS	
S06.31AD	Contusion and laceration of right cerebrum with	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	loss of consciousness status unknown,		HEMATOMA/EDEMA WITH PERSISTENT	
	subsequent encounter		SYMPTOMS	
S06.31AS	Contusion and laceration of right cerebrum with	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	loss of consciousness status unknown, sequela		HEMATOMA/EDEMA WITH PERSISTENT	
			SYMPTOMS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
S06.32AA	Contusion and laceration of left cerebrum with	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	loss of consciousness status unknown, initial		HEMATOMA/EDEMA WITH PERSISTENT	
	encounter		SYMPTOMS	
S06.32AD	Contusion and laceration of left cerebrum with	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	loss of consciousness status unknown,		HEMATOMA/EDEMA WITH PERSISTENT	
	subsequent encounter		SYMPTOMS	
S06.32AS	Contusion and laceration of left cerebrum with	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	loss of consciousness status unknown, sequela		HEMATOMA/EDEMA WITH PERSISTENT	
			SYMPTOMS	
S06.33AA	Contusion and laceration of cerebrum,	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	unspecified, with loss of consciousness status		HEMATOMA/EDEMA WITH PERSISTENT	
	unknown, initial encounter		SYMPTOMS	
S06.33AD	Contusion and laceration of cerebrum,	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	unspecified, with loss of consciousness status		HEMATOMA/EDEMA WITH PERSISTENT	
	unknown, subsequent encounter		SYMPTOMS	
S06.33AS	Contusion and laceration of cerebrum,	Similar codes are on line 91	91 SEVERE/MODERATE HEAD INJURY:	
	unspecified, with loss of consciousness status		HEMATOMA/EDEMA WITH PERSISTENT	
	unknown, sequela		SYMPTOMS	
S06.34AA	Traumatic hemorrhage of right cerebrum with	Similar codes are on line 196	196 SUBARACHNOID AND	
	loss of consciousness status unknown, initial		INTRACEREBRAL	
	encounter		HEMORRHAGE/HEMATOMA; CEREBRAL	
			ANEURYSM; COMPRESSION OF BRAIN	
S06.34AD	Traumatic hemorrhage of right cerebrum with	Similar codes are on line 196	196 SUBARACHNOID AND	
	loss of consciousness status unknown,		INTRACEREBRAL	
	subsequent encounter		HEMORRHAGE/HEMATOMA; CEREBRAL	
			ANEURYSM; COMPRESSION OF BRAIN	
S06.34AS	Traumatic hemorrhage of right cerebrum with	Similar codes are on line 196	196 SUBARACHNOID AND	
	loss of consciousness status unknown, sequela		INTRACEREBRAL	
			HEMORRHAGE/HEMATOMA; CEREBRAL	
			ANEURYSM; COMPRESSION OF BRAIN	
S06.35AA	Traumatic hemorrhage of left cerebrum with	Similar codes are on line 196	196 SUBARACHNOID AND	
	loss of consciousness status unknown, initial		INTRACEREBRAL	
	encounter		HEMORRHAGE/HEMATOMA; CEREBRAL	
			ANEURYSM; COMPRESSION OF BRAIN	
ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
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S06.35AD	Traumatic hemorrhage of left cerebrum with loss of consciousness status unknown, subsequent encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.35AS	Traumatic hemorrhage of left cerebrum with loss of consciousness status unknown, sequela	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.36AA	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness status unknown, initial encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.36AD	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness status unknown, subsequent encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.36AS	Traumatic hemorrhage of cerebrum, unspecified, with loss of consciousness status unknown, sequela	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.37AA	Contusion, laceration, and hemorrhage of cerebellum with loss of consciousness status unknown, initial encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.37AD	Contusion, laceration, and hemorrhage of cerebellum with loss of consciousness status unknown, subsequent encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
S06.37AS	Contusion, laceration, and hemorrhage of cerebellum with loss of consciousness status unknown, sequela	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.38AA	Contusion, laceration, and hemorrhage of brainstem with loss of consciousness status unknown, initial encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.38AD	Contusion, laceration, and hemorrhage of brainstem with loss of consciousness status unknown, subsequent encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.38AS	Contusion, laceration, and hemorrhage of brainstem with loss of consciousness status unknown, sequela	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.4XAA	Epidural hemorrhage with loss of consciousness status unknown, initial encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.4XAD	Epidural hemorrhage with loss of consciousness status unknown, subsequent encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
SO6.4XAS	Epidural hemorrhage with loss of consciousness status unknown, sequela	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
SO6.5XAA	Traumatic subdural hemorrhage with loss of consciousness status unknown, initial encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.5XAD	Traumatic subdural hemorrhage with loss of consciousness status unknown, subsequent encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
SO6.5XAS	Traumatic subdural hemorrhage with loss of consciousness status unknown, sequela	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
SO6.6XAA	Traumatic subarachnoid hemorrhage with loss of consciousness status unknown, initial encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.6XAD	Traumatic subarachnoid hemorrhage with loss of consciousness status unknown, subsequent encounter	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
SO6.6XAS	Traumatic subarachnoid hemorrhage with loss of consciousness status unknown, sequela	Similar codes are on line 196	196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN	
S06.81AA	Injury of right internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness status unknown, initial encounter	Similar codes such as S06.811A (Injury of right internal carotid artery, intracranial portion, not elsewhere classified with loss of consciousness of 30 minutes or less, initial encounter) are on the dysfunction lines	71,292,345,377	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
S06.81AD	Injury of right internal carotid artery,	See above	71,292,345,377	
	intracranial portion, not elsewhere classified			
	with loss of consciousness status unknown,			
	subsequent encounter			
S06.81AS	Injury of right internal carotid artery,	See above	71,292,345,377	
	intracranial portion, not elsewhere classified			
	with loss of consciousness status unknown,			
	sequela			
S06.82AA	Injury of left internal carotid artery, intracranial	See above	71,292,345,377	
	portion, not elsewhere classified with loss of			
	consciousness status unknown, initial encounter			
S06.82AD	Injury of left internal carotid artery, intracranial	See above	71,292,345,377	
	portion, not elsewhere classified with loss of			
	consciousness status unknown, subsequent			
	encounter			
S06.82AS	Injury of left internal carotid artery, intracranial	See above	71,292,345,377	
	portion, not elsewhere classified with loss of			
	consciousness status unknown, sequela			
S06.89AA	Other specified intracranial injury with loss of	Similar codes such as S06.891A (Other specified	71,292,345,377	
	consciousness status unknown, initial encounter	intracranial injury with loss of consciousness of 30		
		minutes or less, initial encounter) are on the		
		dysfunction lines		
S06.89AD	Other specified intracranial injury with loss of	See above	71,292,345,377	
	consciousness status unknown, subsequent			
	encounter			
S06.89AS	Other specified intracranial injury with loss of	See above	71,292,345,377	
	consciousness status unknown, sequela			
S06.8A0A	Primary blast injury of brain, not elsewhere	Similar brain injury codes are on the dysfunction	71,292,345,377	
	classified without loss of consciousness, initial	lines		
	encounter			
S06.8A0D	Primary blast injury of brain, not elsewhere	See above	71,292,345,377	
	classified without loss of consciousness,			
	subsequent encounter			
S06.8A0S	Primary blast injury of brain, not elsewhere	See above	71,292,345,377	
	classified without loss of consciousness, sequela			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
S06.8A1A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 30 minutes or less, initial encounter	See above	71,292,345,377	
S06.8A1D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 30 minutes or less, subsequent encounter	See above	71,292,345,377	
S06.8A1S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 30 minutes or less, sequela	See above	71,292,345,377	
S06.8A2A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 31 minutes to 59 minutes, initial encounter	See above	71,292,345,377	
S06.8A2D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 31 minutes to 59 minutes, subsequent encounter	See above	71,292,345,377	
S06.8A2S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 31 minutes to 59 minutes, sequela	See above	71,292,345,377	
S06.8A3A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 1 hour to 5 hours 59 minutes, initial encounter	See above	71,292,345,377	
S06.8A3D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 1 hour to 5 hours 59 minutes, subsequent encounter	See above	71,292,345,377	
S06.8A3S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 1 hour to 5 hours 59 minutes, sequela	See above	71,292,345,377	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
S06.8A4A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 6 hours to 24 hours, initial encounter	See above	71,292,345,377	
S06.8A4D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 6 hours to 24 hours, subsequent encounter	See above	71,292,345,377	
S06.8A4S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of 6 hours to 24 hours, sequela	See above	71,292,345,377	
S06.8A5A	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours with return to pre-existing conscious level, initial encounter	See above	71,292,345,377	
S06.8A5D	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours with return to pre-existing conscious level, subsequent encounter	See above	71,292,345,377	
S06.8A5S	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours with return to pre-existing conscious level, sequela	See above	71,292,345,377	
S06.8A6A	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, initial encounter	See above	71,292,345,377	
S06.8A6D	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours without return to pre-existing conscious level with patient surviving, subsequent encounter	See above	71,292,345,377	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
S06.8A6S	Primary blast injury of brain, not elsewhere classified with loss of consciousness greater than 24 hours without return to pre-existing	See above	71,292,345,377	
	conscious level with patient surviving, sequela			
S06.8A7A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of any duration with death due to brain injury prior to regaining consciousness, initial encounter	See above	71,292,345,377	
S06.8A8A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of any duration with death due to other cause prior to regaining consciousness, initial encounter	See above	71,292,345,377	
S06.8A9A	Primary blast injury of brain, not elsewhere classified with loss of consciousness of unspecified duration, initial encounter	See above	71,292,345,377	
S06.8A9D	Primary blast injury of brain, not elsewhere classified with loss of consciousness of unspecified duration, subsequent encounter	See above	71,292,345,377	
S06.8A9S	Primary blast injury of brain, not elsewhere classified with loss of consciousness of unspecified duration, sequela	See above	71,292,345,377	
S06.8AAA	Primary blast injury of brain, not elsewhere classified with loss of consciousness status unknown, initial encounter	See above	71,292,345,377	
S06.8AAD	Primary blast injury of brain, not elsewhere classified with loss of consciousness status unknown, subsequent encounter	See above	71,292,345,377	
S06.8AAS	Primary blast injury of brain, not elsewhere classified with loss of consciousness status unknown, sequela	See above	71,292,345,377	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
S06.9XAA	Unspecified intracranial injury with loss of	See above	71,292,345,377	
	consciousness status unknown, initial encounter			
S06.9XAD	Unspecified intracranial injury with loss of	See above	71,292,345,377	
	consciousness status unknown, subsequent			
	encounter			
S06.9XAS	Unspecified intracranial injury with loss of	See above	71,292,345,377	
	consciousness status unknown, sequela			
T43.651A	Poisoning by methamphetamines accidental	Poisoning codes are on line 102	102 POISONING BY INGESTION,	
	(unintentional), initial encounter		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.651D	Poisoning by methamphetamines accidental	Poisoning codes are on line 102	102 POISONING BY INGESTION,	
	(unintentional), subsequent encounter		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.651S	Poisoning by methamphetamines accidental	Poisoning codes are on line 102	102 POISONING BY INGESTION,	
	(unintentional), sequela		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.652A	Poisoning by methamphetamines intentional	Poisoning codes even when intentional self-harm	102 POISONING BY INGESTION,	
	self-harm, initial encounter	are on line 102	INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.652D	Poisoning by methamphetamines intentional	Poisoning codes even when intentional self-harm	102 POISONING BY INGESTION,	
	self-harm, subsequent encounter	are on line 102	INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.652S	Poisoning by methamphetamines intentional	Poisoning codes even when intentional self-harm	102 POISONING BY INGESTION,	
	self-harm, sequela	are on line 102	INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.653A	Poisoning by methamphetamines, assault, initial	Poisoning codes are on line 102	102 POISONING BY INGESTION,	
	encounter		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.653D	Poisoning by methamphetamines, assault,	Poisoning codes are on line 102	102 POISONING BY INGESTION,	
	subsequent encounter		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.653S	Poisoning by methamphetamines, assault,	Poisoning codes are on line 102	102 POISONING BY INGESTION,	
	sequela		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.654A	Poisoning by methamphetamines,	Poisoning codes are on line 102	102 POISONING BY INGESTION,	
	undetermined, initial encounter		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
T43.654D	Poisoning by methamphetamines,	Poisoning codes are on line 102	102 POISONING BY INGESTION,	
	undetermined, subsequent encounter		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.654S	Poisoning by methamphetamines,	Poisoning codes are on line 102	102 POISONING BY INGESTION,	
	undetermined, sequela		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.655A	Adverse effect of methamphetamines, initial	Adverse effects of illicit drugs are on line 102	102 POISONING BY INGESTION,	
	encounter		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.655D	Adverse effect of methamphetamines,	Adverse effects of illicit drugs are on line 102	102 POISONING BY INGESTION,	
	subsequent encounter		INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.655S	Adverse effect of methamphetamines, sequela	Adverse effects of illicit drugs are on line 102	102 POISONING BY INGESTION,	
			INJECTION, MEDICINAL AND NON-	
			MEDICINAL AGENTS	
T43.656A	Underdosing of methamphetamines, initial	Other underdosing codes are DWF	DIAGNOSTIC WORKUP FILE (DWF)	
	encounter			
T43.656D	Underdosing of methamphetamines,	Other underdosing codes are DWF	DIAGNOSTIC WORKUP FILE (DWF)	
	subsequent encounter			
T43.656S	Underdosing of methamphetamines, sequela	Other underdosing codes are DWF	DIAGNOSTIC WORKUP FILE (DWF)	
V20.01XA	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with pedestrian or animal in nontraffic			
	accident, initial encounter			
V20.01XD	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with pedestrian or animal in nontraffic			
	accident, subsequent encounter			
V20.01XS	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with pedestrian or animal in nontraffic			
	accident, sequela			
V20.09XA	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	pedestrian or animal in nontraffic accident,			
	initial encounter			
V20.09XD	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	pedestrian or animal in nontraffic accident,			
	subsequent encounter			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V20.09XS	Other motorcycle driver injured in collision with pedestrian or animal in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.11XA	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.11XD	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.11XS	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.19XA	Other motorcycle passenger injured in collision with pedestrian or animal in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.19XD	Other motorcycle passenger injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.19XS	Other motorcycle passenger injured in collision with pedestrian or animal in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.21XA	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.21XD	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.21XS	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.29XA	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V20.29XD	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.29XS	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedestrian or animal, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedestrian or animal, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedestrian or animal, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.39XA	Person boarding or alighting other motorcycle injured in collision with pedestrian or animal, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.39XD	Person boarding or alighting other motorcycle injured in collision with pedestrian or animal, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.39XS	Person boarding or alighting other motorcycle injured in collision with pedestrian or animal, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.41XA	Electric (assisted) bicycle driver injured in collision with pedestrian or animal in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.41XD	Electric (assisted) bicycle driver injured in collision with pedestrian or animal in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.41XS	Electric (assisted) bicycle driver injured in collision with pedestrian or animal in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.49XA	Other motorcycle driver injured in collision with pedestrian or animal in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V20.49XD	Other motorcycle driver injured in collision with pedestrian or animal in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.49XS	Other motorcycle driver injured in collision with pedestrian or animal in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.51XA	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.51XD	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.51XS	Electric (assisted) bicycle passenger injured in collision with pedestrian or animal in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.59XA	Other motorcycle passenger injured in collision with pedestrian or animal in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.59XD	Other motorcycle passenger injured in collision with pedestrian or animal in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.59XS	Other motorcycle passenger injured in collision with pedestrian or animal in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.91XA	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.91XD	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.91XS	Unspecified electric (assisted) bicycle rider injured in collision with pedestrian or animal in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.99XA	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V20.99XD	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V20.99XS	Unspecified rider of other motorcycle injured in collision with pedestrian or animal in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.01XA	Electric (assisted) bicycle driver injured in collision with pedal cycle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.01XD	Electric (assisted) bicycle driver injured in collision with pedal cycle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.01XS	Electric (assisted) bicycle driver injured in collision with pedal cycle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.09XA	Other motorcycle driver injured in collision with pedal cycle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.09XD	Other motorcycle driver injured in collision with pedal cycle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.09XS	Other motorcycle driver injured in collision with pedal cycle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.11XA	Electric (assisted) bicycle passenger injured in collision with pedal cycle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.11XD	Electric (assisted) bicycle passenger injured in collision with pedal cycle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.11XS	Electric (assisted) bicycle passenger injured in collision with pedal cycle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.19XA	Other motorcycle passenger injured in collision with pedal cycle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V21.19XD	Other motorcycle passenger injured in collision with pedal cycle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.19XS	Other motorcycle passenger injured in collision with pedal cycle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.21XA	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.21XD	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.21XS	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.29XA	Unspecified rider of other motorcycle injured in collision with pedal cycle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.29XD	Unspecified rider of other motorcycle injured in collision with pedal cycle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.29XS	Unspecified rider of other motorcycle injured in collision with pedal cycle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedal cycle, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedal cycle, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with pedal cycle, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.39XA	Person boarding or alighting other motorcycle injured in collision with pedal cycle, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V21.39XD	Person boarding or alighting other motorcycle injured in collision with pedal cycle, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.39XS	Person boarding or alighting other motorcycle injured in collision with pedal cycle, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.41XA	Electric (assisted) bicycle driver injured in collision with pedal cycle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.41XD	Electric (assisted) bicycle driver injured in collision with pedal cycle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.41XS	Electric (assisted) bicycle driver injured in collision with pedal cycle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.49XA	Other motorcycle driver injured in collision with pedal cycle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.49XD	Other motorcycle driver injured in collision with pedal cycle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.49XS	Other motorcycle driver injured in collision with pedal cycle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.51XA	Electric (assisted) bicycle passenger injured in collision with pedal cycle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.51XD	Electric (assisted) bicycle passenger injured in collision with pedal cycle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.51XS	Electric (assisted) bicycle passenger injured in collision with pedal cycle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.59XA	Other motorcycle passenger injured in collision with pedal cycle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.59XD	Other motorcycle passenger injured in collision with pedal cycle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V21.59XS	Other motorcycle passenger injured in collision with pedal cycle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.91XA	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.91XD	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.91XS	Unspecified electric (assisted) bicycle rider injured in collision with pedal cycle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.99XA	Unspecified rider of other motorcycle injured in collision with pedal cycle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.99XD	Unspecified rider of other motorcycle injured in collision with pedal cycle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V21.99XS	Unspecified rider of other motorcycle injured in collision with pedal cycle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.01XA	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.01XD	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.01XS	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.09XA	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V22.09XD	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.09XS	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.11XA	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.11XD	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.11XS	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.19XA	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.19XD	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.19XS	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.21XA	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V22.21XD	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.21XS	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.29XA	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.29XD	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.29XS	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with two- or three-wheeled motor vehicle, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with two- or three-wheeled motor vehicle, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with two- or three-wheeled motor vehicle, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.39XA	Person boarding or alighting other motorcycle injured in collision with two- or three-wheeled motor vehicle, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V22.39XD	Person boarding or alighting other motorcycle injured in collision with two- or three-wheeled motor vehicle, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.39XS	Person boarding or alighting other motorcycle injured in collision with two- or three-wheeled motor vehicle, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.41XA	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.41XD	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.41XS	Electric (assisted) bicycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.49XA	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.49XD	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.49XS	Other motorcycle driver injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.51XA	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.51XD	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V22.51XS	Electric (assisted) bicycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.59XA	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.59XD	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.59XS	Other motorcycle passenger injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.91XA	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.91XD	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.91XS	Unspecified electric (assisted) bicycle rider injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.99XA	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.99XD	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V22.99XS	Unspecified rider of other motorcycle injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V23.01XA	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in			
	nontraffic accident, initial encounter			
V23.01XD	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in			
	nontraffic accident, subsequent encounter			
V23.01XS	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in			
	nontraffic accident, sequela			
V23.09XA	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	car, pick-up truck or van in nontraffic accident,			
	initial encounter			
V23.09XD	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	car, pick-up truck or van in nontraffic accident,			
	subsequent encounter			
V23.09XS	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	car, pick-up truck or van in nontraffic accident,			
	sequela			
V23.11XA	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in			
	nontraffic accident, initial encounter			
V22 11VD				
V23.11XD	collision with car, pick up truck or yon in	V Codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	nontraffic assident, subsequent encounter			
	nontranic accident, subsequent encounter			
V23.11XS	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in			
	nontraffic accident, sequela			
V23.19XA	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with car, pick-up truck or van in nontraffic	, , , , , , , , , , , , , , , , , , ,		
	accident, initial encounter			
V23.19XD	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with car, pick-up truck or van in nontraffic			
	accident, subsequent encounter			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V23.19XS	Other motorcycle passenger injured in collision with car, pick-up truck or van in nontraffic	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	accident, sequela			
V23.21XA	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with car, pick-up truck or van			
	in nontraffic accident, initial encounter			
V23.21XD	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with car, pick-up truck or van			
	in nontraffic accident, subsequent encounter			
V23.21XS	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with car, pick-up truck or van			
	in nontraffic accident, sequela			
V23.29XA	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in			
	nontraffic accident, initial encounter			
V23.29XD	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in			
	nontraffic accident, subsequent encounter			
V23.29XS	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in			
	nontraffic accident, sequela			
V23.31XA	Person boarding or alighting an electric	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	(assisted) bicycle injured in collision with car,			
	Person boarding or alighting an electric	"//" codes are generally INFORMATIONAL		
V25.517D	(assisted) bicycle iniured in collision with car.			
	pick-up truck or van, subsequent encounter			
	P of a second s			
V23.31XS	Person boarding or alighting an electric	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	(assisted) bicycle injured in collision with car,			
	pick-up truck or van, sequela			
V23.39XA	Person boarding or alighting other motorcycle	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with car, pick-up truck or van,			
	initial encounter			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V23.39XD	Person boarding or alighting other motorcycle injured in collision with car, pick-up truck or van, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.39XS	Person boarding or alighting other motorcycle injured in collision with car, pick-up truck or van, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.41XA	Electric (assisted) bicycle driver injured in collision with car, pick-up truck or van in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.41XD	Electric (assisted) bicycle driver injured in collision with car, pick-up truck or van in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.41XS	Electric (assisted) bicycle driver injured in collision with car, pick-up truck or van in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.49XA	Other motorcycle driver injured in collision with car, pick-up truck or van in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.49XD	Other motorcycle driver injured in collision with car, pick-up truck or van in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.49XS	Other motorcycle driver injured in collision with car, pick-up truck or van in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.51XA	Electric (assisted) bicycle passenger injured in collision with car, pick-up truck or van in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.51XD	Electric (assisted) bicycle passenger injured in collision with car, pick-up truck or van in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.51XS	Electric (assisted) bicycle passenger injured in collision with car, pick-up truck or van in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V23.59XA	Other motorcycle passenger injured in collision with car, pick-up truck or van in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V23.59XD	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with car, pick-up truck or van in traffic accident,			
	subsequent encounter			
V23.59XS	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with car, pick-up truck or van in traffic accident,			
	sequela			
V23.91XA	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with car, pick-up truck or van			
	in traffic accident, initial encounter			
V22 01VD	Un on optical plantation (posting all biomala at day			
V23.91XD	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with car, pick-up truck or van			
	In traffic accident, subsequent encounter			
V23.91XS	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with car, pick-up truck or van			
	in traffic accident, sequela			
V23.99XA	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in traffic			
	accident, initial encounter			
V23.99XD	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with car, pick-up truck or van in traffic			
	accident, subsequent encounter			
V22.00VC				
V23.99XS	Unspecified rider of other motorcycle injured in	V codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	consident sequels			
V24 01XA	Electric (assisted) bicycle driver injured in			
V24.017A	collision with beavy transport vehicle or hus in		INI ONMATIONAL DIAGNOSES	
	nontraffic accident initial encounter			
	nontrame decident, initial cheoditer			
V24.01XD	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with heavy transport vehicle or bus in			
	nontraffic accident, subsequent encounter			
104.041/6				
V24.01XS	Electric (assisted) bicycle driver injured in	v" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	consion with neavy transport vehicle or bus in			
	nontraffic accident, sequela			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V24.09XA	Other motorcycle driver injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.09XD	Other motorcycle driver injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.09XS	Other motorcycle driver injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.11XA	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.11XD	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.11XS	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.19XA	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.19XD	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.19XS	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.21XA	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V24.21XD	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.21XS	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.29XA	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.29XD	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.29XS	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with heavy transport vehicle or bus, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with heavy transport vehicle or bus, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with heavy transport vehicle or bus, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.39XA	Person boarding or alighting other motorcycle injured in collision with heavy transport vehicle or bus, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.39XD	Person boarding or alighting other motorcycle injured in collision with heavy transport vehicle or bus, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V24.39XS	Person boarding or alighting other motorcycle injured in collision with heavy transport vehicle or bus, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.41XA	Electric (assisted) bicycle driver injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.41XD	Electric (assisted) bicycle driver injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.41XS	Electric (assisted) bicycle driver injured in collision with heavy transport vehicle or bus in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.49XA	Other motorcycle driver injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.49XD	Other motorcycle driver injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.49XS	Other motorcycle driver injured in collision with heavy transport vehicle or bus in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.51XA	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.51XD	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.51XS	Electric (assisted) bicycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.59XA	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V24.59XD	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.59XS	Other motorcycle passenger injured in collision with heavy transport vehicle or bus in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.91XA	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.91XD	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.91XS	Unspecified electric (assisted) bicycle rider injured in collision with heavy transport vehicle or bus in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.99XA	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.99XD	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V24.99XS	Unspecified rider of other motorcycle injured in collision with heavy transport vehicle or bus in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.01XA	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.01XD	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V25.01XS	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.09XA	Other motorcycle driver injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.09XD	Other motorcycle driver injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.09XS	Other motorcycle driver injured in collision with railway train or railway vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.11XA	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.11XD	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.11XS	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.19XA	Other motorcycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.19XD	Other motorcycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.19XS	Other motorcycle passenger injured in collision with railway train or railway vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V25.21XA	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.21XD	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.21XS	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.29XA	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.29XD	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.29XS	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with railway train or railway vehicle, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with railway train or railway vehicle, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with railway train or railway vehicle, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.39XA	Person boarding or alighting other motorcycle injured in collision with railway train or railway vehicle, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V25.39XD	Person boarding or alighting other motorcycle injured in collision with railway train or railway vehicle, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.39XS	Person boarding or alighting other motorcycle injured in collision with railway train or railway vehicle, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.41XA	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.41XD	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.41XS	Electric (assisted) bicycle driver injured in collision with railway train or railway vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.49XA	Other motorcycle driver injured in collision with railway train or railway vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.49XD	Other motorcycle driver injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.49XS	Other motorcycle driver injured in collision with railway train or railway vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.51XA	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.51XD	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V25.51XS	Electric (assisted) bicycle passenger injured in collision with railway train or railway vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.59XA	Other motorcycle passenger injured in collision with railway train or railway vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.59XD	Other motorcycle passenger injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.59XS	Other motorcycle passenger injured in collision with railway train or railway vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.91XA	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.91XD	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.91XS	Unspecified electric (assisted) bicycle rider injured in collision with railway train or railway vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.99XA	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.99XD	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V25.99XS	Unspecified rider of other motorcycle injured in collision with railway train or railway vehicle in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V26.01XA	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in			
	nontraffic accident, initial encounter			
V26.01XD	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in			
	nontraffic accident, subsequent encounter			
V26.01XS	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in			
	nontraffic accident, sequela			
V26.09XA	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	other nonmotor vehicle in nontraffic accident,			
	initial encounter			
V26.09XD	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	other nonmotor vehicle in nontraffic accident,			
	subsequent encounter			
V26.09XS	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	other nonmotor vehicle in nontraffic accident,			
	sequela			
V26.11XA	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in			
	nontraffic accident, initial encounter			
V26.11XD	ellision with other normator vahials in	V Codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	consion with other hormotor venicle in			
	nontranic accident, subsequent encounter			
V26.11XS	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in			
	nontraffic accident, sequela			
V26.19XA	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with other nonmotor vehicle in nontraffic	, , , , , , , , , , , , , , , , , , ,		
	accident, initial encounter			
V26.19XD	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with other nonmotor vehicle in nontraffic			
	accident, subsequent encounter			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V26.19XS	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with other nonmotor vehicle in nontraffic			
	accident, sequela			
V26.21XA	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other nonmotor vehicle			
	in nontraffic accident, initial encounter			
V26.21XD	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other nonmotor vehicle			
	in nontraffic accident, subsequent encounter			
V26.21XS	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other nonmotor vehicle			
	in nontraffic accident, sequela			
V26.29XA	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in			
	nontraffic accident, initial encounter			
V26.29XD	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in			
	nontraffic accident, subsequent encounter			
V26.29XS	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in			
	nontraffic accident, sequela			
V26.31XA	Person boarding or alighting an electric	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	(assisted) bicycle injured in collision with other			
	nonmotor vehicle, initial encounter			
V26.31XD	Person boarding or alighting an electric	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	(assisted) bicycle injured in collision with other			
	nonmotor vehicle, subsequent encounter			
V26.31XS	Person boarding or alighting an electric	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	(assisted) bicycle injured in collision with other			
	nonmotor vehicle, sequela			
V26.39XA	Person boarding or alighting other motorcycle	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other nonmotor vehicle,			
	initial encounter			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V26.39XD	Person boarding or alighting other motorcycle	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other nonmotor vehicle,			
	subsequent encounter			
V26.39XS	Person boarding or alighting other motorcycle	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other nonmotor vehicle,			
	sequela			
V26.41XA	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in traffic			
	accident, initial encounter			
V26.41XD	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in traffic			
	accident, subsequent encounter			
V26.41XS	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in traffic			
	accident, sequela			
V26.49XA	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	other nonmotor vehicle in traffic accident, initial			
	encounter			
V26.49XD	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	other nonmotor vehicle in traffic accident,			
	subsequent encounter			
V26.49XS	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	other nonmotor vehicle in traffic accident,			
	sequela			
V26.51XA	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in traffic			
	accident, initial encounter			
V26.51XD	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in traffic			
	accident, subsequent encounter			
V26.51XS	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in traffic			
	accident, sequela			
V26.59XA	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with other nonmotor vehicle in traffic accident,			
	initial encounter			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V26.59XD	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with other nonmotor vehicle in traffic accident,			
	subsequent encounter			
V26.59XS	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with other nonmotor vehicle in traffic accident,			
	sequela			
V26.91XA	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other nonmotor vehicle			
	in traffic accident, initial encounter			
V26.91XD	Unspecified electric (assisted) bicycle rider	V codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other honmotor vehicle			
	In tranic accident, subsequent encounter			
V26.91XS	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other nonmotor vehicle			
	in traffic accident, sequela			
V26.99XA	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in traffic			
	accident, initial encounter			
V26.99XD	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other nonmotor vehicle in traffic			
	accident, subsequent encounter			
	Unspecified rider of other metersyste injured in	" // codes are generally INFORMATIONAL		
V20.99X3	collicion with other nonmotor vehicle in traffic		INFORMATIONAL DIAGNOSES	
	accident sequela			
V27.01XA	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
-	collision with fixed or stationary object in			
	nontraffic accident, initial encounter			
V27.01XD	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with fixed or stationary object in			
	nontraffic accident, subsequent encounter			
V27.01XS	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with fixed or stationary object in			
	nontraffic accident, sequela			
ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
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V27.09XA	Other motorcycle driver injured in collision with fixed or stationary object in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.09XD	Other motorcycle driver injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.09XS	Other motorcycle driver injured in collision with fixed or stationary object in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.11XA	Electric (assisted) bicycle passenger injured in collision with fixed or stationary object in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.11XD	Electric (assisted) bicycle passenger injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.11XS	Electric (assisted) bicycle passenger injured in collision with fixed or stationary object in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.19XA	Other motorcycle passenger injured in collision with fixed or stationary object in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.19XD	Other motorcycle passenger injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.19XS	Other motorcycle passenger injured in collision with fixed or stationary object in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.21XA	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.21XD	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V27.21XS	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.29XA	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.29XD	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.29XS	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.31XA	Person boarding or alighting an electric (assisted) bicycle injured in collision with fixed or stationary object, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.31XD	Person boarding or alighting an electric (assisted) bicycle injured in collision with fixed or stationary object, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.31XS	Person boarding or alighting an electric (assisted) bicycle injured in collision with fixed or stationary object, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.39XA	Person boarding or alighting other motorcycle injured in collision with fixed or stationary object, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.39XD	Person boarding or alighting other motorcycle injured in collision with fixed or stationary object, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.39XS	Person boarding or alighting other motorcycle injured in collision with fixed or stationary object, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.41XA	Electric (assisted) bicycle driver injured in collision with fixed or stationary object in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V27.41XD	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with fixed or stationary object in traffic			
	accident, subsequent encounter			
V27.41XS	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with fixed or stationary object in traffic			
	accident, sequela			
V27.49XA	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	fixed or stationary object in traffic accident,			
	initial encounter			
V27.49XD	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	fixed or stationary object in traffic accident,			
	subsequent encounter			
V27.49XS	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	fixed or stationary object in traffic accident,			
	sequela			
V27.51XA	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with fixed or stationary object in traffic			
	accident, initial encounter			
V27.51XD	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with fixed or stationary object in traffic			
	accident, subsequent encounter			
V27.51XS	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with fixed or stationary object in traffic			
	accident, sequela			
V27.59XA	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with fixed or stationary object in traffic accident,			
	initial encounter			
V27.59XD	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with fixed or stationary object in traffic accident,			
	subsequent encounter			
V27.59XS	Other motorcycle passenger injured in collision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	with fixed or stationary object in traffic accident,			
	sequela			
V27.91XA	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with fixed or stationary			
	object in traffic accident, initial encounter			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V27.91XD	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.91XS	Unspecified electric (assisted) bicycle rider injured in collision with fixed or stationary object in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.99XA	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.99XD	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V27.99XS	Unspecified rider of other motorcycle injured in collision with fixed or stationary object in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.01XA	Electric (assisted) bicycle driver injured in noncollision transport accident in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.01XD	Electric (assisted) bicycle driver injured in noncollision transport accident in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.01XS	Electric (assisted) bicycle driver injured in noncollision transport accident in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.09XA	Other motorcycle driver injured in noncollision transport accident in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.09XD	Other motorcycle driver injured in noncollision transport accident in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.09XS	Other motorcycle driver injured in noncollision transport accident in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V28.11XA	Electric (assisted) bicycle passenger injured in noncollision transport accident in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.11XD	Electric (assisted) bicycle passenger injured in noncollision transport accident in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.11XS	Electric (assisted) bicycle passenger injured in noncollision transport accident in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.19XA	Other motorcycle passenger injured in noncollision transport accident in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.19XD	Other motorcycle passenger injured in noncollision transport accident in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.19XS	Other motorcycle passenger injured in noncollision transport accident in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.21XA	Unspecified electric (assisted) bicycle rider injured in noncollision transport accident in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.21XD	Unspecified electric (assisted) bicycle rider injured in noncollision transport accident in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.21XS	Unspecified electric (assisted) bicycle rider injured in noncollision transport accident in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.29XA	Unspecified rider of other motorcycle injured in noncollision transport accident in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V28.29XD	Unspecified rider of other motorcycle injured in noncollision transport accident in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V28.29XS	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in nontraffic			
	accident, sequela			
V28.31XA	Person boarding or alighting an electric	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	(assisted) bicycle injured in noncollision			
	transport accident, initial encounter			
V28.31XD	Person boarding or alighting an electric	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	(assisted) bicycle injured in noncollision			
	transport accident, subsequent encounter			
V28.31XS	Person boarding or alighting an electric	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	(assisted) bicycle injured in noncollision			
	transport accident, sequela			
V28.39XA	Person boarding or alighting other motorcycle	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in noncollision transport accident, initial			
	encounter			
V28.39XD	Person boarding or alighting other motorcycle	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in noncollision transport accident,			
	subsequent encounter			
V28.39XS	Person boarding or alighting other motorcycle	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in noncollision transport accident,			
	sequela			
V28.41XA	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, initial encounter			
V28.41XD	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, subsequent encounter			
V28.41XS	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, sequela			
V28.49XA	Other motorcycle driver injured in noncollision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	transport accident in traffic accident, initial			
	encounter			
V28.49XD	Other motorcycle driver injured in noncollision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	transport accident in traffic accident,			
	subsequent encounter			
V28.49XS	Other motorcycle driver injured in noncollision	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	transport accident in traffic accident, sequela			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V28.51XA	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, initial encounter			
V28.51XD	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, subsequent encounter			
V28.51XS	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, sequela			
V28.59XA	Other motorcycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, initial encounter			
V28.59XD	Other motorcycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, subsequent encounter			
V28.59XS	Other motorcycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, sequela			
V28.91XA	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in noncollision transport accident in			
	traffic accident, initial encounter			
V28.91XD	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in noncollision transport accident in			
	traffic accident, subsequent encounter			
V28.91XS	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in noncollision transport accident in			
	traffic accident, sequela			
V28.99XA	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, initial encounter			
V28.99XD	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, subsequent encounter			
V28.99XS	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	noncollision transport accident in traffic			
	accident, sequela			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V29.001A	Electric (assisted) bicycle driver injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.001D	Electric (assisted) bicycle driver injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.001S	Electric (assisted) bicycle driver injured in collision with unspecified motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.008A	Other motorcycle driver injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.008D	Other motorcycle driver injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.008S	Other motorcycle driver injured in collision with unspecified motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.091A	Electric (assisted) bicycle driver injured in collision with other motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.091D	Electric (assisted) bicycle driver injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.091S	Electric (assisted) bicycle driver injured in collision with other motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.098A	Other motorcycle driver injured in collision with other motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.098D	Other motorcycle driver injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V29.098S	Other motorcycle driver injured in collision with other motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.101A	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.101D	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.101S	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.108A	Other motorcycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.108D	Other motorcycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.108S	Other motorcycle passenger injured in collision with unspecified motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.191A	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.191D	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.191S	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.198A	Other motorcycle passenger injured in collision with other motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V29.198D	Other motorcycle passenger injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.198S	Other motorcycle passenger injured in collision with other motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.201A	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.201D	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.201S	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.208A	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.208D	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.208S	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in nontraffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.291A	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in nontraffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.291D	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in nontraffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V29.291S	Unspecified electric (assisted) bicycle rider	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in collision with other motor vehicles in			
	nontraffic accident, sequela			
V29.298A	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other motor vehicles in nontraffic			
	accident, initial encounter			
V29 298D	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
123.2300	collision with other motor vehicles in nontraffic			
	accident subsequent encounter			
V29.298S	Unspecified rider of other motorcycle injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other motor vehicles in nontraffic			
	accident, sequela			
V29.31XA	Electric (assisted) bicycle (driver) (passenger)	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in unspecified nontraffic accident, initial			
	encounter			
V29.31XD	Electric (assisted) bicycle (driver) (passenger)	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in unspecified nontraffic accident,			
	subsequent encounter			
V29.31XS	Electric (assisted) bicycle (driver) (passenger)	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	injured in unspecified nontraffic accident,	с ,		
	sequela			
V29.39XA	Other motorcycle (driver) (passenger) injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	unspecified nontraffic accident, initial encounter			
V29.39XD	Other motorcycle (driver) (passenger) injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	unspecified nontraffic accident, subsequent			
	encounter			
V29.39XS	Other motorcycle (driver) (passenger) injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	unspecified nontraffic accident, sequela			
V29.401A	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with unspecified motor vehicles in			
	traffic accident, initial encounter			
V29.401D	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with unspecified motor vehicles in			
	traffic accident, subsequent encounter			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V29.401S	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with unspecified motor vehicles in			
	traffic accident, sequela			
V29.408A	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	unspecified motor vehicles in traffic accident,			
	initial encounter			
V29.408D	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	unspecified motor vehicles in traffic accident,			
	subsequent encounter			
V29.408S	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	unspecified motor vehicles in traffic accident,			
	sequela			
V29.491A	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other motor vehicles in traffic			
	accident, initial encounter			
V29.491D	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other motor vehicles in traffic			
	accident, subsequent encounter			
V29.491S	Electric (assisted) bicycle driver injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with other motor vehicles in traffic			
	accident, sequela			
V29.498A	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	other motor vehicles in traffic accident, initial			
	encounter			
V29.498D	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	other motor vehicles in traffic accident,			
	subsequent encounter			
V29.498S	Other motorcycle driver injured in collision with	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	other motor vehicles in traffic accident, sequela			
V29.501A	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with unspecified motor vehicles in			
	traffic accident, initial encounter			
V29.501D	Electric (assisted) bicycle passenger injured in	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
	collision with unspecified motor vehicles in			
	traffic accident, subsequent encounter			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V29.501S	Electric (assisted) bicycle passenger injured in collision with unspecified motor vehicles in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.508A	Other motorcycle passenger injured in collision with unspecified motor vehicles in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.508D	Other motorcycle passenger injured in collision with unspecified motor vehicles in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.508S	Other motorcycle passenger injured in collision with unspecified motor vehicles in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.591A	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.591D	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.591S	Electric (assisted) bicycle passenger injured in collision with other motor vehicles in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.598A	Other motorcycle passenger injured in collision with other motor vehicles in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.598D	Other motorcycle passenger injured in collision with other motor vehicles in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.598S	Other motorcycle passenger injured in collision with other motor vehicles in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.601A	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V29.601D	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.601S	Unspecified electric (assisted) bicycle rider injured in collision with unspecified motor vehicles in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.608A	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.608D	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.608S	Unspecified rider of other motorcycle injured in collision with unspecified motor vehicles in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.691A	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.691D	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.691S	Unspecified electric (assisted) bicycle rider injured in collision with other motor vehicles in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.698A	Unspecified rider of other motorcycle injured in collision with other motor vehicles in traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.698D	Unspecified rider of other motorcycle injured in collision with other motor vehicles in traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V29.698S	Unspecified rider of other motorcycle injured in collision with other motor vehicles in traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.811A	Electric (assisted) bicycle rider (driver) (passenger) injured in transport accident with military vehicle, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.811D	Electric (assisted) bicycle rider (driver) (passenger) injured in transport accident with military vehicle, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.811S	Electric (assisted) bicycle rider (driver) (passenger) injured in transport accident with military vehicle, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.818A	Rider (driver) (passenger) of other motorcycle injured in transport accident with military vehicle, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.818D	Rider (driver) (passenger) of other motorcycle injured in transport accident with military vehicle, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.818S	Rider (driver) (passenger) of other motorcycle injured in transport accident with military vehicle, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.881A	Electric (assisted) bicycle rider (driver) (passenger) injured in other specified transport accidents, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.881D	Electric (assisted) bicycle rider (driver) (passenger) injured in other specified transport accidents, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.881S	Electric (assisted) bicycle rider (driver) (passenger) injured in other specified transport accidents, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.888A	Rider (driver) (passenger) of other motorcycle injured in other specified transport accidents, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
V29.888D	Rider (driver) (passenger) of other motorcycle injured in other specified transport accidents, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.888S	Rider (driver) (passenger) of other motorcycle injured in other specified transport accidents, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.91XA	Electric (assisted) bicycle rider (driver) (passenger) injured in unspecified traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.91XD	Electric (assisted) bicycle rider (driver) (passenger) injured in unspecified traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.91XS	Electric (assisted) bicycle rider (driver) (passenger) injured in unspecified traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.99XA	Rider (driver) (passenger) of other motorcycle injured in unspecified traffic accident, initial encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.99XD	Rider (driver) (passenger) of other motorcycle injured in unspecified traffic accident, subsequent encounter	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
V29.99XS	Rider (driver) (passenger) of other motorcycle injured in unspecified traffic accident, sequela	"V" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
W23.2XXA	Caught, crushed, jammed or pinched between a moving and stationary object, initial encounter	"W" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
W23.2XXD	Caught, crushed, jammed or pinched between a moving and stationary object, subsequent encounter	"W" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
W23.2XXS	Caught, crushed, jammed or pinched between a moving and stationary object, sequela	"W" codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z03.83	Encounter for observation for suspected conditions related to home physiologic monitoring device ruled out	Many "observation codes" are DWF to allow ER visits, etc.	DIAGNOSTIC WORKUP FILE (DWF)	
Z28.310^	Unvaccinated for COVID-19		INFORMATIONAL DIAGNOSES	Already placed
Z28.311^	Partially vaccinated for COVID-19		INFORMATIONAL DIAGNOSES	Already placed

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
Z28.39^	Other underimmunization status		INFORMATIONAL DIAGNOSES	Already placed
Z59.82	Transportation insecurity	Similar codes are INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z59.86	Financial insecurity	Similar codes are INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z59.87	Material hardship	Similar codes are INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z71.87	Encounter for pediatric-to-adult transition		DIAGNOSTIC WORKUP FILE (DWF)	Discussed and approved by BHAP
	counseling			
Z71.88	Encounter for counseling for socioeconomic		DIAGNOSTIC WORKUP FILE (DWF)	Discussed and approved by BHAP
	factors			
Z72.823	Risk of suffocation (smothering) under another		INFORMATIONAL DIAGNOSES	
	while sleeping			
Z79.60	Long term (current) use of unspecified	Similar codes are Diagnostic as use may require	DIAGNOSTIC WORKUP FILE (DWF)	
	immunomodulators and immunosuppressants	lab monitoring		
Z79.61	Long term (current) use of immunomodulator		DIAGNOSTIC WORKUP FILE (DWF)	
779 620	long term (current) use of immunosuppressive		DIAGNOSTIC WORKUP FILE (DWE)	
_/010_0	biologic			
Z79.621	Long term (current) use of calcineurin inhibitor		DIAGNOSTIC WORKUP FILE (DWF)	
Z79.622	Long term (current) use of Janus kinase inhibitor		DIAGNOSTIC WORKUP FILE (DWF)	
Z79.623	Long term (current) use of mammalian target of		DIAGNOSTIC WORKUP FILE (DWF)	
	rapamycin (mTOR) inhibitor			
Z79.624	Long term (current) use of inhibitors of		DIAGNOSTIC WORKUP FILE (DWF)	
	nucleotide synthesis			
Z79.630	Long term (current) use of alkylating agent		DIAGNOSTIC WORKUP FILE (DWF)	
Z79.631	Long term (current) use of antimetabolite agent		DIAGNOSTIC WORKUP FILE (DWF)	
Z79.632	Long term (current) use of antitumor antibiotic		DIAGNOSTIC WORKUP FILE (DWF)	
Z79.633	Long term (current) use of mitotic inhibitor		DIAGNOSTIC WORKUP FILE (DWF)	
770 604				
279.634	Long term (current) use of topoisomerase		DIAGNOSTIC WORKUP FILE (DWF)	
770.64				
279.64	Long term (current) use of myelosuppressive		DIAGNOSTIC WORKUP FILE (DWF)	
770.60	ageni			
219.09	Long term (current) use of other		DIAGNOSTIC WORKUP FILE (DWF)	
	initiation odulators and initiatiosuppressants			

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
Z79.85	Long-term (current) use of injectable non-insulin antidiabetic drugs		DIAGNOSTIC WORKUP FILE (DWF)	
Z87.61	Personal history of (corrected) necrotizing enterocolitis of newborn	Simlar codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	If results in short bowel syndrome, can use that diagnosis for further treatment
Z87.68	Personal history of other (corrected) conditions arising in the perinatal period	Simlar codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z87.731	Personal history of (corrected) tracheoesophageal fistula or atresia	Simlar codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z87.732	Personal history of (corrected) persistent cloaca or cloacal malformations	Simlar codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z87.760	Personal history of (corrected) congenital diaphragmatic hernia or other congenital diaphragm malformations	Simlar codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z87.761	Personal history of (corrected) gastroschisis	Simlar codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z87.762	Personal history of (corrected) prune belly malformation	Simlar codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z87.763	Personal history of other (corrected) congenital abdominal wall malformations	Simlar codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z87.768	Personal history of other specified (corrected) congenital malformations of integument, limbs and musculoskeletal system	Simlar codes are generally INFORMATIONAL	INFORMATIONAL DIAGNOSES	
Z91.110	Patient's noncompliance with dietary regimen due to financial hardship	Parent code Z91.11 (Patient's noncompliance with dietary regimen) was on INFORMATIONAL DIAGNOSES	INFORMATIONAL DIAGNOSES	
Z91.118	Patient's noncompliance with dietary regimen for other reason	See Z91.110	INFORMATIONAL DIAGNOSES	
Z91.119	Patient's noncompliance with dietary regimen due to unspecified reason	See Z91.110	INFORMATIONAL DIAGNOSES	
Z91.190	Patient's noncompliance with other medical treatment and regimen due to financial hardship	Parent code Z91.19 (Patient's noncompliance with other medical treatment and regimen) was on INFORMATIONAL DIAGNOSES	INFORMATIONAL DIAGNOSES	
Z91.198	Patient's noncompliance with other medical treatment and regimen for other reason	See Z91.190	INFORMATIONAL DIAGNOSES	

ICD10 Code	Code Description	Similar Codes	Recommended Placement	Comments
Z91.199	Patient's noncompliance with other medical	See Z91.190	INFORMATIONAL DIAGNOSES	
	treatment and regimen due to unspecified			
	reason			
Z91.A10	Caregiver's noncompliance with patient's dietary		INFORMATIONAL DIAGNOSES	
	regimen due to financial hardship			
Z91.A18	Caregiver's noncompliance with patient's dietary		INFORMATIONAL DIAGNOSES	
	regimen for other reason			
Z91.A20	Caregiver's intentional underdosing of patient's		INFORMATIONAL DIAGNOSES	
	medication regimen due to financial hardship			
Z91.A28	Caregiver's intentional underdosing of		INFORMATIONAL DIAGNOSES	
	medication regimen for other reason			
Z91.A3	Caregiver's unintentional underdosing of		INFORMATIONAL DIAGNOSES	
	patient's medication regimen			
Z91.A4	Caregiver's other noncompliance with patient's		INFORMATIONAL DIAGNOSES	
	medication regimen			
Z91.A5	Caregiver's noncompliance with patient's renal		INFORMATIONAL DIAGNOSES	
	dialysis			
Z91.A9	Caregiver's noncompliance with patient's other		INFORMATIONAL DIAGNOSES	
	medical treatment and regimen			

1) Postural orthostatic tachycardia syndrome (POTS)

Plain Language: An abnormal increase in heart rate that occurs after sitting up or standing. Some typical symptoms include dizziness and fainting.

Recommendation: Add to uncovered line 535 HYPOTENSION as well as covered lines to allow supportive care, including medication OR only add to line 535 HYPOTENSION as treatment is mostly self-care.

- a. Code: G90.A Postural orthostatic tachycardia syndrome [POTS]
- b. Definition: POTS is an abnormal increase in heart rate that occurs after sitting up or standing. Symptoms can include dizziness and fainting. Treatment is generally lifestyle changes such as increasing fluid intake, rising slowly from laying or sitting, and including more salt in the diet. Medications such as beta blockers, midodrine, fludrocortisone, and SSRIs may be used.
- c. Similar codes, such ag ICD-10-CM G90.01 (Carotid sinus syncope) are on the dysfunction lines and on line 535 HYPOTENSION
- d. HERC staff recommendation
 - i. Place G90.A (Postural orthostatic tachycardia syndrome [POTS]) on the dysfunction lines and line 535 HYPOTENSION
 - ii. Alternative: place on just line 535, but this would not allow medications to be prescribed for this condition
- 2) Fatigue syndromes
 - a. Codes
 - i. **G93.31** Postviral fatigue syndrome
 - ii. **G93.32** Myalgic encephalomyelitis/chronic fatigue syndrome
 - iii. **G93.39** Other post infection and related fatigue syndromes
 - b. Definition: Chronic fatigue syndrome and postviral fatigue syndrome are conditions characterized by profound fatigue, sleep abnormalities, pain, and other symptoms that are made worse by exertion. The cause of this condition is unknown, but may include environmental or genetic factors. The main symptom is fatigue for over six months. The fatigue often worsens with activity, but doesn't improve with rest. There is no cure or approved treatment for this condition.
 - c. Similar codes:
 - i. Parent code G93.2 (Postviral fatigue syndrome) is on the DIAGNOSTIC WORKUP FILE (DWF)
 - ii. R53.82 (Chronic fatigue, unspecified) is on line 531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS
 - iii. U09.9 (Post COVID condition, unspecified) is on line 399 INFLUENZA, COVID-19 AND OTHER NOVEL RESPIRATORY VIRAL ILLNESS. This code is used for long COVID
 - d. HERC staff recommendation:

- i. Place the G93.3X codes on line 531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS
- 3) Refractory angina

Plain Language: Long-lasting chest pain or pressure (>3 months), a symptom of heart disease not controllable by the best available medical treatment which includes bypass surgery.

Recommendation: Add to covered line 189 CHRONIC ISCHEMIC HEART DISEASE to allow for medications, repeat bypass grafting (taking a blood vessel from another body part, attaching it to the artery that supplies blood to the heart above and below the narrowed area that is blocked) and rehabilitation.

- a. Codes
 - i. **I20.2** Refractory angina pectoris
 - ii. **I25.112** Atherosclerotic heart disease of native coronary artery with refractory angina pectoris
 - iii. **I25.702, I25.712, I25.722, I25.732, I25.792** Atherosclerosis of various types of coronary artery bypass graft(s), with refractory angina pectoris
 - iv. **I25.752** Atherosclerosis of native coronary artery of transplanted heart with refractory angina pectoris
 - v. **I25.762** Atherosclerosis of bypass graft of coronary artery of transplanted heart with refractory angina pectoris
- b. Definition: Refractory angina (RA) is conventionally defined as a chronic condition (≥3 months in duration) characterized by angina in the setting of coronary artery disease (CAD), which cannot be controlled by a combination of optimal medical therapy, angioplasty or bypass surgery, and where reversible myocardial ischemia has been clinically established to be the cause of the symptoms
- c. Treatment includes beta blockers, calcium channel antagonists, vasodilators, PCI, redoing cardiac bypass grafting, and cardiac rehabilitation. Several investigational procedures are being studied for this condition including external enhanced counterpulsation, extracorporeal shockwave myocardial revascularization therapy, spinal cord stimulators.
- d. HERC staff recommendation:
 - i. Place this code series on line 189 CHRONIC ISCHEMIC HEART DISEASE
 - 1. Contains most other angina diagnosis codes
- 4) Antineutrophilic cytoplasmic antibody vasculitis

Plain Language: This is a blood test that looks for specific antibodies in blood. Autoantibodies are proteins made by the immune system that mistakenly targets normal tissues. If the antibodies are found vasculitis (swelling of blood vessels) could develop.

Recommendation: Add to covered lines 99 END STAGE RENAL DISEASE,129 GRANULOMATOSIS WITH POLYANGIITIS, and 219 PULMONARY FIBROSIS to allow for treatment of kidney, heart and lung diseases.

- a. Code: 177.81 Antineutrophilic cytoplasmic antibody [ANCA] vasculitis
- b. Definition: Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) is a group of three main diseases, which are granulomatosis with polyangiitis (GPA; formerly known as Wegener granulomatosis), eosinophilic granulomatosis with polyangiitis (EGPA; previously known as Churg-Strauss syndrome), and microscopic polyangiitis (MPA). Other ANCA-associated diseases are drug-induced vasculitis and renal limited vasculitis.
- c. Similar codes
 - i. Wegener granulomatosis is coded with M31.3X, which is on lines 99,129,219
 - ii. Churg-Strauss syndrome is coded with M30.1, which is on lines 99,129,219
- d. HERC staff recommendation
 - i. Place 177.81 on lines 99 END STAGE RENAL DISEASE,129 GRANULOMATOSIS WITH POLYANGIITIS, and 219 PULMONARY FIBROSIS
- 5) Transfusion-associated dyspnea (TAD)

Plain Language: An acute breathing problem that develops within 24 hours after getting a blood transfusion but less severe than an allergic reaction.

Recommendation: Add to covered line 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT for treatment of this condition.

- a. Code: J95.87 Transfusion-associated dyspnea (TAD)
- b. Definition: The National Healthcare Safety Network hemovigilance protocol defines transfusion associated dyspnea (TAD) as acute respiratory distress occurring without 24 hours of cessation of transfusion but does not meet the definition of allergic reaction, transfusion associated circulatory overload (TACO) and transfusion related acute lung injury (TRALI)
- c. Very little literature found regarding treatment of this condition
- d. Similar codes
 - i. Transfusion associated circulatory overload (TACO) is coded with E87.71 which is on line 221 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE
 - ii. Transfusion related acute lung injury (TRALI) is coded with J95.84 which is on 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
- e. HERC staff recommendation
 - i. Place J95.87 on line 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

Endometriosis of the intestine

Plain Language: Endometriosis is an ongoing, painful condition in which tissue like the kind that lines the uterus (the endometrium) grows outside of the uterus. When this condition affects the bowels, it appears in two forms: Superficial (on the surface of your bowel) Deep (passes through your bowel wall).

Recommendation: Add codes for superficial and unspecified diagnosis to covered line 395 ENDOMETRIOSIS AND ADENOMYOSIS. Add deep bowel diagnosis codes to covered line 41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION

- a. Codes:
 - i. **N80.50-NN80.569** Superficial, deep and unspecified endometriosis of various parts of the bowel
- b. Definition: Endometriosis is a common benign gynecological disease defined by the presence of endometrium glands outside the uterine cavity. Bowel endometriosis typically presents as a single nodule, with a diameter larger than 1 cm, commonly infiltrating the muscularis of the bowel and the surrounding structures. Bowel involvement accounts for 5% to 12% of the women presenting with the disease, with the rectum and sigmoid involved in up to 90% of all intestinal lesions. Symptoms of bowel endometriosis can be non-specific consisting of dysmenorrhea and dyspareunia. More specific bowel-related symptoms such as diarrhea, constipation, dyschezia and rarely bowel obstruction depend on disease localization, size of nodule and depth of involvement of the bowel wall. Treatment can be medical (oral contraceptives, Lupron, etc.). Surgical treatment of superficial lesions can be done as with other pelvic endometriosis (e.g. laparoscopic excision or ablation). If the endometriosis is deep, the bowel may need to be shaved or resected.
- c. Similar codes
 - i. Current endometriosis codes are all on line 395 ENDOMETRIOSIS AND ADENOMYOSIS. This line contains laparoscopy codes but no CPT codes for intestinal resection
 - Bowel resection CPT codes are on line 13 lines, including lines 29 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE, 41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION, 100 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION, various bowel cancer lines and line 638 BENIGN NEOPLASMS OF DIGESTIVE SYSTEM
- d. HERC staff recommendation:
 - i. Place superficial and unspecified bowel endometriosis diagnoses on line 395 ENDOMETRIOSIS AND ADENOMYOSIS.
 - Place deep bowel endometriosis diagnoses on line 395 and on line 41
 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS
 FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
 - 1. Line 41 will have all bowel resection codes and would be appropriate if the endometriosis results in bowel obstruction

6) Endometriosis of the bladder and ureters

Plain Language: This is a rare form of deep infiltrating endometriosis (DIE) in which growth of endometriosis (tissue resembling the endometrium) occurs in the bladder, ureters and kidneys.

Recommendation: Add codes for superficial and unspecified bladder/ureter endometriosis diagnoses on covered line 395 ENDOMETRIOSIS AND ADENOMYOSIS. Add deep bladder/ureter endometriosis diagnoses on covered lines 395 and 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION.

- a. Codes: N80.A0-N80.A69 Superficial, deep and unspecified endometriosis of the bladder and ureters
- b. Description: deep endometriosis of the bladder can result in acute urethral syndrome with frequency, tenesmus, burning sensation, pain during micturition, dysuria, hematuria, and suprapubic discomfort and pain. Treatment can be medical (OCPs, GnRH agonists, etc.). Surgical treatment includes partial cystectomy and transurethral resection of lesions
- c. Similar codes
 - i. Current endometriosis codes are all on line 395 ENDOMETRIOSIS AND ADENOMYOSIS. This line contains laparoscopy codes but no CPT codes for intestinal resection
 - Cystoscopy codes with resection of lesions appear on lines 86 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, 214 CANCER OF KIDNEY AND OTHER URINARY ORGANS, 271 CANCER OF BLADDER AND URETER and 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
 - iii. Partial cystoscopy codes appear on lines 86, 214, and 271
- d. HERC staff recommendation:
 - i. Place superficial and unspecified bladder/ureter endometriosis diagnoses on line 395 ENDOMETRIOSIS AND ADENOMYOSIS.
 - Place deep bladder/ureter endometriosis diagnoses on line 395 and on line 327
 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM
 INCLUDING BLADDER OUTLET OBSTRUCTION
 - 1. Line 327 has the majority of treatment codes needed for cystectomy and urethroplasty
- 7) Endometriosis of the lung and thoracic cavity

Plain Language: A rare condition that happens when endometriosis patches grow on or around the lungs. This can cause shortness of breath, chest pain, cough, and in some cases, a collapsed lung.

Recommendation: Add codes to covered lines 372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS and 395 ENDOMETRIOSIS AND ADENOMYOSIS.

- a. Codes: **N80.B1-N80.B6** Endometriosis of the pleura, lung, diaphragm, mediastinal and cardiothoracic space
- b. Definition: Thoracic Endometriosis Syndrome (TES) is an extremely rare condition that involves around the lungs such as pleura, pulmonary parenchyma, diaphragm, air ways and pericardium. Symptoms can include pneumothorax, hemothorax, hemoptysis, lung nodules as well middle mediastinal involvements such as pericardial effusion, pericardial nodules, and hemopericardium. Medical treatment would include OCPs and GnRH agonists as with other types of endometriosis. If the pulmonary disease is recurrent or progressive, thoracotomy, excision of lesions or pleurodesis may be necessary.
- c. Similar codes
 - i. Current endometriosis codes are all on line 395 ENDOMETRIOSIS AND ADENOMYOSIS. This line contains laparoscopy codes but no CPT codes for intestinal resection
 - Thoracotomy and resection of thoracic lesion CPT codes appear on several lines, including line 372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS
- d. HERC staff recommendation:
 - i. Place N80.B1-N80.B6 on lines 372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS and 395 ENDOMETRIOSIS AND ADENOMYOSIS.
- 8) Isthmocele

Plain Language: A uterine isthmocele is a defect on the inside wall of the womb at the site of a C-section scar.

Recommendation: Add codes to covered line 423 MENSTRUAL BLEEDING DISORDERS

- a. Code: N85.A Isthmocele
- b. Definition: A cesarean scar defect, which represents a myometrial discontinuity with the base communicating to the uterine cavity. The majority are asymptomatic. Symptomatic isthmoceles present with postmenstrual bleeding, secondary infertility, and/or pelvic pain. Symptomatic isthmocele or asymptomatic isthmocele in patients desiring future pregnancy are treated with surgery to close the defect, which can be done hysteroscopically, laparoscopically or transvaginally. In symptomatic patients not desiring fertility, hysterectomy can be a treatment option.
- c. CPT 58520 (Hysterorrhaphy, repair of ruptured uterus (nonobstetrical)) is on line 79 INJURY TO INTERNAL ORGANS
- d. CPT codes for hysterectomy appear on multiple lines, including 423 MENSTRUAL BLEEDING DISORDERS. Line 423 also contains CPT codes for hysteroscopy

- e. HERC staff recommendation
 - i. Place N85.A (Isthmocele) on line 423 MENSTRUAL BLEEDING DISORDERS
 - ii. Add CPT 58520 (Hysterorrhaphy, repair of ruptured uterus (nonobstetrical)) to line 423
- 9) Phakomatoses/tumor syndromes
 - a. Codes:
 - i. **Q85.81** PTEN tumor syndrome
 - ii. Q85.82 Other Cowden syndrome
 - iii. Q85.83 Von Hippel-Lindau syndrome
 - iv. Q85.89 Other phakomatoses, not elsewhere classified
 - b. Similar code: Parent code Q85.8 (Other phakomatoses, not elsewhere classified) was on line 125 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD. One specified subdiagnosis of this code was Von Hippel-Lindau syndrome. Other subdiagnoses include Peutz-Jeghers Syndrome and Sturge-Weber syndrome
 - c. Definitions
 - The PTEN hamartoma tumor syndrome (PHTS) is a spectrum of disorders caused by mutations of the PTEN tumor suppressor gene. These disorders are characterized by multiple hamartomas that can affect various areas of the body. People with PTEN mutations have an elevated risk of multiple cancers (see Cowden Syndrome below). 80% of patients with Cowden syndrome have a PTEN mutation.
 - Per NCCN Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic Version 2.2022, PTEN elevates breast cancer risk with a lifetime risk of 40-60%. Patients with PTEN mutation/Cowden syndrome should have breast cancer screening with annual mammograms and breast MRIs starting at age 35. Risk reducing mastectomy should be considered. Colon cancer screening should start at age 35 and occur at a minimum of every 5 years
 - ii. Cowden syndrome is a genetic disorder characterized by multiple noncancerous, tumor-like growths called hamartomas and an increased risk of developing certain cancers. Cowden syndrome is associated with an increased risk of developing cancers of the breast, thyroid, endometrium, kidney, colorectal cancer and melanoma. See above for NCCN guidelines regarding screening and treatment recommendations
 - iii. Von Hippel-Lindau syndrome is a rare, genetic disorder that causes tumors and cysts to grow in certain parts of the body, including the brain, spinal cord, eyes, inner ear, adrenal glands, pancreas, kidney, and reproductive tract. The tumors are usually benign, but some may be malignant. Patients with von Hippel-Lindau syndrome have an increased risk of certain types of cancer, especially kidney cancer and pancreatic cancer. It is caused by a mutation in the VHL gene.
 - iv. Phakomatoses, also known as neurocutaneous syndromes, are a broad group of congenital disorders that are characterized by hamartomatous lesions of the skin and the central and peripheral nervous systems.

- d. Additional Prioritized List information
 - i. PTEN and Cowden Syndrome are mentioned in Diagnostic Guideline D25, HEREDITARY CANCER GENETIC TESTING:
 - 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) or Genetic/Familial High-Risk Assessment: Colorectal V1.2021 (5/11/21) www.nccn.org).
 - ii. Other syndromes with elevated risk of breast cancer, such as BRCA, are included on line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
 - iii. Z15.01 (Genetic susceptibility to malignant neoplasm of breast) is on line 191.
 Z15.04 (Genetic susceptibility to malignant neoplasm of endometrium) and
 Z15.09 (Genetic susceptibility to other malignant neoplasm) are on
 INFORMATIONAL DIAGNOSES
- e. HERC staff recommendations
 - i. Place Q85.81 and Q85.82 on line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
 - 1. Allows prophylactic mastectomy
 - ii. Place Q85.83 and Q85.89 on line 125 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD
 - 1. Previous subdiagnoses of the parent code Q85.8 which was on line 125
 - iii. <u>As a 2024 Biennial Review item, consider creating a new line for conditions</u> which place a person at high risk of cancers
 - 1. <u>This line will take the high risk for breast cancer diagnoses/treatments,</u> and add additional treatments such as prophylactic colectomy, and have <u>a guideline allowing more frequent or more intensive screening</u>

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REVIEW

Bowel Endometriosis: Current Perspectives on Diagnosis and Treatment

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¹Department of Obstetrics and Gynaecology, Beaujon Hospital-University of Paris, Clichy Cedex 92110, France; ²Department of Molecular and Developmental Medicine, University of Siena, Ospedale Santa Maria alle Scotte, Siena 53100, Italy; ³Department of Colorectal Surgery-Delafontaine Hospital, Saint Denis 93200, France; ⁴Department of Obstetrics and Gynaecology, Whittington Hospital, London, UK **Abstract:** Endometriosis is a chronic condition primarily affecting young women of reproductive age. Although some women with bowel endometriosis may be asymptomatic patients typically report a myriad of symptoms such as alteration in bowel habits (constipation/diarrhoea) dyschezia, dysmenorrhoea and dyspareunia in addition to infertility. To date, there are no clear guidelines on the evaluation of patients with suspected bowel endometriosis. Several techniques have been proposed including transvaginal and/or transrectal ultrasonography, magnetic resonance imaging, and double-contrast barium enema. These different imaging modalities provide greater information regarding presence, location and extent of endometriosis ensuring patients are adequately informed whilst also optimizing preoperative planning. In cases where surgical management is indicated, surgery should be performed by experienced surgeons, in centres with access to multidisciplinary care. Treatment should be tailored according to patient symptoms and wishes with a view to excising as much disease as possible, whilst at the same time preserving organ function. In this review article current perspectives on diagnosis and management of bowel endometriosis are discussed.

Keywords: endometriosis, bowel endometriosis, segmental resection, recurrence, infertility

Background

Endometriosis is a common benign gynaecological disease defined by the presence of endometrium glands outside the uterine cavity. It is frequently diagnosed in the third decade of life, affecting 10–12% women of reproductive age.¹ The gold standard for diagnosis of endometriosis is visual inspection by laparoscopy. An experienced surgeon, familiar with the disease process and its varying clinical presentation, should perform the laparoscopy so as to safeguard that cases are not missed or overlooked. This ensures an accurate diagnosis is made in a timely manner with the best opportunity for a positive health outcome.^{2–4}

Deep endometriosis (DE) is defined as subperitoneal invasion by lesions exceeding 5 mm in depth. Disease involving the bowel can be associated with severe pain.^{5–7} DE can be found at multiple locations within the pelvis, but more frequently remain localized to the posterior compartment where it can involve the ureters, the torus uterinum, the uterosacral ligaments, the bowel, and the vaginal wall.

Bowel endometriosis typically presents as a single nodule, with a diameter larger than 1 cm, commonly infiltrating the muscularis of the bowel and the surrounding structures.^{8–10} Bowel involvement accounts for 5% to 12% of the women presenting with the disease, with the rectum and sigmoid involved in up to 90% of all intestinal lesions.^{4,11}

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Review

Urol Int 2012;89:249–258 DOI: 10.1159/000339519 Published online: July 20, 2012

Diagnosis and Treatment of Bladder Endometriosis: State of the Art

Key Words

Urinary tract endometriosis • Bladder endometriosis • Symptoms • Diagnosis • Treatment

Abstract

Background: The bladder is the most common affected site in urinary tract endometriosis, being diagnosed during gynecologic follow-up. The surgical urological treatment might lead to good results. Study Objective: To define the state of the art in the diagnosis and treatment of bladder endometriosis. *Methods:* We performed a literature review by searching the MEDLINE database for articles published between 1996 and 2011, limiting the searches to the words: urinary tract endometriosis, bladder endometriosis, symptoms, diagnosis and treatment. Results: Deep pelvic endometriosis usually involves the urinary system, with the bladder being affected in 85% of cases. The diagnosis has to be considered as a step-by-step procedure. Currently, the treatment is usually surgical, consisting of either transurethral resection or partial cystectomy, and eventually associated with hormonal therapy. The hormonal therapy alone counteracts only the stimulus of endometriotic tissue proliferation, with no effects on the scarring caused by this tissue. The overall recurrence rate is about 30% for combined therapies and about 35% for the hormonal treatment alone. Conclusions: The

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Accessible online at: www.karger.com/uin bladder is the most common affected site in urinary tract endometriosis. Most of the time, this condition is diagnosed because of the complaint of urinary symptoms during gynecologic follow-up procedures for a deep pelvic endometriosis: a close collaboration between the gynecologist and the urologist is advisable, especially in highly specialized centers. The surgical urological treatment might lead to good results in terms of patients' compliance and prognosis.

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Introduction

Deep infiltrating pelvic endometriosis (DIE) is defined as implantation of the stroma and/or endometrial glandular epithelium outside the endometrial cavity and the uterine musculature, penetrating into the retroperitoneal space or the wall of the pelvic organs to a depth of at least 5 mm [1]. Locations of DIE include: the torus uteri, posterior fornix, uterosacral ligaments, rectum, vagina, and urinary tract [2].

The incidence of urinary tract endometriosis (UTE) has increased during the last few years and, nowadays, it ranges from 0.3 up to 12%, considering all women affected by endometriosis [2–10].

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Cardiac Involvement Resulting from Thoracic Endometriosis

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Abstract

Endometriosis usually occurs in the pelvis and the most commonly involved sites are the ovaries, the uterosacral and broad ligaments and the parietal pelvic peritoneum. However, involvement of extra-pelvic organs is not uncommon. Much more uncommon sites for extrapelvic endometriosis are lungs, heart and brain involvement. It has been hypothesized that retrograde menstruations can lead to metastatic peritoneal implantations or the serous cells may be stimulated towards a metaplastic differentiation. We reported a 28-years old woman who suffered from thoracic endometriosis syndrome accompanied by cardiac involvement. Also our patient is the third report of surgically documented thoracic endometriosis syndrome, involving right side pleura and pericardium. She was urgently taken to operation room. Right side thoracotomy was carried out and complicated regions were resected and repaired.

Keywords: Endometriosis; Hemothorax; Hemopericardium; Thoracic endometriosis syndrome; Infertility; Dyspareunia; Dysmenorrhea; Major depressive disorder; Endometrial nodule

Abbreviations

TES: Thoracic Endometriosis Syndrome; OCPs: Oral Contraceptives; MDD: Major Depressive Disorder; MD: Major Depression; TCAs: Tricyclic Antidepressants; SSRIs: Selective Serotonin Reuptake Inhibitors; CXR: Chest X Ray; TAH: Total Abdominal Hysterectomy; BSO: Bilateral Salpingo-ophorectomy

Introduction

Endometriosis is defined as the presence of a normal endometrial tissue, including the stroma and glands, implanted outside the uterine cavity [1]. It affects as many as 10%-20% of fertile females and approximately 50% of infertile woman [2]. Carl von Rokitansky was the first one to identify endometriosis histologically under microscope. It commonly occurs in the genital organs (uterus, ovaries, vaginal fornix, posterior portion of cervix) leading to symptoms like dyspareunia, dysmenorrhea and dysuria [3]. It is presence in sites other than in genital organs is termed extra genital endometriosis and it can be subdivided into pelvic and extra pelvic endometriosis. The most frequently involved pelvic structures are the uterosacral ligaments (70%), vagina (14%), rectum (10%) and rectovaginal septum or bladder (6%). Extrapelvic endometriosis is a rare condition occurring in 8.9% of cases of endometriosis and may be seen in the abdominal wall and diaphragm .Much more uncommon sites for

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*Corresponding author: Zahra Sepehrmanesh, Department of Psychiatry, Kashan University of Medical Sciences, Iran, Tel: 00963112133000, 00963112133020; Fax: 00963112121620; E-mail: z.sepehrmanesh@gmail.com extrapelvic endometriosis are lungs, heart and brain involvement [4]. Thoracic Endometriosis Syndrome (TES) is an extremely rare condition that involves around the lungs such as pleura, pulmonary Parenchyma, diaphragm, air ways and pericardium. Most frequently involved mechanism accounting for the extragenital endometriosis is unclear. It has been hypothesized that retrograde menstruations can lead to metastatic peritoneal implantations or the serous cells may be stimulated towards a metaplastic differentiation. Despite extraperitoneal localizations could be owing to vascular or lymphatic dissemination [5,6].

Case Presentation

Our case was a 28 - years old, nulliparous female who had carried the past medical history of dysmenorrhea and infertility as well as Major Depressive Disorder (MDD) for almost 5-years. She had taken GNRH and OCPs for infertility also antidepressants (TCAs and SSRIs) for treatment of Major Depression (MD). 8-Months before her recent presentation, she experienced right upper quadrant abdominal pain and distention with high pitched bowel sounds. Abdominal ultrasound evaluation was unremarkable and the pain eventually resolved spontaneously. Two months after aforementioned history, she presented to the emergency ward of surgical department because of the left sided cramping abdominal pain accompanied by non bilious emesis. Abdominal CT scan and laparoscopic findings demonstrated extrinsic compression on the mid portion of the sigmoid due to peritoneal mass with adhesion in the pelvis. After that the patient underwent laparatomy and resection of sigmoid and appendectomy. The biopsy of the mass and its histopathology evaluation demonstrated the endometriosis. She was admitted to our center (cardiovascular surgery center) last week because of chest pain, breathlessness, palpitation, weaknesses, fatigue, feeling sick and faintness lasting 2-hours. She complained from severe sharp stabbing chest pain behind the breast bone. The pain intensified with coughing, lying down and deep inspiration and subsided with leaning forward. CXR showed pleural effusion on the right side and one liter of hemorrhagic fluid was drained from the pleural cavity (Figure 1).

Section 6.0 Biennial Review

Plain Language Summary:

<u>Background:</u> Surgical and medical treatment for disorders of the jaw muscles, temporomandibular joints (TMJ) and the nerves associated with chronic face pain.

<u>Should OHP cover this treatment?</u> Staff recommends not to cover this treatment because the evidence of effectiveness of treatment is extremely limited.

<u>Question</u>: Should any treatment for temporal mandibular joint (TMJ) syndrome be moved into the funded region of the Prioritized List?

Question source: HERC leadership/below the line review

<u>Issue</u>: Surgical and medical treatments for TMJ are on two separate lines below the funding line. As part of the below the line review, HERC staff were asked to look at whether any therapy for TMJ has evidence of effectiveness.

Temporomandibular disorders (TMDs) are a group of more than 30 conditions that cause pain and dysfunction in the jaw joint and muscles that control jaw movement. Symptoms include pain in the jaw joint or face, jaw stiffness, or limited movement or locking of the jaw. Treatment includes eating soft foots, taking NSAIDs or other over the counter pain medications, stopping chewing gum or jaw clenching, physical therapy, relaxation techniques, opioids, intraoral devices, and surgery.

<u>Previous HSC/HERC review</u>: no mention of TMJ were found in the meeting minutes from 1991 onward. January 2000: code D7871 (Reduction of dislocation and management of other temporomandibular joint dysfunctions, non-arthroscopic lysis and lavage) will become part of the exclude list (never covered).

November 2014:

- Remove 20605 (Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance) from lines 51 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS, 422 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 3 THROUGH 6, 430 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY, 544 LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS, 601 GANGLION, 612 DISORDERS OF SOFT TISSUE
- Place 20606 (Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting) on lines 50, 157, 290, 306, 468, 511, 533, 597
- Place D9130 (temporomandibular joint dysfunction non-invasive physical therapies) on line 547 TMJ DISORDER

November 2020:

- 1) Add D0320 (Temporomandibular joint arthrogram, including injection) to line 643 TMJ DISORDERS and remove from DIAGNOSTIC PROCEDURES file
- 2) Add D0321 (Other temporomandibular joint radiographic images, by report) to line 643 TMJ DISORDERS and remove from DIAGNOSTIC PROCEDURES file

Current Prioritized List status

Line 550 TMJ DISORDER Treatment: TMJ SPLINTS (includes office visits and other outpatient care) Line 643 TMJ DISORDER Treatment: TMJ SURGERY

Evidence

- 1) **CADTH 2018,** systematic review of reviews of interventions for temporomandibular joint disorder
 - a. N=22 systematic reviews
 - i. Interventions covered by the included SRs included psychological interventions, orthodontics, surgical interventions, laser therapy, and occlusal appliances
 - ii. Comparators included were no treatment or placebo/sham treatment
 - iii. Overall, the quality of the included studies was low. Based on the AMSTAR 2 assessment, confidence in the SRs was rated high for two included SRs, moderate in one SR, low in three SRs, and critically low in the remaining 16 SRs
 - b. Overall, low-quality evidence showed potentially favorable results for long-term cognitive behavior therapy, low level laser therapy, acupuncture, manual therapy, cyclobenzaprine hydrochloride, Botulinum toxin, Ping-On ointment, inferior or double spaces injections of hyaluronate or prednisolone, open surgery, and arthroscopy. Mixed or neutral results were found regarding stabilization splints and oral pharmacological treatments. Potentially unfavorable results were found for hypnosis and intra-articular injections of corticosteroids. No evidence was found for orthodontic interventions
 - i. <u>Psychological interventions</u>: Two SRs examined psychological interventions for TMD. We have low confidence in the results of one SR and critically low confidence in the results from the other SR. They included a total of 18 primary studies. Generally, the evidence regarding various psychological treatments for TMD was of low quality and at unclear or high risk of bias. Additionally, most of the results from MAs were either inconclusive or insignificant.
 - ii. <u>Acupuncture or laser therapy</u>: Three SRs examined acupuncture or laser therapy for TMD, and we have critically low confidence in the results from all three SRs. The SRs included a total of 73 primary studies. Overall, much of the evidence regarding acupuncture and laser therapies for the treatment of TMD had unclear or high risk for bias and there was substantial heterogeneity. Interventions that may be associated with improvements in pain are low level laser therapy (LLLT) (versus placebo) and acupuncture (versus sham acupuncture). LLLT may also be associated with improvements in mouth opening (versus placebo)
 - iii. <u>Physical therapy:</u> Two SRs examined the effects of manual therapy for TMD, and we have critically low confidence in the results from both SRs. These SRs reported on 57 primary studies and examined a variety of manual therapies such as jaw or neck exercises. Overall, much of the evidence regarding manual and physical therapies for the treatment of TMD was of moderate quality. Interventions that may be associated with improvements in pain are manual therapy targeted to the orofacial region (versus other controls; in patient with myogenous TMD) and manual therapy plus jaw exercises (versus other control;

in patients with arthrogenous TMD). Musculoskeletal manual approaches (versus active control) may be associated with unfavorable pain results.

- iv. <u>Splint therapy:</u> Three SRs examined splint therapy for TMD treatment, and we had critically low confidence in the results from all three SRs. These SRs reported on 89 primary studies. Stabilization splints (versus non-occluding appliances), splints (hard, soft, or unspecified; versus other control) and hard stabilization appliances (versus non-occluding appliances) may be associated with improvements in pain scores. None of the comparisons yielded statistically significantly unfavorable results with respect to pain scores. Splints (hard, soft, or unspecified) (versus other control) may be associated with improvements in mouth opening; however, one SR found that stabilization splints (versus other control) had unfavorable results
- v. <u>Orthodontic interventions</u>: One SR was identified on the use of orthodontics for treating TMD; however, no primary studies were identified in the SR and therefore no results could be reported. We have moderate confidence in the results of this SR, as there were no critical flaws
- vi. Injections: Six SRs investigated the effects of injecting various pharmacological agents for TMD symptoms. We have low confidence in the results from one SR, and critically low confidence in the results from the other five SRs. The risk of bias relating to the evidence regarding pharmacological injections was mixed, though most of the statistically significantly favorable results had low, medium, and moderate risk of bias. Injectable pharmacological interventions that may be associated with improvements in pain were cyclobenzaprine hydrochloride (versus placebo), botulinum toxin (versus placebo), inferior space injection or double spaces injection of hyaluronate or prednisolone (versus the same drug administered as a superior space injection), and pingon (versus placebo). None of the comparisons yielded statistically significantly unfavorable results with respect to pain. Inferior space injection or double spaces injection of hyaluronate or prednisolone (versus the same drug administered as a superior space injection) may also be associated with improvements in mouth opening and corticosteroid intra-articular injection after arthrocentesis (versus saline or Ringer's lactate intra-articular injection with arthrocentesis) may be associated with unfavorable mouth opening results.
- c. Conclusions: Due to the low quality of included literature, the limited evidence regarding TMJ clicking and adverse events, and the heterogeneity of SRs included in this report, firm conclusions regarding the optimal interventions for TMD cannot be made
- 2) CADTH 2020: rapid review of botulinum toxin for temporomandibular disorders
 - a. N=5 studies
 - i. Four systematic reviews were included including three systematic reviews without meta-analysis and one systematic review with a network meta-analysis. One open-label, parallel group RCT was included
 - ii. These reports included comparisons of botulinum toxin to occlusive splints, physiotherapy (fascial manipulation, dry needling), pharmacotherapy, placebo, acupuncture, psychological approaches, complementary therapies, saline injections, lidocaine and laser
 - iii. None of the included systematic reviews expressed confidence in the efficacy of botulinum toxin for treating TMD. There were some primary studies that

reported improvements in pain scores relative to saline injections. However, this result was not reproduced in several primary studies, and the clinical significance of observed changes is uncertain.

- 3) **Riley 2020**, Health technology assessment of oral splints for patients with temporomandibular disorders or bruxism
 - a. N=52 trials
 - i. The evidence identified was of very low quality with unclear reporting
 - b. there was no evidence that splints reduced pain [standardized mean difference (at up to 3 months) –0.18, 95% confidence interval –0.42 to 0.06; substantial heterogeneity] when compared with no splints or a minimal intervention. There was no evidence that other outcomes, including temporomandibular joint noises, decreased mouth-opening, and quality of life, improved when using splints
 - c. Conclusions: The very low-quality evidence identified did not demonstrate that splints reduced pain in temporomandibular disorders as a group of conditions
- 4) Rigon 2011, Cochrane review of arthroscopy for TMJ
 - a. N=7 RCTs (n = 349)
 - b. All studies were either at high or unclear risk of bias. The outcome pain was evaluated after 6 months in two studies. No statistically significant differences were found between the arthroscopy versus nonsurgical groups (standardized mean difference (SMD) = 0.004; 95% confidence interval (CI) -0.46 to 0.55, P = 0.81). Two studies, analyzed pain 12 months after surgery (arthroscopy and arthrocentesis) in 81 patients. No statistically significant differences were found (mean difference (MD) = 0.10; 95% CI -1.46 to 1.66, P = 0.90).
 - c. Authors' conclusions Both arthroscopy and nonsurgical treatments reduced pain after 6 months. When compared with arthroscopy, open surgery was more effective at reducing pain after 12 months. Nevertheless, there were no differences in mandibular functionality or in other outcomes in clinical evaluations.

Other payer policies

1) Aetna 2022

- a. Note: many plans do not cover TMD or TMJ dysfunction
- **b.** Medically necessary comprehensive non-surgical management of TMJ/TMD includes *all* of the following, unless contraindicated:
 - i. Reversible Intra-Oral Appliances
 - (i.e., removable occlusal orthopedic appliances-orthotics, stabilization appliances, occlusal splints, bite appliances/planes/splints, mandibular occlusal repositioning appliances [MORAs])
 - Reversible intra-oral appliances may be considered medically necessary in selected cases only when there is evidence of clinically significant masticatory impairment with documented pain and/or loss of function. Prolonged (greater than 6 months) application of TMD/J intraoral appliances is not considered medically necessary unless, upon individual case review, documentation is provided that supports prolonged intra-oral appliance use.
 - ii. Aetna considers physical therapy to be a medically necessary conservative method of TMD/TMJ treatment

- iii. Aetna considers non-opiate analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) medically necessary for mild-to-moderate inflammatory conditions and pain. Low-dosage tricyclic antidepressants (e.g., amitriptyline) are considered medically necessary for treatment of chronic pain, sleep disturbance and nocturnal bruxism. Adjuvant pharmacologic therapies, including anticonvulsants, membrane stabilizers, and sympatholytic agents, are considered medically necessary for unremitting TMJ pain. Opiate analgesics, corticosteroids, anxiolytics, and muscle relaxants are considered medically necessary in refractory pain.
- iv. Aetna considers relaxation therapy, electromyographic biofeedback and cognitive behavioral therapy medically necessary for treatment of TMJ/TMD.
- v. Aetna considers acupuncture and trigger point injections medically necessary for persons with temporomandibular pain. For acute pain, generally 2 visits per week for 2 weeks are considered medically necessary. Additional treatment is considered medically necessary when pain persists and further improvement is expected.
- c. Surgical Procedures
 - Medically necessary surgical procedures for TMJ/TMD include therapeutic arthroscopy, arthrocentesis, condylotomy/eminectomy, modified condylotomy, arthroplasty, and joint reconstruction using autogenous or alloplastic materials. In general, the least invasive appropriate surgical treatments should be attempted prior to progression to more complicated surgeries

2) Regence BCBS 2021

- a. Coverage does not include treatment of temporomandibular joint disorder or developmental maxillofacial conditions that result in overbite, crossbite, malocclusion or similar developmental irregularities of the teeth.
- 3) MODA 2022, TMJ non-surgical treatment
 - a. Treatment of temporomandibular joint (TMJ) dysfunction may be a limited or excluded benefit under some Moda Health medical plans
 - b. Treatment of TMJ will be covered to plan limitations when 1 or more of the following criteria are met:
 - i. Non-surgical treatment with a custom intra-oral prosthetic devices/splints will be covered with ALL of the following:
 - 1. At least 2 or more of the following symptoms are present:
 - a. Extra-articular pain related to muscles of the head and neck region, or earaches, headaches, masticatory or cervical myalgias
 - b. Painful chewing
 - c. Restricted range of motion
 - d. Popping in the jaw
 - e. Diagnosis confirmed by Dental/Periodontal/Maxillofacial Imaging
 - 2. Failure to respond to total of 6 weeks of conservative treatment with at least 3 or more of the following:
 - a. Removal of precipitating activities, analgesics, NSAID's, soft diet and proper chewing techniques
 - b. Failure to respond to a course of physical therapy
 - c. Use of TENS unit when performed by PT or a dentist
2024 Biennial Review Temporamandibular Joint Syndrome

- d. Ultrasound
- e. Hot/Cold packs
- f. Acupuncture
- g. Trigger point injections
- ii. The following TMJ treatments will NOT be covered. This includes but is not limited to ALL of the following:
 - 1. Bite (occlusal) adjustment/equilibration
 - 2. Crowns, bridges, amalgams, etc. to restore tooth alignment or to balance the bite
 - 3. Orthodontia
 - 4. Appliances strictly for the treatment of bruxism (grinding of the teeth)
 - 5. Botox injections
 - 6. Continuous passive motion (CPM)
 - 7. Intra-oral appliances for the treatment of headaches or trigeminal neuralgia are considered experimental and investigational, as there is insufficient data on the effectiveness of this therapy
 - 8. Chiropractic adjustment treatments
 - 9. Use of TENS units (unless performed by PT or a dentist)
 - 10. EMG as it is considered investigational since medical necessity has not been established
- iii. Orthognathic Surgery this is typically a plan exclusion.

2024 Biennial Review Temporamandibular Joint Syndrome

HERC staff summary

The evidence regarding the effectiveness of any treatment for TMJ is extremely limited. Most major insurers note that many of their plans do not cover TMJ treatment.

HERC staff recommendation:

Make no change in the current prioritization of medical and surgical treatment of TMJ on unfunded lines

CADTH RAPID RESPONSE REPORT: SYSTEMATIC REVIEW Interventions for Temporomandibular Joint Disorder: An Overview of Systematic Reviews

Service Line:Rapid Response ServiceVersion:1.0Publication Date:September 28, 2018Report Length:108 Pages

Executive Summary

Issue

Temporomandibular disorders (TMD) are disorders involving the temporomandibular joint (TMJ) and associated structures, and affect 5% to 12% of individuals. TMD can lead to chronic pain, tooth grinding, and cervical spine and mobility issues, all of which are precursors to more serious impairment of function. There are a plethora of different strategies to treat TMD, including pharmacological interventions, non-surgical interventions, and surgery.

This overview of reviews aims to summarize evidence regarding the clinical effectiveness and safety of interventions in adults (17 and older) and children (0 to 17) with TMD.

Objectives

The objective of the current report was to answer the following research question:

What are the optimal interventions for the treatment of TMD in children and adults in terms of clinical effectiveness and safety?

Clinical Evidence

Methods

An overview and critical appraisal of systematic reviews (SRs) relevant to the clinical effectiveness of pharmacological and non-pharmacological interventions for TMD was conducted. Published literature was identified by searching the following bibliographic databases: MEDLINE through Ovid; Embase through Ovid; PsycINFO through Ovid; the Cochrane Library through Wiley; and PubMed. The search strategy consisted of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The search was limited by study design, with only health technology assessments, SRs, and meta-analyses (MAs) retrieved, and limited to English-language documents published since January 1, 2008. Results were screened independently by two reviewers, and data were extracted by one reviewer and verified by another.

The quality of included SR and MAs were assessed independently by two reviewers using the AMSTAR 2 tool. The results were narratively summarized and categorized based on the interventions and stratified by outcomes.

Results

There were 45 SRs that met the criteria for inclusion into the review. After assessment of overlap in primary studies between the SRs, 22 SRs were included in the final report. Within the 22 SRs, one study was a network meta-analysis, and 13 SRs included an MA within the results.

Interventions covered by the included SRs included psychological interventions, orthodontics, surgical interventions, laser therapy, and occlusal appliances. Outcomes of interest for this report included pain, maximal mouth opening, TMJ clicking, and adverse

events. Overall, the quality of the included studies was low. Based on the AMSTAR 2 assessment, confidence in the SRs was rated high for two included SRs, moderate in one SR, low in three SRs, and critically low in the remaining 16 SRs. Issues contributing to low confidence in some SRs included inappropriate MAs, high heterogeneity of primary studies, potential of publication bias of primary studies, inadequate descriptions of included studies, and no a priori protocols.

Overall, low-quality evidence showed potentially favourable results for long-term cognitive behaviour therapy, low level laser therapy, acupuncture, manual therapy, cyclobenzaprine hydrochloride, Botulinum toxin, Ping-On ointment, inferior or double spaces injections of hyaluronate or prednisolone, open surgery, and arthroscopy. Mixed or neutral results were found regarding stabilization splints and oral pharmacological treatments. Potentially unfavourable results were found for hypnosis and intra-articular injections of corticosteroids. No evidence was found for orthodontic interventions, and very limited evidence was found regarding TMJ clicking and adverse events. However, many studies used differing comparative groups, and many comparisons have critically low confidence associated with them, so these presented results should be interpreted with caution.

Conclusions

Due to the low quality of included literature, the limited evidence regarding TMJ clicking and adverse events, and the heterogeneity of SRs included in this report, firm conclusions regarding the optimal interventions for TMD cannot be made.

Limitations of the current report include exclusion of some primary studies due to overlap in SRs, reliability on interpretations of primary studies by authors of the SRs, low quality of evidence, and large proportions of primary studies rated as high risks for bias. Additionally, as inclusion criteria for the current report were broad, the volume of literature obtained was large and heterogeneous, making solid conclusions based on the current literature challenging.

Context and Policy Issues

Introduction

Temporomandibular disorders (TMDs) are defined by the Royal College of Dental Surgeons of Ontario (RCDSO) as "complex ailments involving the temporomandibular joints themselves and associated structures."¹ It is estimated that the prevalence of TMD is between 5% and 12%.² TMD is associated with chronic orofacial pain, bruxism (tooth grinding), as well as conditions affecting the cervical spine and mobility, all of which can lead to more serious health concerns.^{3,4} Symptoms include, but are not limited to, temporomandibular joint (TMJ) pain, noise in the joint, masticatory muscle tenderness, and limited mandibular movement.⁵ The TMJ of the mandible connects the jawbone to the skull, and acts as both a rotational and translational joint.⁶ The bones that interact in the joint are covered with fibrocartilage and are separated by a shock-absorbing disc to keep movements smooth (for the anatomical features of the TMJ, see Appendix 1, Figure 1).⁶ The TMJ allows the jaw to move and perform basic functions such as chewing and talking.⁷ Although the underlying cause of many cases of TMJ symptoms are unclear, issues with the joint can arise if the disc erodes or is it not properly aligned, the cartilage is damaged by arthritis, or the joint is damaged by an impact.⁶



CADTH RAPID RESPONSE REPORT: SUMMARY WITH CRITICAL APPRAISAL Botulinum Toxin for Temporomandibular Disorders: A Review of Clinical Effectiveness, Cost-Effectiveness, and Guidelines

Service Line:Rapid Response ServiceVersion:1.0Publication Date:February 25, 2020Report Length:24 Pages

Limitations

The main limitations of this review are related to the quality of the available evidence and the heterogeneity of the condition and existing treatment approaches.

Through the quality assessment of the systematic reviews it was evident that they were of low to moderate quality. In the included systematic reviews, the descriptions of populations, interventions, comparators and results were often incomplete. TMD has a heterogeneous clinical presentation and there are also many possible differences in techniques for administration of botulinum toxin and other treatments.^{1,16,17} This heterogeneity and the lack of information about these key aspects of the primary studies limit our ability to generalize the findings of the systematic reviews reviewed in this report.

A significant weakness of the primary studies in the included systematic reviews is that, like the included RCT, many of them used open-label designs. Placebo effect has been shown to impact outcome evaluation in TMD treatment and an open-label approach would be expected to introduce bias into pain assessments.¹⁸ The generalizability of the results of the RCT is also limited because it was performed at a single center study located in Turkey and the interventions were administered by one clinician.

Future research could reduce uncertainty and would include well-designed RCTs with blinded methodology. In addition, many of the primary studies described in the systematic reviews were small (N<30) and therefore future studies should have adequate statistical power to detect differences between botulinum toxin and other treatment approaches.

Conclusions and Implications for Decision or Policy Making

A total of five relevant publications were identified that met the inclusion criteria for this report including four systematic reviews,¹¹⁻¹⁴ and one RCT.¹² These reports included comparisons of botulinum toxin to occlusive splints, physiotherapy (fascial manipulation, dry needling), pharmacotherapy, placebo, acupuncture, psychological approaches, complementary therapies, saline injections, lidocaine and laser.

None of the included systematic reviews expressed confidence in the efficacy of botulinum toxin for treating TMD. There were some primary studies that reported improvements in pain scores relative to saline injections. However, this result was not reproduced in several primary studies, and the clinical significance of observed changes is uncertain. No systematic reviews reported improvements in mouth opening for botulinum toxin. In the primary studies, there was heterogeneity in TMD clinical presentation, botulinum toxin administration techniques and comparator treatment approaches and this creates significant uncertainty about the clinical utility for botulinum toxin in TMD. Assessing generalizability of the results to the Canadian context is difficult given these issues.

While there have been no consistent signals of increased risk of harm for botulinum toxin relative to control groups in the data reviewed, none of the primary studies were rigorously designed to study harms. This is an important issue to be addressed in future research since botulinum toxin treatment for TMD is an invasive procedure with risks inherent in its administration.

There was no evidence to inform the cost effectiveness of botulinum toxin in TMD and no clinical practice guidelines were identified.



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Oral splints for patients with temporomandibular disorders or bruxism: a systematic review and economic evaluation

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This report

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Abstract

Oral splints for patients with temporomandibular disorders or bruxism: a systematic review and economic evaluation

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Background: Splints are a non-invasive, reversible management option for temporomandibular disorders or bruxism. The clinical effectiveness and cost-effectiveness of splints remain uncertain.

Objectives: The objectives were to evaluate the clinical effectiveness and cost-effectiveness of splints for patients with temporomandibular disorders or bruxism. This evidence synthesis compared (1) all types of splint versus no/minimal treatment/control splints and (2) prefabricated versus custom-made splints, for the primary outcomes, which were pain (temporomandibular disorders) and tooth wear (bruxism).

Review methods: Four databases, including MEDLINE and EMBASE, were searched from inception until 1 October 2018 for randomised clinical trials. The searches were conducted on 1 October 2018. Cochrane review methods (including risk of bias) were used for the systematic review. Standardised mean differences were pooled for the primary outcome of pain, using random-effects models in temporomandibular disorder patients. A Markov cohort, state-transition model, populated using current pain and Characteristic Pain Intensity data, was used to estimate the incremental cost-effectiveness ratio for splints compared with no splint, from an NHS perspective over a lifetime horizon. A value-of-information analysis identified future research priorities.

Results: Fifty-two trials were included in the systematic review. The evidence identified was of very low quality with unclear reporting by temporomandibular disorder subtype. When all subtypes were pooled into one global temporomandibular disorder group, there was no evidence that splints reduced pain [standardised mean difference (at up to 3 months) -0.18, 95% confidence interval -0.42 to 0.06; substantial heterogeneity] when compared with no splints or a minimal intervention. There was no evidence that other outcomes, including temporomandibular joint noises, decreased mouth-opening, and quality of life, improved when using splints. Adverse events were generally not reported, but seemed infrequent when reported. The most plausible base-case incremental cost-effectiveness ratio was uncertain and driven by the lack of clinical effectiveness evidence. The cost-effectiveness acceptability curve showed splints becoming more cost-effective at a willingness-to-pay threshold of \approx £6000, but the probability never exceeded 60% at higher levels of willingness to pay. Results were

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sensitive to longer-term extrapolation assumptions. A value-of-information analysis indicated that further research is required. There were no studies measuring tooth wear in patients with bruxism. One small study looked at pain and found a reduction in the splint group [mean difference (0–10 scale) –2.01, 95% CI –1.40 to –2.62; very low-quality evidence]. As there was no evidence of a difference between splints and no splints, the second objective became irrelevant.

Limitations: There was a large variation in the diagnostic criteria, splint types and outcome measures used and reported. Sensitivity analyses based on these limitations did not indicate a reduction in pain.

Conclusions: The very low-quality evidence identified did not demonstrate that splints reduced pain in temporomandibular disorders as a group of conditions. There is insufficient evidence to determine whether or not splints reduce tooth wear in patients with bruxism. There remains substantial uncertainty surrounding the most plausible incremental cost-effectiveness ratio.

Future work: There is a need for well-conducted trials to determine the clinical effectiveness and cost-effectiveness of splints in patients with carefully diagnosed and subtyped temporomandibular disorders, and patients with bruxism, using agreed measures of pain and tooth wear.

Study registration: This study is registered as PROSPERO CRD42017068512.

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Cochrane Database of Systematic Reviews

Arthroscopy for temporomandibular disorders (Review)

Rigon M, Pereira LM, Bortoluzzi MC, Loguercio AD, Ramos AL, Cardoso JR

Rigon M, Pereira LM, Bortoluzzi MC, Loguercio AD, Ramos AL, Cardoso JR. Arthroscopy for temporomandibular disorders. *Cochrane Database of Systematic Reviews* 2011, Issue 5. Art. No.: CD006385. DOI: 10.1002/14651858.CD006385.pub2.

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TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	3
OBJECTIVES	4
METHODS	4
RESULTS	5
Figure 1	6
Figure 2	7
DISCUSSION	8
AUTHORS' CONCLUSIONS	8
ACKNOWLEDGEMENTS	9
REFERENCES	10
CHARACTERISTICS OF STUDIES	12
HISTORY	18
CONTRIBUTIONS OF AUTHORS	18
DECLARATIONS OF INTEREST	18
SOURCES OF SUPPORT	18
INDEX TERMS	18



[Intervention Review]

Arthroscopy for temporomandibular disorders

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ABSTRACT

Background

Temporomandibular disorders (TMDs) are considered a collection of disorders involving many organic, psychological and psychosocial factors. They can involve the masticatory muscles or the temporomandibular joint (TMJ) and associated structures, or both. It is estimated that 40% to 75% of the population displays at least one sign of the disease and 33% of the population reports at least one symptom. Arthroscopy has been used to reduce signs and symptoms of patients with TMD but the effectiveness has still not been totally explained.

Objectives

To assess the effectiveness of arthroscopy for the management of signs and symptoms in patients with TMDs.

Search methods

The Cochrane Oral Health Group Trials Register (to 23 December 2010), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, Issue 4, 2010), MEDLINE via OVID (1950 to 23 December 2010), EMBASE via OVID (1980 to 23 December 2010), LILACS via BIREME Virtual Health Library (1982 to 23 December 2010), Allied and Complementary Medicine Database (AMED) via OVID (1985 to 23 December 2010). There were no restrictions regarding the language or date of publication.

Selection criteria

Randomized controlled clinical trials of arthroscopy for treating TMDs were included.

Data collection and analysis

Two review authors independently extracted data, and three review authors independently assessed the risk of bias of included trials. The authors of the selected articles were contacted for additional information.

Main results

Seven randomized controlled trials (n = 349) met the inclusion criteria. All studies were either at high or unclear risk of bias. The outcome pain was evaluated after 6 months in two studies. No statistically significant differences were found between the arthroscopy versus nonsurgical groups (standardized mean difference (SMD) = 0.004; 95% confidence interval (CI) -0.46 to 0.55, P = 0.81). Two studies, analyzed pain 12 months after surgery (arthroscopy and arthrocentesis) in 81 patients. No statistically significant differences were found (mean difference (MD) = 0.10; 95% CI -1.46 to 1.66, P = 0.90). Three studies analyzed the same outcome in patients who had been submitted to arthroscopic surgery or to open surgery and a statistically significant difference was found after 12 months (SMD = 0.45; 95% CI 0.01 to 0.89, P = 0.05) in favor of open surgery. The two studies compared the maximum interincisal opening in six different clinical outcomes (interincisal opening over 35 mm; maximum protrusion over 5 mm; click; crepitation; tenderness on palpation in the TMJ and the jaw



muscles 12 months after arthroscopy and open surgery). The outcome measures did not present statistically significant differences (odds ratio (OR) = 1.00; 95% CI 0.45 to 2.21, P = 1.00). Two studies compared the maximum interincisal opening after 12 months of postsurgical follow-up. A statistically significant difference in favor of the arthroscopy group was observed (MD = 5.28; 95% CI 3.46 to 7.10, P < 0.0001). The two studies compared the mandibular function after 12 months of follow-up with 40 patients evaluated. The outcome measure was mandibular functionality (MFIQ). This difference was not statistically significant (MD = 1.58; 95% CI -0.78 to 3.94, P = 0.19).

Authors' conclusions

Both arthroscopy and nonsurgical treatments reduced pain after 6 months. When compared with arthroscopy, open surgery was more effective at reducing pain after 12 months. Nevertheless, there were no differences in mandibular functionality or in other outcomes in clinical evaluations. Arthroscopy led to greater improvement in maximum interincisal opening after 12 months than arthrocentesis; however, there was no difference in pain.

PLAIN LANGUAGE SUMMARY

Arthroscopy for temporomandibular disorders

Temporomandibular disorder (TMD) is a term describing problems with the chewing muscles or the jaw joint and associated structures, or both. There are different types of treatments for TMDs. Arthroscopy (a form of surgery) has been used to reduce signs and symptoms of patients with TMD, but the effectiveness has still not been totally explained. This review found no differences after treatment in mandibular functionality or in clinical evaluations. Arthroscopy led to greater improvement in maximum interincisal opening after 12 months than arthrocentesis. When compared with arthroscopy, open surgery was more effective at reducing pain after 12 months.

BACKGROUND

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Temporomandibular disorder (TMD) is a collective term embracing a number of clinical problems that involve the masticatory muscles, the temporomandibular joint and associated structures, or both (Okeson 1996). TMD is also considered a collection of disorders involving many organic, psychological and psychosocial factors (Suvinen 2005). The etiology of TMD is still not clear, but reports have been made regarding: parafunctional activity (Israel 1999), hormonal influence (Warren 2001), stress (Bonjardim 2005), previous trauma (Westermark 2001), morphology of the temporomandibular joint (TMJ) (Sulun 2001), presence of bacteria in the TMJ synovial fluid (Kim 2003) and other causes such as orthodontic treatment, condyle position (superior-anteriormedial) and occlusion (Rinchuse 2005; Shen 2005). A study in Belgium showed that 80.9% of children, aged 6 to 12 years, experienced the presence of TMD symptoms (Tuerlings 2004). A study carried out in Germany found that 38% of geriatric patients exhibited symptoms of TMD (joint sounds on opening) (Schmitter 2005), and 20% to 30% of adults have experienced some TMJ dysfunctions (Swift 1998). The guidelines of the American Academy of Orofacial Pain estimates 40% to 75% of the population displays at least one sign of the disease and 33% of the population reports at least one symptom (Okeson 1996).

The most common signs and symptoms include facial and jaw pain which can be aggravated by jaw movements, TMD joint noises (clicking or crepitus), and restriction of mandibular movements (Guo 2009). The diagnosis for TMD may require special investigations methods such as magnetic resonance imaging (MRI), transcranial tomograms (for concomitant condylar disorder) or arthroscopy (Katzberg 2005; Kurita 2005; Truelove 1992).

The heterogeneity of these TMDs led to the development of the research diagnostic criteria for TMDs providing clear inclusion criteria for some TMD subgroups. Since then, part of TMD research has implemented these criteria. Indeed, from 1992 onwards, it will probably be possible to focus on treatment efficacy on particular subgroups of TMD (e.g. myofascial pain, internal derangements), based upon the research diagnostic criteria (Dworkin 1992).

Different treatments are accepted worldwide, divided into nonsurgical methods and surgical intervention such as (Goudot 2000; Yuasa 2001):

- Physical therapy: Exercises of active and passive jaw protrusion and opening movements. In cases of pain manual/finger massages of the masticatory muscles and their insertion points, ultrasound, ionophoresis (electrogalvanic stimulation with transdermal transport of medical agents);
- Occlusion and splint therapy: Removable appliance covering some or all of the occlusal surfaces of the teeth in either the maxillary or mandibular arches. It should provide even simultaneous contacts on closure on the retruded axis with all opposing teeth and anterior guidance, causing immediate disclusion of the posterior teeth and splint surface outside;
- Drug therapies: Nonsteroidal anti-inflammatory drugs (NSAIDS), skeletal muscle relaxers, ansiolitic and antidepressant drugs;
- Diet alteration: Soft diet.

If these methods prove unsuccessful for a patient, they are sometimes followed by surgical interventions such as (Holmlund 2001; Miyamoto 1999; Politi 2007):

- Arthrocentesis: Lavage of the upper joint space, hydraulic pressure and manipulation to release adhesions and improve motion. The procedure can be completed with local anaesthesia.
- Open surgery (high condylectomy): Surgical procedures for the treatment of the internal derangement of the TMJ, bone recontouring, condylar reduction a surgical technique including the removal of 2 to 4 mm of the top of the condyle. It is performed through a preauricular incision and a deep subfascial approach. After joint exposure a 2 to 3 mm section of the anterior-superior slope of the condyle is removed and the articular surface reshaped. The cortical edges is then smoothed by shaving. The disc is repositioned by traction of the lateral ligament. Finally, repositioning and suturing of the lateral ligament.
- Lysis and Lavage: An inferolateral approach is used for trocar puncture, and an outflow needle is placed through the skin 5 mm anterior to and slightly below the entry of the trocar. The upper compartment of the TMJ is examined with a telescope. Any fibrous adhesions are released using a blunt trocar. The upper compartment is irrigated with isotonic saline solution, using the outflow needle for injection and the arthroscopic cannula for outflow. After, the patient remains in the clinic for about 1 hour to recover, before being discharged. All arthroscopic procedures are performed in the outpatient clinic under local anaesthesia and intravenous sedation.
- AALCR: Arthroscopic anterolateral capsular release (AALCR). The disc and capsule are released anteriorly by electrocautery and the capsule is released laterally.
- Dyscectomy: It is performed under general anaesthesia. The joint is exposed through a preauricular incision. After excision of the disc, any irregularities on the condyle are smoothed with a diamond file. No autogenous or alloplastic replacement materials are inserted.
- Arthroscopy: Arthroscopy is performed with the patient under general anaesthesia. The superior joint space is lavaged, intracapsular adhesions lysis, and intracapsular betamethasone is injected. Success is assessed when the mandible can be manually moved through excursive movements. Arthroscopic surgery is performed through an inferolateral approach (single puncture technique) for trocar puncture, and an outflow needle is placed through the skin 5 mm anterior to and slightly below the entry of the trocar. The upper compartment of the TMJ is examined with a telescope and irrigated with lactated Ringer's solution. Any fibrous adhesions are released in a semiblind fashion using a blunt trocar. Then a Moses elevator is inserted into the superior joint compartment via the inferolateral portal to perform a lateral eminence release and capsular stretch. No steroid injection is given. Sodium hyaluronate is injected in the upper joint space at the end of the procedure.

In 1975, Ohnishi adapted the orthopaedic arthroscopy for use in the small dimensions of the TMJ (Ohnishi 1975). Over the following decades, TMJ arthroscopy has lead to a better understanding of the normal and abnormal relationships of the intra-articular disc and associated diseases, which has led to an improved understanding of TMJ pain and dysfunction (Indresano 2001). Arthroscopy is accomplished with a rigid optic fibre with diameter

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varying between 1.7 and 2.7 mm. Through this procedure someone can obtain visualization of cavities and joint tissues, perform diagnosis, irrigations, biopsies, remove adhesions (intra-articular), correct traumas located in the lateral capsules and even take photographs (Moses 1989).

A previous review has compared arthroscopy with arthrocentesis (Guo 2009), however there is still not consensus regarding the use of arthroscopy in the management of signs and symptoms in patients with TMD. Few studies have dealt with the efficacy of arthroscopy for treating TMD and most of them have some bias in the methodological design (Goudot 2000; Reston 2003). This systematic review, comparing arthroscopy with all other treatment options, will help both clinicians and patients to make safe informative decisions.

OBJECTIVES

To compare the effectiveness of arthroscopy when compared to open surgery, arthocentesis and nonsurgical treatment for the outcomes: pain, functionality and clinical signs.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled clinical trials (RCTs) of arthroscopy for treating temporomandibular disorders (TMDs) were included.

Types of participants

Adults (older than 18 years) with a diagnosis of: synovitis, disc displacement with or without reduction, myofascial dysfunction, degenerative diseases or psycho-affective disorders with orofacial pain.

Types of interventions

Active intervention: arthroscopy for TMD. Control: no treatment, splint therapy, physiotherapy, surgery or pharmacological treatment.

Types of outcome measures

Primary outcomes

Relief of pain in the temporomandibular joint (TMJ) and masticatory muscles (clinical symptoms), as well as tenderness during palpation of TMJ and masticatory muscles. Also, joint sounds or crepitation were included. This included the Helkimo anamnestic index or the dysfunction index or both.

Secondary outcomes

Clinical examination by the professional, such as maximum interincisal opening, quantitative measurements of lateral movement and protrusion, tenderness during palpation of the TMJ and determination of joint sounds during movement. The proportion of patients who improved after treatment ('improvement' assessed by the patient or by the clinical assessment carried out by the professional), quality of life and adverse events.

Search methods for identification of studies

For the identification of studies included or considered for this review, detailed search strategies were developed for each database searched. These were based on the search strategy developed for MEDLINE (OVID) but revised appropriately for each database. The search strategy used a combination of controlled vocabulary and free text terms and was linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials (RCTs) in MEDLINE: sensitivitymaximizing version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011) (Higgins 2011). Details of the MEDLINE search are provided in Appendix 1. The searches of EMBASE and CINAHL were linked to the Cochrane Oral Health Group filters for identifying RCTs, and the search of LILACS was linked to the Brazilian Cochrane Center filter.

- The Cochrane Oral Health Group Trials Register (to 23 December 2010) (Appendix 2)
- The Cochrane Central Register of Controlled Trials (CENTRAL) (via *The Cochrane Library*, Issue 4, 2010) (Appendix 3)
- MEDLINE via OVID (1950 23 December 2010) (Appendix 1)
- EMBASE via OVID (1980 23 December 2010) (Appendix 4)
- CINAHL via EBSCO (1980 23 December 2010) (Appendix 5)
- The Allied and Complementary Medicine Database (AMED) via OVID (1985 23 December 2010) (Appendix 6)
- LILACS via BIREME Virtual Health Library (1982 23 December 2010) (Appendix 7)

There were no restrictions regarding language or date of publication.

Handsearching

The reference lists of the included articles were checked manually to identify any additional studies. Handsearching was performed by two review authors in the following journals:

BBO (Bibliografia Brasileira em Odontologia - Oral Brazilian Bibliography) (1979-2010)

Chinese Journal of Dental Research (2007-2010)

Chinese Journal of Stomatology (1991-2010)

Chinese Journal of Orthodontics (1994-2010)

Chinese Journal of Implantology (1996-2010)

Journal of Stomatology (1991-2010)

Journal of Practical Stomatology (1991-2010)

Chinese Journal of Conservative Dentistry (1991-2010)

Journal of Maxillofacial Surgery (1991-2010)

Shaghai Journal of Stomatology (1991-2010)

Beijing Journal of Stomatology (1993-2010)

Chinese Journal of Dental Prevention and Treatment (1993-2010)

Chinese Journal of Orthodontics (1994-2010)

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Arthroscopy for temporomandibular disorders (Review)



Chinese Jounal of Implantology (1996-2010)

Unpublished literature

The proceedings of international conferences regarding dental, oral and maxillofacial surgery from 1990 were manually searched. The key words 'arthroscopy' and 'temporomandibular joint' were used as screening words.

Data collection and analysis

Selection of studies

Titles and abstracts of identified studies were assessed independently by two review authors to judge if the studies match the inclusion criteria. Then, the full texts of the potentially relevant studies were examined by the same authors. Reasons for excluding studies are in Characteristics of excluded studies.

Data extraction and management

Two review authors, independently and in duplicate, assessed the titles and abstracts of all reports of trials identified by the electronic searching outlined above. Hard copies of the full text of studies that possibly fulfil the inclusion criteria were obtained. Divergences were solved by a third review author, or by consensus. Further information was requested from the authors whose papers contained insufficient information and a decision about eligibility was made.

Assessment of risk of bias in included studies

The quality of all studies that were considered eligible for the review were assessed independently by two review authors, and disagreements will be resolved by a consensus meeting with a third review author. In the case of discrepancies, the authors of the paper were contacted for details, if necessary. The methods described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (Higgins 2011) were used.

Six main quality criteria were examined: (1) Adequate sequence generation; (2) Allocation concealment; (3) Blinding; (4) Incomplete outcome data addressed; (5) Free of selective reporting; and (6) Follow-up. These items were assessed according to the Cochrane Collaboration standard scheme: 'low risk', 'high risk' or 'unclear risk'.

After taking into account the additional information provided by the authors of the trials, studies were grouped into the following categories.

- Low risk of bias (plausible bias unlikely to seriously alter the results) if all criteria were met.
- Unclear risk of bias (plausible bias that raises some doubt about the results) if one or more criteria were assessed as unclear.
- High risk of bias (plausible bias that seriously weakens confidence in the results) if one or more criteria were not met.

Data synthesis

Comparisons were made separately according to the type of control group (no treatment, splint, physical therapy, open surgery and pharmacological treatment). Pooling of trials was only attempted if at least two trials of comparable protocols, with the same conditions and similar outcome measurements were available. Statistical analysis was performed using RevMan software, and in

Arthroscopy for temporomandibular disorders (Review)

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accordance with the Cochrane Collaboration statistical guidelines. The significance of discrepancies in the estimates of treatment effects from the different trials were assessed by inspection of a graphical display and by means of Cochran's test for heterogeneity. The I^2 statistic was also examined.

Odds ratios, along with 95% confidence intervals (CI) for categorical data and mean differences with 95% CI for continuous data were calculated. A fixed-effect or random-effects model was used when appropriate.

Subgroup analysis and investigation of heterogeneity

There were too few studies identified for these to be undertaken.

Sensitivity analysis

There were too few studies identified for these to be undertaken.

RESULTS

Description of studies

Results of the search

Sixty-two potentially eligible studies were found.

Included studies

Seven randomized controlled trials (RCTs) (n = 349) met the inclusion criteria (Fridrich 1996; Goudot 2000; Holmlund 2001; Miyamoto 1999; Politi 2007; Schiffman 2007; Stegenga 1993).

Of these seven included studies, two compared the effects of arthroscopy and arthrocentesis for pain reduction and the reestablishment of function (Fridrich 1996; Goudot 2000). The five remaining studies compared arthroscopy with other surgical and nonsurgical techniques. Schiffman 2007 compared arthroscopy with: medical management (education, self-help programs, pharmaceuticals), open surgery (arthroplasty) and rehabilitation in patients with pain, limited mouth opening and closed lock (stage III or IV). Politi 2007 compared arthroscopy with open surgery (high condylectomy and disc repositioning) in patients with chronic temporomandibular joint (TMJ) closed lock. Holmlund 2001 compared arthroscopy with open surgery (dyscectomy) in patients with chronic closed lock. Miyamoto 1999 compared the effects of two distinct techniques of arthroscopy (lysis/ lavage and arthroscopic anterolateral capsular release) in patients with internal TMJ derangement. Finally, Stegenga 1993 compared arthroscopy with nonsurgical treatment in patients with TMJ osteoarthritis and internal derangement.

Details of the included studies are presented in the Characteristics of included studies tables.

Excluded studies

A total of 95 of these studies were indexed in two or more databases. Fourteen out of 50 were not related to the subject (other types of treatments), and although 25 others were related to the subject, they were not RCTs. Eleven complete studies were evaluated; four were excluded because they were classified as quasi-randomized; they are presented in the Characteristics of excluded studies tables.



Risk of bias in included studies

The risk of bias in the included studies were assessed by two review authors. Only one study reported allocation concealment and sequence generation (Schiffman 2007). Other studies were described as randomized, but information about allocation concealment was missing. Only one study used an outcome measure blinded assessor (Schiffman 2007). Others forms of blinding were not found (participants and professionals). Given the interventions being studied, it would not have been feasible to have blinded the participants or carers to the treatment group. Fridrich 1996 and Holmlund 2001 had incomplete outcome data. Fridrich 1996, Goudot 2000 and Schiffman 2007 presented unclear study protocols and Holmlund 2001 did not present the study protocol. All studies had follow-ups. Summary of risk of bias is presented in Figure 1 and Figure 2.







Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Effects of interventions

Arthroscopy versus open surgery

Pain after 12 months

Three studies were included in this comparison (Holmlund 2001; Politi 2007; Schiffman 2007). The clinical outcome was assessed by visual analogue scale (VAS) and symptom severity index (SSI) after 12 months of follow-up in 81 patients who had been submitted to arthroscopic surgery or to open surgery. A statistically significant difference was found in favor of the open surgery group (standardized mean difference (SMD) = 0.45; 95% confidence interval (CI) 0.01 to 0.89, P = 0.05) (Analysis 1.1).

Mandibular function after 12 months

Two studies were included in this comparison (Holmlund 2001; Politi 2007), with 40 patients evaluated after 12 months of followup. The outcome measure was mandibular functionality (MFIQ). This difference was not statistically significant (mean difference (MD) = 1.58; 95% CI -0.78 to 3.94, P = 0.19) (Analysis 1.2).

Clinical evaluations: 12 months after surgery

In two studies, the maximum interincisal opening was compared in six clinical evaluations (interincisal opening over 35 mm; maximum protrusion over 5 mm; click; crepitation; tenderness on palpation in TMJ and the jaw muscles 12 months after surgery). The outcome



measures did not present statistically significant differences (odds ratio (OR) = 1.00; 95% CI 0.45 to 2.21, P = 1.00) (Analysis 1.3) (Holmlund 2001; Politi 2007).

Arthroscopy versus arthrocentesis

Maximum interincisal opening: 12 months after surgery

Two studies comparing the maximum interincisal opening (in millimetres (mm)), with 81 patients who underwent arthroscopy or arthrocentesis were included. After twelve months of postsurgical follow-up, a statistically significant difference in favor of the arthroscopy group was observed (MD = 5.28; 95% CI 3.46 to 7.10, P < 0.0001) (Analysis 2.1) (Fridrich 1996; Goudot 2000).

Pain: 12 months after surgery

Fridrich 1996 and Goudot 2000 analyzed postsurgical pain (arthroscopy and arthrocentesis) (Analysis 2.2) in 81 patients. The measurement instrument used in the 12 months postsurgical period was VAS. No statistically significant differences were found (MD = 0.10; 95% CI -1.46 to 1.66, P = 0.90).

Arthroscopy versus nonsurgical treatment

Pain: 6 months after surgery

Two studies were included in this comparison (Schiffman 2007; Stegenga 1993), with a total of 62 patients (Analysis 3.1). Pain was evaluated after 6 months. No statistically significant differences were found between the groups (SMD = 0.004; 95% CI -0.46 to 0.55, P = 0.86).

DISCUSSION

Meta-analysis combined the results of the studies in six comparisons. Due to different outcome measures, it was necessary to subdivide the studies for comparison. This caused a further reduction in the number of studies for analysis and was also mentioned in Reston 2003.

Therefore, due to a restricted number of randomized controlled trials (RCTs), many of which present a high risk of bias, the role of this type of treatment has not been clearly established in the literature. The number of studies found in the databases was insufficient in number, and only six RCTs were used to compare temporomandibular joint (TMJ) arthroscopy with other surgical and nonsurgical techniques. Only one of these compared two different techniques of arthroscopy. A search in the main databases of Brazilian and Latin American studies (Brazilian Bibliography of Odontology, Scielo and Latin American and the Caribbean Literature in Sciences of the Health) did not identify a single RCT conforming to the criteria of this review.

In four studies, the number of patients was considered too low. Holmlund 2001 compared two techniques (arthroscopy and open surgery) with two groups that contained 10 patients each. They calculated the sample size and the number of patients to detect differences between these techniques would have to have been too large to be practical. Stegenga 1993 evaluated only nine patients in the arthroscopy group and 12 in the nonsurgical group (patients with osteoarthritis). The authors discussed the sample size in terms of the dilemma of having a small but homogenous sample or having a large but heterogeneous sample and suggested care in the interpretation of the results of the study. Politi 2007 compared condylectomy with arthroscopy in patients with chronic closed lock, using 10 subjects in each group. The authors justified the low number of participants included in the study explaining the difficulty of finding this type of dysfunction. Fridrich 1996 also evaluated a small number of patients (arthroscopy = 11 and arthrocentesis = 8) and concluded that this affected the statistical power of their study as well.

Only one study (Schiffman 2007) could be considered of better quality than the others because it was the only study that demonstrated correct randomization, allocation concealment and blinding of outcome assessment. This is also the only study with a higher number of patients (106). The other studies provided inadequate methodological documentation, for example: a) vagueness about the application of information-gathering instruments (scales, questionnaires and evaluations); b) a lack of important statistical data in some tables (measure of central tendency and variability); and c) vagueness of randomization and allocation concealment description.

One RCT with a higher sample size was not added in this review because of difference in patient inclusion criteria. Morey-Mas 2010, through an RCT, investigated if patients (n = 40), with Wilkes stage III and IV disease, who did arthroscopic lysis and lavage and also received sodium hyaluronate (SH) or Ringer lavage injections, resulted in better postoperative pain control and TMJ function. They concluded that an SH injection after arthroscopic lysis and lavage is effective in reducing pain in patients with TMJ dysfunction. SH maintained its analgesic effect for 6 months, justifying its postarthroscopic use.

Reston 2003 published a systematic review, with meta-analysis of two RCTs (Fridrich 1996, Miyamoto 1999), in order to identify which surgical procedures were more effective in patients with degenerative TMJ diseases and previous disc displacement, with or without reduction. The authors commented on the low quality of the included studies, as well as the limited number of comparative studies in this area. Due to these limitations, it was not possible to establish the effects of these interventions. Hall 2005 criticized the use of small numbers of studies for meta-analysis in dentistry, and affirmed that it is necessary to have more RCTs in order to demonstrate the effectiveness of the different surgical techniques. If there is difficulty in achieving a minimum number of patients according to specific inclusion criteria, multicenter studies should be conducted as a way to qualify the effect of either treatment. An updated systematic review could help clinicians decide on the best treatment for TMDs, because the role of this type of treatment has not been clearly established in the literature.

AUTHORS' CONCLUSIONS

Implications for practice

For professionals and patients (with closed lock), the results of this review suggest that, when compared to arthroscopy, open surgery can reduce pain after 12 months. After 12 months, maximum interincisal opening can be expected in (disc displacement with or without reduction) in patients undergoing arthroscopy compared to arthrocentesis. However, surgical interventions (open, arthroscopy or arthrocentesis) should be considered if nonsurgical treatments have been failed.



Implications for research

One of the main implications of this systematic review is highlighting the necessity for new studies investigating the effectiveness of arthroscopy in patients with temporomandibular disorders. The evaluation of outcome measurements should take place after 1, 3, 6 and 12 months (or even more). New RCTs should also follow Consort-Statement (www.consortstatement.org) guidelines and that would contribute to clinical decision-making in dentistry.

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REFERENCES

References to studies included in this review

Fridrich 1996 {published data only}

Fridrich KL, Wise JM, Zeitler DL. Prospective comparison of arthroscopy and arthrocentesis for temporomandibular joint disorders. *Journal of Oral and Maxillofacial Surgery* 1996;**54**(7):816-20.

Goudot 2000 {published data only}

Goudot P, Jaquinet AR, Hugonnet S, Haefliger W, Richter M. Improvement of pain and function after arthroscopy and arthrocentesis of the temporomandibular joint: a comparative study. *Journal of Cranio-Maxillo-Facial Surgery* 2000;**28**(1):39-43.

Holmlund 2001 {published data only}

Holmlund AB, Axelsson S, Gynther GW. A comparison of discectomy and arthroscopic lysis and lavage for the treatment of chronic closed lock of the temporomandibular joint: a randomized outcome study. *Journal of Oral and Maxillofacial Surgery* 2001;**59**(9):972-7.

Miyamoto 1999 {published data only}

Miyamoto H, Sakashita H, Miyata M, Goss AN. Arthroscopic surgery of the temporomandibular joint: comparison of two successful techniques. *British Journal of Oral and Maxillofacial Surgery* 1999;**37**(5):397-400.

Politi 2007 {published data only}

Politi M, Sembronio S, Robiony M, Costa F, Torro C, Undt G. High condylectomy and disc repositioning compared to arthroscopic lysis, lavage, and capsular stretch for the treatment of chronic closed lock of the temporomandibular joint. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics* 2007;**103**(1):27-33.

Schiffman 2007 {published data only}

Schiffman EL, Look JO, Hodges JS, Swift JQ, Decker KL, Hathaway KM, et al. Randomized effectiveness study of four therapeutics strategies for TMJ closed lock. *Journal of Dental Research* 2007;**86**(1):58-63.

Stegenga 1993 {published data only}

Stegenga B, de Bont LG, Dijkstra PU, Boering G. Short-term outcome of arthroscopic surgery of temporomandibular joint osteoarthrosis and internal derangement: a randomized controlled clinical trial. *British Journal of Oral and Maxillofacial Surgery* 1993;**31**(1):3-14.

References to studies excluded from this review

Hall 2005 {published data only}

Hall HD, Indressano AT, Kirk WS, Dietrich MS. Prospective multicenter comparison of 4 temporomandibular joint operations. *Journal of Oral and Maxillofacial Surgery* 2005;**63**(8):1174-9.

Morey-Mas 2010 {published data only}

Morey-Mas MA, Caubet-Biayna J, Varela-Sende L, Iriarte-Ortabe JI. Sodium hyaluronate improves outcomes after arthroscopic lysis and lavage in patients with Wilkes stage III and IV disease. *Journal of Oral and Maxillofacial Surgery* 2010;**68**(5):1069-74.

Murakami 1995 {published data only}

Murakami K, Hosaka H, Moriya Y, Segami N, lizuka T. Shortterm treatment outcome study for the management of temporomandibular joint closed lock. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics* 1995;**80**(3):253-7.

Sanroman 2004 {published data only}

Sanromán JF. Closed lock (MRI fixed disc): a comparison of arthrocentesis and arthroscopy. *International Journal of Oral and Maxillofacial Surgery* 2004;**33**(4):344-8.

Sato 2003 {published data only}

Sato J, Segami N, Nishimura M, Suzuki T, Kaneyama K, Fujimura K. Clinical evaluation of arthroscopic eminoplasty for habitual dislocation of the temporomandibular joint: comparative study with conventional open eminectomy. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics* 2003;**95**(4):390-5.

Additional references

Bonjardim 2005

Bonjardim LR, Gaviao MB, Pereira LJ, Castelo PM. Anxiety and depression in adolescents and their relationship with signs and symptoms of temporomandibular disorders. *International Journal of Prosthodontics* 2005;**18**(4):347-52.

Dimitroulis 2005a

Dimitroulis G. The prevalence of osteoarthrosis in cases of advanced internal derangement of the temporomandibular joint: a clinical, surgical and histological study. *International Journal of Oral and Maxillofacial Surgery* 2005;**34**(4):345-9.

Dimitroulis 2005b

Dimitroulis G. The role of surgery in the management of disorders of the temporomandibular joint: a critical review of the literature. Part 1. *International Journal of Oral and Maxillofacial Surgery* 2005;**34**(2):107-13.

Dworkin 1992

Dworkin SF, LeResche L. Research diagnostic criteria for temporomandibular disorders: review, criteria, examinations and specifications, critique. *Journal of Craniomandibular Disorders: Facial and Oral Pain* 1992;**6**(4):301-55.

Emshoff 2002

Emshoff R, Innerhofer K, Rudisch A, Bertram S. The biological concept of "internal derangement and osteoarthrosis": a diagnostic approach in patients with temporomandibular joint pain?. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics* 2002;**93**(1):39-44.

Arthroscopy for temporomandibular disorders (Review)



Goudot 2000

Goudot P, Jaquinet AR, Hugonnet S, Haefliger W, Richter M. Improvement of pain and function after arthroscopy and arthrocentesis of the temporomandibular joint: a comparative study. *Journal of Cranio-Maxillo-Facial Surgery* 2000;**28**(1):39-43.

Guo 2009

Guo C, Shi Z, Revington P. Arthrocentesis and lavage for treating temporomandibular joint disorders. *Cochrane Database of Systematic Reviews* 2009, Issue 4. [Art. No.: CD004973. DOI: 10.1002/14651858.CD004973.pub2]

Higgins 2011

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Indresano 2001

Indresano AT. Surgical arthroscopy as the preferred treatment for internal derangements of the temporomandibular joint. *Journal of Oral and Maxillofacial Surgery* 2001;**59**(3):308-12.

Israel 1999

Israel HA, Diamond B, Saed-Nejad F, Ratcliffe A. The relationship between parafunctional masticatory activity and arthroscopically diagnosed temporomandibular joint pathology. *Journal of Oral and Maxillofacial Surgery* 1999;**57**(9):1034-9.

Katzberg 2005

Katzberg RW, Tallents RH. Normal and abnormal temporomandibular joint disc and posterior attachment as depicted by magnetic resonance imaging in symptomatic and asymptomatic subjects. *Journal of Oral and Maxillofacial Surgery* 2005;**63**(8):1155-61.

Kim 2003

Kim SJ, Park YH, Hong SP, Cho BO, Park JW, Kim SG. The presence of bacteria in the synovial fluid of the temporomandibular joint and clinical significance: preliminary study. *Journal of Oral and Maxillofacial Surgery* 2003;**61**(10):1156-61.

Kurita 2005

Kurita K, Ogi N, Miyamoto K, Goss AN. Diagnostic evaluation of an ultrathin 15,000 fiberoptic arthroscope: comparison of arthroscopic and histologic findings in a sheep model. *Journal* of Oral and Maxillofacial Surgery 2005;**63**(3):319-22.

Moses 1989

Moses JJ, Sartoris D, Glass R, Tanaka T, Poker I. The effect of arthroscopic surgical lysis and lavage of the superior joint space on TMJ disc position and mobility. *Journal of Oral and Maxillofacial Surgery* 1989;**47**(7):674-8.

Ohnishi 1975

Ohnishi M. Arthroscopy of the temporomandibular joint. *Journal of the Japanese Stomatology Society* 1975;**42**:207-12.

Okeson 1996

Okeson JP. Guidelines for assessment, diagnosis, and management. Orofacial pain. Chicago: Quintessence Publishing Co, Inc, 1996:116-7.

Reston 2003

Reston JT, Turkelson CM. Meta-analysis of surgical treatments for temporomandibular articular disorders. *Journal of Oral and Maxillofacial Surgery* 2003;**61**(1):3-10.

Rinchuse 2005

Rinchuse DJ, Rinchuse DJ, Kandasamy S. Evidence-based versus experience-based views on occlusion and TMD. *American Journal of Orthodontics and Dentofacial Orthopedics* 2005;**127**(2):249-54.

Schmitter 2005

Schmitter M, Rammelsberg P, Hassel A. The prevalence of signs and symptoms of temporomandibular disorders in very old subjects. *Journal of Oral Rehabilitation* 2005;**32**(7):467-73.

Shen 2005

Shen YH, Chen YK, Chuang SY. Condylar resorption during active orthodontic treatment and subsequent therapy: report of a special case dealing with iatrogenic TMD possibly related to orthodontic treatment. *Journal of Oral Rehabilitation* 2005;**32**(5):332-6.

Sulun 2001

Sulun T, Cemgil T, Duc JM, Rammelsberg P, Jager L, Gernet W. Morphology of the mandibular fossa and inclination of the articular eminence in patients with internal derangement and in symptom-free volunteers. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics* 2001;**92**(1):98-107.

Suvinen 2005

Suvinen TI, Reade PC, Kemppainen P, Kononen M, Dworkin SF. Review of aetiological concepts of temporomandibular pain disorders: towards a biopsychosocial model for integration of physical disorder factors with psychological and psychosocial illness impact factors. *European Journal of Pain* 2005;**9**(6):613-33.

Swift 1998

Swift JQ, Roszkowski MT, Alton T, Hargreaves KM. Effect of intraarticular versus systemic anti-inflammatory drugs in a rabbit model of temporomandibular joint inflammation. *Journal of Oral and Maxillofacial Surgery* 1998;**56**(11):1288-95.

Truelove 1992

Truelove EL, Sommers EE, LeResche L, Dworkin SF, Von Korff M. Clinical diagnostic criteria for TMD. New classification permits multiple diagnoses. *Journal of the American Dental Association* 1992;**123**(4):47-54.

Tuerlings 2004

Tuerlings V, Limme M. The prevalence of temporomandibular joint dysfunction in the mixed dentition. *European Journal of Orthodontics* 2004;**26**(3):311-20.



Verhagen 1998

Verhagen AP, de Vet HCW, de Bie RA, Kessels AG, Boers M, Bouter LM, et al. The Delphi list: a criteria list for quality assessment of randomized clinical trials for conducting systematic reviews developed by Delphi consensus. *Journal of Clinical Epidemiology* 1998;**51**(12):1235-41.

Warren 2001

Warren MP, Fried JL. Temporomandibular disorders and hormones in women. *Cells, Tissues, Organs* 2001;**169**(3):187-92.

Westermark 2001

Westermark A, Shayeghi F, Thor A. Temporomandibular dysfunction in 1,516 patients before and after orthognathic surgery. *International Journal of Adult Orthodontics and Orthognathic Surgery* 2001;**16**(2):145-51.

Yuasa 2001

Yuasa H, Kurita K. Treatment group on temporomandibular disorders randomized clinical trial of primary treatment for temporomandibular joint disk displacement without reduction and without osseous changes: a combination of NSAIDs and mouth-opening exercise versus no treatment. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics* 2001;**91**(6):671-5.

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Fridrich 1996			
Methods	Randomized controlle	d trial.	
Participants	19 female patients with internal derangement (10 unilateral and 9 bilateral) with reduction on opening (ADDR) and anterior disc displacement without reduction on opening (ADDW).		
	Age: 15 to 56 years.		
Interventions	Group I: Arthroscopy g sweep of the superior j la from the superior joi	roup (n = 11) lysis and lavage (lactated Ringer's solution) as well as an instrument joint space. 6 mg betamethasone was deposited just before removing the cannu- int space.	
	Group II: Arthrocentesi by a dual-port lavage t the superior joint spac	is group (n = 8) the hydraulic distention of the superior joint space was followed echnique with lactated Ringer's solution and betamethasone was infused into e.	
Outcomes	Maximum incisal open	ing, clicking, VAS for pain, jaw function.	
Notes			
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Unclear risk	Quote: "were randomized to one of two surgical groups".	
Allocation concealment (selection bias)	Unclear risk	No description.	
Blinding (performance bias and detection bias)	High risk	No description about the blinding of patients, surgeons and the outcomes evaluators.	
Incomplete outcome data (attrition bias) All outcomes	High risk	Data regarding reasons for variation in follow up provided. Only 4/19 partici- pants available at 26 month follow-up.	
Selective reporting (re- porting bias)	Unclear risk	Insufficient information.	

Arthroscopy for temporomandibular disorders (Review)

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Fridrich 1996 (Continued)

Follow-up

Low risk

1 week, and 1, 3, 4, 12 and 26 months postoperatively.

Goudot 2000

Methods	Randomized controlled	l trial.	
Participants	62 patients with internal derangement (disco-ligamentous dysfunction) and muscular dysfunction un- responsive to nonsurgical treatment over a 6-month period.		
	Age: 16 to 72 years		
Interventions	Group I (n = 33): Arthroscopy with lactated Ringer's solution.		
	Group II (n = 29): Arthro	ocentesis (Nitzan's technique).	
Outcomes	TMJ pain using a VAS a sions).	TMJ pain using a VAS and mandibular movements in all directions (opening, protrusion, lateral excursions).	
Notes			
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Unclear risk	Quote: "The choice of technique was randomized".	
Allocation concealment (selection bias)	Unclear risk	Insufficient information.	
Blinding (performance bias and detection bias)	High risk	No information about the blinding of patients, surgeons and the outcomes evaluators.	
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs reported.	
Selective reporting (re- porting bias)	Unclear risk	Insufficient information.	
Follow-up	Low risk	1 year after surgery.	

Holmlund 2001

Methods	Randomized controlled trial.
Participants	20 patients with clinical diagnosis of chronic closed lock of the TMJ, unilateral involvement and unsuc- cessful nonsurgical treatment for at least 3 months.
	Age: 22 to 53 years.
Interventions	Group I (n = 10): Arthroscopy lysis and lavage.
	Group II (n = 10): Discectomy (excision of the disc and smoothed of irregularities on the condyle).

Arthroscopy for temporomandibular disorders (Review)

Holmlund 2001 (Continued)

Outcomes

TMJ pain using a VAS and mandibular function using the Mandibular Function Impairment Questionnaire (MFIQ).

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	Quote: "they were then randomized to either discectomy or arthroscopy lysis and lavage using a randomization format"
Allocation concealment (selection bias)	High risk	No description.
Blinding (performance bias and detection bias)	High risk	No information about the blinding of patients, surgeons and the outcomes evaluators.
Incomplete outcome data (attrition bias) All outcomes	High risk	There were two drop-outs.
Selective reporting (re- porting bias)	High risk	The study protocol is not available and clear.
Follow-up	Low risk	1 year follow-up.

Miyamoto 1999

Methods	Randomized controlled	d trial.
Participants	101 patients with adva firmed by magnetic res treatments and anti-in Mean age: 28 years.	nced internal derangement of one or both TMJ diagnosed clinically and con- conance imaging and double contrast arthrography; non response to nonsurgical flammatory drugs used for 3 three months without resolution of the problem.
Interventions	Group I (n = 35): Arthro Group II (n = 66): Arthro after which the disc an	scopy lysis and lavage (ALL). oscopy lysis and lavage plus arthroscopy anterolateral capsular release (AALCR), d the capsule was released laterally.
Outcomes	TMJ pain using a VAS; r by questioning; change	naximum intercisal opening measured with a ruler; alteration in diet assessed es in appearance of the joint evaluated by radiography.
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	Quote: " were randomly assigned to one of two types of two types of arthroscopy surgery"

Arthroscopy for temporomandibular disorders (Review)

Miyamoto 1999 (Continued)

Allocation concealment (selection bias)	High risk	No description.
Blinding (performance bias and detection bias)	High risk	No information about the blinding of patients, surgeons and the outcomes evaluators.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs reported.
Selective reporting (re- porting bias)	Unclear risk	Insufficient information.
Follow-up	Low risk	Patients assessed immediately preoperatively and postoperatively at 1, 3, 6 and 12 months.

Politi 2007

Methods	Randomized controlled trial.
Participants	20 patients with clinical diagnosis and radiologic diagnosis of chronic dosed lock of TMJ and unsuc- cessful nonsurgical treatment. Age: 25 to 67 years.
Interventions	Group I (n = 10): Arthroscopy (an inferolateral approach - single puncture technique). Group II (n = 10): Open surgery (high condylectomy).
Outcomes	TMJ pain (opening of the mouth, chewing, biting, yawning) using a VAS; mandibular function measured by Mandibular Function Impairment Questionnaire (MFIQ).

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	Quote: "patients were randomized to either open or arthroscopic surgery"
Allocation concealment (selection bias)	High risk	Comment: Insufficient information.
Blinding (performance bias and detection bias)	High risk	No description about the blinding of patients, surgeons and the outcomes evaluators.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs reported.
Selective reporting (re- porting bias)	Low risk	The study protocol is available and clear.
Follow-up	Low risk	1 year after surgery.

Arthroscopy for temporomandibular disorders (Review)



Schiffman 2007

Methods	Randomized controlled	d trial.
Participants	106 patients with daily pain in affected joint w	pain in affected joints aggravated by jaw movement and function, duplication of as examined and limited mouth opening.
	Age: 18 to 65 years.	
Interventions	Group I (n = 26): Arthro	scopy surgery lysis and lavage.
	Group II (n = 26): Arthro	oplasty with discoplasty and discectomy.
	Group III (n = 25): Reha	bilitation with dentist treatment, physical therapist and health psychologist.
	Group IV (n = 29): Media regimen of oral methyl to 6 weeks. Muscle rela	cal management with optimistic counseling, a self-help program and a 6-day prednisolone followed by non-steroidal anti-inflammatory drugs (NSAIDs) for 3 ixants and over-the-counter analgesics were used as needed.
Outcomes	Jaw pain and dysfunct Severity Index (SSI).	ion measured by Craniomandibular Index (CMI) and the modified Symptom
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Low risk	Quote: " the randomized allocation"
Allocation concealment (selection bias)	Low risk	Comment: With sealed envelopes.
Blinding (performance bias and detection bias)	Low risk	A single examiner, blinded to treatment assignment, performed all clinical measures.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs reported.
Selective reporting (re- porting bias)	Unclear risk	Insufficient information.
Follow-up	Low risk	3, 6, 12, 18, 24 and 60-month follow-up.

Stegenga 1993

Methods	Randomized controlled trial.
Participants	21 patients with osteoarthritis and internal TMJ disorders with presence of preauricular pain, perceived restriction of mandibular movements of sudden onset, and restriction of horizontal excursion towards the opposite side of < 8 mm.
	Age: 16 to 45 years.

Arthroscopy for temporomandibular disorders (Review)

Stegenga 1993 (Continued)	
Interventions	Group I (n = 9): Arthroscopy (triangular techniques according to McCain, capsular release, lysis or resec- tion of adhesions, coagulation of hypervascular tissues and retrodiscal tissues and mobilization of the disc) and physical therapy started on the first day postoperatively.
	Group II (n = 12): No surgery treatment (physical therapy and exercises).
Outcomes	TMJ pain, mandibular movement restriction, mandibular function impairment, and impact of painful restriction on daily life situations and general well-being. These measures were made using VAS, the Mandibular Function Impairment Questionnaire, The West Haven-Yale Multidimensional Pain Inventory (MPI) and the General Health Questionnaire (GHQ). Evaluations were made before surgery and 6 months after surgery.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera- tion (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	High risk	No description.
Blinding (performance bias and detection bias)	High risk	No description about the blinding of patients, surgeons and the outcomes evaluators.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs reported.
Selective reporting (re- porting bias)	Low risk	The study protocol is not available but it is clear that the published reports in- clude all expected outcomes.
Follow-up	Low risk	6 months after surgery.

TMJ: temporomandibular joint

VAS: visual analogue scale

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Hall 2005	Quasi-random
Morey-Mas 2010	Quasi-random
Murakami 1995	Quasi-random
Sanroman 2004	Quasi-random
Sato 2003	Quasi-random



HISTORY

Protocol first published: Issue 1, 2007 Review first published: Issue 5, 2011

Date	Event	Description
3 September 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Jefferson R Cardoso (JC) and Marcelo Rigon (MR) proposed the protocol and co-ordinated the review. Marcelo C Bortoluzzi (MB), Alessandro Loguercio (AL) and JC assessed the titles and abstracts identified by the electronic search. MR and AL performed handsearchs in the other databases. JC and Adilson Ramos (AR) undertook the assessment of risk of bias. Ligia Pereira (LP) and MR extracted the information from the RCT. All authors corrected the last draft.

DECLARATIONS OF INTEREST

None known.

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Internal sources

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External sources

• No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

Arthralgia [physiopathology] [surgery]; Arthroscopy [*methods]; Randomized Controlled Trials as Topic; Range of Motion, Articular [physiology]; Temporomandibular Joint [*surgery]; Temporomandibular Joint Disorders [*surgery]

MeSH check words

Humans

Section 7.0 Reports for Review

<u>Issue:</u> HERC is required to report to the legislature regarding recommended changes to the Reproductive Health Equity Act (HB 3391) to align with current federal requirements and evidence around coverage of all reproductive and preventive services for women.

Question: Which services remain covered and which services have been updated?

The <u>Reproductive Health Equity Act</u> (HB 3391) requires commercial health benefit plans to cover specific health care services, drugs, devices, products, and procedures related to reproductive health and applies to commercial insurance. In addition, it adds a set of reproductive health benefits for people who could become pregnant and who would be eligible for the Oregon Health Plan if not for their immigration status. Since the passage of this bill, the Legislature has authorized additional benefits for a larger portion of this population. The bill allows exemption for plans sold to religious employers.

Staff was asked to review evidence and federal recommendations for reproductive health services to evaluate whether HERC should recommend any changes to the statute to account for changes in federal law or evidence-based reproductive health services. No major gaps have been identified, but two minor changes would help align coverage with new federal requirements and incorporate updated recommendations about how the listed services should be provided.

Impact:

Staff analysis indicates that the Reproductive Health Equity Act includes the most important services that people with Oregon private health insurance plans, including employee-sponsored coverage, should be able to access without cost sharing regardless of any changes which may occur at the federal level.

While existing law covers the most important services, the statute could be appropriately updated to include new and updated preventive services as recommended by the United States Preventive Services Task Force (USPSTF) or Health Resources and Services Administration (HRSA) since the passage of the bill, or that are not listed in the bill:

Summary of Reproductive and Preventive Services for Women and Adolescents					
Preventive Service	Recommendation	Coverage year*			
Screening for diabetes mellitus after pregnancy	HRSA	2016			
Screening for gestational diabetes	USPSTF, HRSA	2016			
Screening for urinary incontinence	HRSA	2017			
Screening for anxiety	HRSA, USPSTF	2019, 2022 (NEW)			
Screening for interpersonal and domestic violence	USPSTF, HRSA	2016			
Perinatal depression: preventive interventions	USPSTF	2019			
Screening for breast cancer	USPSTF, HRSA	2016 (update in progress)			
Screening for women with a family history of certain cancers for BRCA1/2 with an appropriate brief risk assessment tool	USPSTF	2018 (updated)			
Breast cancer: medication use to reduce risk	USPSTF	2019			
Cervical cancer screening	USPSTF, HRSA	2018 (update in progress)			
Behavioral counseling for healthy weight gain during pregnancy (USPSTF)		2021 (New)			
Breastfeeding services and supplies	HRSA	2022 (expanded)			
Contraception	HRSA	2022 (expanded)			
Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality: Preventive Medication	USPSTF	2021 (updated)			
Screening for Chlamydial Infection (updated 2021)	USPSTF	2021 (updated)			
Screening for Gonococcal Infection (USPSTF updated 2021)	USPSTF	2021 (updated)			
Screening for Gestational Diabetes (USPSTF updated 2021)	USPSTF	2021 (updated)			
STI counseling		2022 (updated)			
Well woman preventive visits	HRSA	2022 (updated)			
HB 3391 Guideline Updates (RHEA Report)

*coverage year indicates most recent year of coverage unless recommendations cover different groups or areas of listed services

Covered services and guidelines can also be found at: <u>https://www.womenspreventivehealth.org/wp-content/uploads/FINAL_WPSI_WWC_11x17_2022Update.pdf</u>

2022

Recommendations to update preventive health services

Health Evidence Review Commission's Recommendations to the Legislature on HB 3391 (2017) Reproductive Health Equity Act

Acknowledgments

Health Evidence Review Commission

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Oregon Health Authority Health Evidence Review Commission. Recommendations to update preventive services: Health Evidence Review Commission's Recommendations to the Legislature on HB 3391 Reproductive Health Equity Act. Oregon Health Authority. Portland, OR. 2022 November.

Contents

Acknowledgments	i
Contents	ii
Executive summaryi	ii
Introduction	1
Background	1
HERC Review	1
HERC Recommendations to the Legislature	2
Update dates to align with current evidence	2
Clarify that services should be provided in accordance with guidelines	2
Conclusion	4

Executive summary

House Bill 3391 (2017) includes a list of preventive, reproductive health and other services to be provided without cost sharing to people insured under state-regulated health plans. In addition, the bill created a program covering these services for individuals who can become pregnant and who would be eligible for medical assistance if not for federal law excluding certain immigrants from medical assistance programs (8 U.S.C. 1611 and 1612). Before November 1 of each even numbered year, the bill requires the Health Evidence Review Commission to report to the legislature on recommended changes to the coverage listed in statute.

While existing law covers the most important services, this report provides two recommendations for changes to the list of required preventive services, which are:

- Updating the date referencing United States Preventive Services Task Force (USPSTF) and Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services from January 1, 2017 to January 1, 2022.
- Clarifying that listed preventive services should be covered in accordance with national evidence-based standards, including scope and frequencies as recommended by the United States Preventive Services Task Force (USPSTF) and Health Resources and Services Administrations (HRSA), when applicable.

Introduction

This report outlines recommendations of the Health Evidence Review Commission (HERC) for changes to 743A.067(2) as required by ORS 414.694. These recommendations would align the coverage required in statute with current recommended evidence-based federal standards for commercial coverage and add additional services important for reproductive health.

Background

House Bill 3391 was passed in 2017 to ensure coverage of reproductive health services in Oregon. It requires health plan coverage (including commercial plans and coverage for those who would be eligible for Medicaid but for their immigration status) for screening and other services without a deductible, coinsurance, copayment, or any other cost-sharing requirement.

ORS 414.694 states:

The Health Evidence Review Commission shall review the coverage described in ORS 743A.067 (2) and, no later than November 1 of each even-numbered year, report to the interim committees of the Legislative Assembly related to health any recommended changes to the coverage described in ORS 743A.067 (2) based upon the latest clinical research.

HERC Review

The HERC has reviewed the statute and does not recommend any statutory changes because existing statute generally meets the reproductive health needs of Oregonians.

To further reinforce its commitment to providing updated and inclusive reproductive health and preventive services, the legislature could consider the following minor changes:

- 1) Update the date referencing USPSTF and HRSA to January 1, 2022.
- 2) Clarify that listed preventive services should be covered in accordance with national evidence-based standards (ie, USPSTF, HRSA), when applicable.

HERC Recommendations to the Legislature

Update dates to align with current evidence

1) Revise the reference to the United States Preventive Services Task Force (USPSTF) and Health Resources and Services Administration (HRSA) to include recommendations through January 1, 2022

Rationale:

Currently, the law refers to USPSTF and HRSA recommendations identified as of January 1, 2017. There have been several recommendations approved since that date by these two bodies. Extending that date to January 1, 2022 would ensure coverage of additional more recently identified evidence-based services to align with new or recently updated federal guidelines. These additional services are unlikely to have a large cost impact. Enacting this change would align state requirements with the Affordable Care Act (ACA), preserving the status quo in the event the ACA provisions regarding preventive services are overturned, amended, or repealed.

Impact:

In addition to services outlined in Section 2 of HB 3391, this would result in alignment with current federal requirements around coverage of all reproductive and preventive services for women and adolescents.

Clarify that services should be provided in accordance with guidelines

2) Clarify that the included preventive services required under this law must be covered in accordance with evidence-based guidelines (USPSTF, HRSA), when applicable

Rationale:

House bill 3391 includes a list of preventive, reproductive health, and other services to be provided without cost sharing to people insured under state-regulated health plans. Many of these services or procedures may be considered clinical preventive services in many, but not all, circumstances. The legislature could consider amending 743A.067 (12) to clarify that reasonable medical management techniques can include review to ensure

2 | HERC Recommendations to the Legislature

that preventive services referenced in subsection 2 are being provided in accordance with relevant federal guidelines such as those from USPSTF and HRSA.

Impact:

The statute is currently unclear whether clinical preventive services should be offered in alignment with evidence-based guidelines (i.e., USPSTF, HRSA). This could be misinterpreted to imply that insurers would be required to cover inappropriate preventive services or at intervals that are not consistent with the best evidence. This change would clarify that the intent is to cover these services in alignment with high-quality evidence.

Conclusion

While access to reproductive health services is currently covered by state and federal law, implementing these recommendations would increase access to important preventive and reproductive health services. In addition, it would align Oregon's coverage requirements with national standards. These services would be available without cost sharing to Oregonians with commercial insurance and to low-income Oregonians who could become pregnant and are not eligible for Medicaid due to their immigration status.

HERC appreciates your consideration of these recommendations. We look forward to continuing to assist you so the list of services established by the Reproductive Health Equity Act reflects the most current information on evidence-based health care.

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Section 8.0 BHAP report

BHAP reviewed the following issues at their July 2022 meeting and recommended these changes go forward for approval by VBBS/HERC.

<u>Issue 1</u>: The CPT codes for drug and alcohol screening (AUDIT/DAST 99408 and 99409) were made Diagnostic in March 2021 to allow use at any type of office visit. However, the similar HCPCS codes were not addressed in that review and remain on lines.

Code	Code Description	Current	Recommended
		Placement	Placement
G0396	Alcohol and/or substance (other than tobacco) misuse	600+ lines	DIAGNOSTIC
	structured assessment (e.g., audit, dast), and brief		PROCEDURES
	intervention 15 to 30 minutes		
G0397	Alcohol and/or substance (other than tobacco) misuse	600+ lines	DIAGNOSTIC
	structured assessment (e.g., audit, dast), and intervention,		PROCEDURES
	greater than 30 minutes		
G2011	Alcohol and/or substance (other than tobacco) misuse	600+ lines	DIAGNOSTIC
	structured assessment (e.g., audit, dast), and brief		PROCEDURES
	intervention, 5-14 minutes		
99408	Alcohol and/or substance (other than tobacco) abuse	DIAGNOSTIC	DIAGNOSTIC
	structured screening (eg, AUDIT, DAST), and brief	PROCEDURES	PROCEDURES
	intervention (SBI) services; 15 to 30 minutes		
99409	Alcohol and/or substance (other than tobacco) abuse	DIAGNOSTIC	DIAGNOSTIC
	structured screening (eg, AUDIT, DAST), and brief	PROCEDURES	PROCEDURES
	intervention (SBI) services; greater than 30 minutes		

<u>Issue 2</u>: HERC staff have been reviewing CPT and HCPCS codes related to office visits and/or hospital care. Several of these codes appear on behavioral health lines that do not include inpatient care codes. The HERC staff recommendation is to remove from those lines. Several other lines need one or more of these codes.

Code	Code Description	Current	Recommended Change(s)
		Placement	
G0508	Telehealth consultation, critical care,	500+ lines	Remove from
	initial, physicians typically spend 60		203 DEPRESSION AND OTHER
	minutes communicating with the		MOOD DISORDERS, MILD OR
	patient and providers via telehealth		MODERATE
			438 STEREOTYPED MOVEMENT
			DISORDER WITH SELF-INJURIOUS
			BEHAVIOR DUE TO
			NEURODEVELOPMENTAL DISORDER
			450 REACTIVE ATTACHMENT
			DISORDER OF INFANCY OR EARLY
			CHILDHOOD

			471 ENCOPRESIS NOT DUE TO A PHYSIOLOGICAL CONDITION 523 SEXUAL DYSFUNCTION
G0509	Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth	500+ lines	Remove from 203, 438, 450, 471, 523
99225	Subsequent observation care, per day	500+ lines	Remove from 192 AUTISM SPECTRUM DISORDERS 252 PSYCHOLOGICAL FACTORS AGGRAVATING PHYSICAL CONDITION (E.G., ASTHMA, CHRONIC GI CONDITIONS, HYPERTENSION) 575 PERSONALITY DISORDERS EXCLUDING BORDERLINE AND SCHIZOTYPAL Add to 290 ACUTE STRESS DISORDER
99226	Subsequent observation care, per day	500+ lines	Remove from 192, 252, 575 Add to 290

Issue 3: Additional coding changes identified for substance-induced delirium and personality disorders:

CPT code	Code Description	Recommended Line Addition
90846	Family psychotherapy (without the	65 SUBSTANCE-INDUCED DELIRIUM;
	patient present), 50 minutes	SUBSTANCE INTOXICATION AND
		WITHDRAWAL
90847	Family psychotherapy (conjoint	65
	psychotherapy) (with patient	
	present), 50 minutes	
90849	Multiple-family group	65
	psychotherapy	
90853	Group psychotherapy (other than	65
	of a multiple-family group)	
90785,	Psychotherapy	575 PERSONALITY DISORDERS EXCLUDING
90832-		BORDERLINE AND SCHIZOTYPAL
90840		

Appendix

Consult only lines				
line Condition Treatment		Treatment		
193	AUTISM SPECTRUM DISORDERS	MEDICAL THERAPY/BEHAVIORAL MODIFICATION INCLUDING APPLIED BEHAVIOR ANALYSIS		
551	SOMATIC SYMPTOMS AND RELATED DISORDERS	CONSULTATION		

Behavioral Health Consult Only + ED

line	Condition	Treatment
437	STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER	CONSULTATION/MEDICATION MANAGEMENT/LIMITED BEHAVIORAL MODIFICATION

	Behavioral Health OP only (no ED visits)				
Line	Condition	Treatment			
5	TOBACCO DEPENDENCE	MEDICAL THERAPY/BEHAVIORAL COUNSELING			
121	ATTENTION DEFICIT/HYPERACTIVITY DISORDERS	MEDICAL/PSYCHOTHERAPY			
203	DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE	MEDICAL/PSYCHOTHERAPY			
211	NON-SUBSTANCE-RELATED ADDICTIVE BEHAVIORAL DISORDERS	MEDICAL/PSYCHOTHERAPY			
252	PSYCHOLOGICAL FACTORS AGGRAVATING PHYSICAL CONDITION (E.G., ASTHMA, CHRONIC GI CONDITIONS, HYPERTENSION)	MEDICAL/PSYCHOTHERAPY			
312	GENDER DYSPHORIA/TRANSEXUALISM	MEDICAL AND SURGICAL TREATMENT/PSYCHOTHERAPY			
388	SEPARATION ANXIETY DISORDER	MEDICAL/PSYCHOTHERAPY			
414	OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED	MEDICAL/PSYCHOTHERAPY			
421	OPPOSITIONAL DEFIANT DISORDER	MEDICAL/PSYCHOTHERAPY			
432	PERSISTENT DEPRESSIVE DISORDER	MEDICAL/PSYCHOTHERAPY			
444	ADJUSTMENT DISORDERS	MEDICAL/PSYCHOTHERAPY			
446	TOURETTE'S DISORDER AND TIC DISORDERS	MEDICAL/PSYCHOTHERAPY			
449	REACTIVE ATTACHMENT DISORDER OF INFANCY OR EARLY CHILDHOOD	MEDICAL/PSYCHOTHERAPY			
458	SIMPLE PHOBIAS AND SOCIAL ANXIETY DISORDER	MEDICAL/PSYCHOTHERAPY			
462	OBSESSIVE-COMPULSIVE DISORDERS	MEDICAL/PSYCHOTHERAPY			
470	ENCOPRESIS NOT DUE TO A PHYSIOLOGICAL CONDITION	MEDICAL/PSYCHOTHERAPY			
473	SELECTIVE MUTISM	MEDICAL/PSYCHOTHERAPY			
479	CONDUCT DISORDER, AGE 18 OR UNDER	MEDICAL/PSYCHOTHERAPY			
494	PARAPHILIAS AND OTHER PSYCHOSEXUAL DISORDERS	MEDICAL/PSYCHOTHERAPY			
546	IMPULSE DISORDERS	MEDICAL/PSYCHOTHERAPY			
574	PERSONALITY DISORDERS EXCLUDING BORDERLINE AND SCHIZOTYPAL	MEDICAL/PSYCHOTHERAPY			

Line	Condition	Treatment
631	PICA	MEDICAL/PSYCHOTHERAPY
649	MENTAL DISORDERS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	EVALUATION

Question: Where should various drug induced movement disorders be prioritized?

Question source: HERC staff

<u>Issue</u>: Medications such as atypical antipsychotics can cause movement disorders, including tics, akathisia, dystonia, tremors, and tardive dyskinesia. These disorders are generally classed as extrapyramidal symptoms. The ICD-10-CM codes for these conditions are on inconsistent lines on the Prioritized List. These movement disorders can interfere with a patient's ability to perform ADLs. However, they are also difficult to treat. Usually, treatment consists of reducing the offending medication dose or changing to another medication. There are medications that can treat extrapyramidal symptoms, such as tetrabenazine and deutetrabenazine.

Staff review has found some of these diagnoses on inappropriate lines, such as the disorders of sleep line. These diagnoses need to be moved to a more appropriate line.

Some of these codes appear on the dysfunction lines, where the patient can receive supportive services. Some of these codes appear on the dystonia line, which allows pairing with botulinum toxin injections when appropriate. The dystonia line also has many services such as chronic care management services.

BHAP input:

BHAP reviewed and agreed with staff recommendations.

HERC staff/BHAP recommendations:

ICD-10 Code	Code Descriptions	Current Line(s)	Recommended Line Placement
G24.01	Drug induced subacute	292 NEUROLOGICAL DYSFUNCTION	292, 377
	dyskinesia	IN POSTURE AND MOVEMENT	
		CAUSED BY CHRONIC CONDITIONS	
		377 DYSFUNCTION RESULTING IN	
		LOSS OF ABILITY TO MAXIMIZE	
		LEVEL OF INDEPENDENCE IN SELF-	
		DIRECTED CARE CAUSED BY	
		CHRONIC CONDITIONS THAT CAUSE	
		NEUROLOGICAL DYSFUNCTION	
G24.02	Drug induced acute	362 DYSTONIA (UNCONTROLLABLE);	362
	dystonia	LARYNGEAL SPASM	
G24.09	Other drug induced	362	362
	dystonia		
G25.1	Drug-induced tremor	362	362
G25.4	Drug-induced chorea	292,345,377 (dysfunction lines)	292, 345, 362, 377
		362	
G25.61	Drug induced tics	362	362
G25.70	Drug induced movement	606 DISORDERS OF SLEEP WITHOUT	292, 377
	disorder, unspecified	SLEEP APNEA	

1) Place the codes below on the lines indicated in the 4th column (bold indicates a change from current placement)

Drug Induced Movement Disorders

ICD-10	Code Descriptions	Current Line(s)	Recommended Line
Code			Placement
G25.71	Drug induced akathisia	606	292, 377
G25.79	Other drug induced	606	292, 377
	movement disorders		
G25.89	Other specified	606	292, 377
	extrapyramidal and	655 NEUROLOGIC CONDITIONS	
	movement disorders	WITH NO OR MINIMALLY EFFECTIVE	
		TREATMENTS OR NO TREATMENT	
		NECESSARY	
G25.9	Extrapyramidal and	Dysfunction lines	292, 377
	movement disorder,	362	
	unspecified		
G26	Extrapyramidal and	606	292, 377
	movement disorders in		
	diseases classified		
	elsewhere		

<u>Question</u>: Should conduct disorder be merged into the line with oppositional defiant disorder to allow this diagnosis to be covered?

Question source: multiple

<u>Issue:</u> Conduct disorder is a serious behavioral and emotional disorder that can occur in children and teens. A child with this disorder may display a pattern of disruptive and violent behavior and have problems following rules. Conduct disorder is typically treated with psychotherapy and parent management training. Co-occurring diagnosis such as anxiety or depression can be treated with medications such as SSRIs.

Conduct disorder is currently on line 479 CONDUCT DISORDER, AGE 18 OR UNDER. This line was a covered line until 2012 when the Oregon Legislature moved the funding line up above this level. Multiple agency partners have requested that the HERC review coverage of conduct disorder, including the Oregon Youth Authority, the mental health clinical advisory group, and child welfare.

The Oregon Youth Authority notes that services for children in custody are provided through general funds. However, lack of coverage of conduct disorder results in disruption of care when the children are release back into the community. Child welfare notes that coverage of conduct disorder may improve a child's ability to stay in their current family situation.

Review of denied claims for children also found that ICD-10-CM F63.81 (Intermittent explosive disorder) which is currently on line 547 IMPULSE DISORDERS had multiple denied claims. OHA mental health staff felt that this was an appropriate diagnosis to have on a covered line.

Current Prioritized List status:

F91.0-F91.2, and F91.8 (Conduct disorder) are on line 479 CONDUCT DISORDER, AGE 18 OR UNDER F91.3 (Oppositional defiant disorder) is on line 420 OPPOSITIONAL DEFIANT DISORDER F91.9 (Conduct disorder, unspecified) is on both lines 420 and 479 with a guideline F63.81 (Intermittent explosive disorder) is on 547 IMPULSE DISORDERS

GUIDELINE NOTE 54, CONDUCT DISORDER

Line 479

Conduct disorder rarely occurs in isolation from other psychiatric diagnosis, the patient should have documented screening for attention deficit/hyperactivity disorder (ADHD); chemical dependency (CD); mood disorders such as anxiety and/or depression; and physical, sexual, and family abuse or other trauma (PTSD).

GUIDELINE NOTE 152, UNSPECIFIED CONDUCT DISORDER

Lines 420,479

ICD-10-CM F91.9 (Conduct disorder, unspecified) is included on Line 420 only for children ages 5 and younger who cannot be diagnosed with a more specific mental health diagnosis. This diagnosis is included on Line 479 for older children and adolescents.

Evidence

- 1) **Furlong 2012**, behavioral and cognitive-behavioral group based parenting programs for early onset conduct problems in children aged 3 to 12
 - a. N=13 trials (1078 participants); 2 economic evaluations
 - i. 10 RCTs and 2 quasi-randomized trials
 - b. The results indicate that parent training produced a statistically significant reduction in child conduct problems, whether assessed by parents (standardized mean difference (SMD) -0.53; 95% confidence interval (CI) -0.72 to -0.34) or independently assessed (SMD -0.44; 95% CI -0.77 to 0.11).
 - c. When compared to a waiting list control group, there was a cost of approximately \$2500 (GBP 1712; EUR 2217) per family to bring the average child with clinical levels of conduct problems into the non-clinical range.
 - d. Conclusions: Behavioral and cognitive-behavioral group-based parenting interventions are effective and cost-effective for improving child conduct problems, parental mental health and parenting skills in the short term. The cost of program delivery was modest when compared with the long-term health, social, educational and legal costs associated with childhood conduct problems. Further research is needed on the long-term assessment of outcomes.
- 2) **Wolfenden 2010**, Cochrane review of family and parenting interventions in children and adolescents with conduct disorder
 - a. N=8 RCTs (749 children)
 - i. Intervention: variety of family or parenting interventions
 - ii. Control: no intervention, wait list or usual intervention group
 - b. At follow up, family and parenting interventions significantly reduced the time spent by juvenile delinquents in institutions (WMD 51.34 days, 95%CI 72.52 to 30.16). There was also a significant reduction in the risk of a juvenile delinquent being re-arrested (RR 0.66, 95%CI 0.44 to 0.98) and in their rate of subsequent arrests at 1-3 years (SMD -0.56, 95% CI -1.100 to 0.03). For both of these outcomes there was substantial heterogeneity in the results suggesting a need for caution in interpretation. At present there is insufficient evidence that family and parenting interventions reduce the risk of being incarcerated (RR=0.50, 95% CI 0.20 to 1.21). No significant difference was found for psychosocial outcomes such as family functioning, and child/adolescent behavior.
 - c. Conclusions: The evidence suggests that family and parenting interventions for juvenile delinquents and their families have beneficial effects on reducing time spent in institutions. This has an obvious benefit to the participant and their family and may result in a cost saving for society. These interventions may also reduce rates of subsequent arrest but at present these results need to be interpreted with caution due to the heterogeneity of the results.

BHAP input:

BHAP members were strongly in favor of coverage for conduct disorder. There was acknowledgement that these diagnoses disproportionately affect black and Hispanic children; however, the panel felt that the importance to cover treatment of these diagnoses overrode any concern for disproportionate use in

certain populations. The requirement to consider other possible diagnoses mitigates the risk of inappropriate diagnosis.

HERC staff summary

Treatment of conduct disorder has been shown to reduce incarceration time and improve parental mental health. Multiple stakeholders have requested that this diagnosis be funded, to allow continuity of treatment after incarceration, improve ability to families to stay together, and reduce costs.

HERC staff/BHAP recommendations:

- 1) Effective 1/1/23
 - a. Add ICD-10-CM F91.0-F91.2, and F91.8 (Conduct disorder) to line 420 OPPOSITIONAL DEFIANT DISORDER
 - b. Add ICD-10-CM F63.81 (Intermittent explosive disorder) to line 420 and remove from line 547 IMPULSE DISORDERS
 - c. Change the name of line 420 to OPPOSITIONAL DEFIANT DISORDER; <u>CONDUCT</u> <u>DISORDER AGE 18 OR UNDER</u>
 - d. Strike through line 479
 - e. Modify guideline note 54 as shown below
 - f. Delete guideline note 152

Line: 479

Condition:CONDUCT DISORDER, AGE 18 OR UNDER (See Guideline Notes 54 and 152) Treatment:MEDICAL/PSYCHOTHERAPY ICD 10:F91.0 F91.2,F91.8 F91.9 CPT:90785,90832-90840,90846-90853,90882,90887,98966-98972,99051,99060,99203-99215,99324-99355,99366,99415-99427,99437-99449,99451,99452,99487-99491,99495-99498,99605-99607 HCPCS:G0068,G0071,G0088-G0090,G0176,G0177,G0248-G0250,G0459,G0463,G0466,G0467,G0469,

HCPCS:50058,50071,50088-50090,50176,50177,50248-50250,50459,50453,50466,50467,50469, 60470,60511,62012,62214,62251,62252,H0004,H0017-H0019,H0023,H0032-H0034, H0036-H0039,H0045,H2010,H2012,H2014,H2021-H2023,H2027,H2032,H2033,S5151, S9125,S9480,S9484,T1005

GUIDELINE NOTE 54, CONDUCT DISORDER

Line <u>420, <mark>479</mark></u>

Conduct disorder rarely occurs in isolation from other psychiatric diagnosis, the patient should have documented screening (or documented refusal to be screened) for attention deficit/hyperactivity disorder (ADHD); chemical dependency (CD); mood disorders such as anxiety and/or depression; and physical, sexual, and family abuse or other trauma (PTSD).

ICD-10-CM F91.9 (Conduct disorder, unspecified) is included on Line 420 only for children ages 5 and younger who cannot be diagnosed with a more specific mental health diagnosis.

GUIDELINE NOTE 152, UNSPECIFIED CONDUCT DISORDER

Lines 420,479

ICD 10 CM F91.9 (Conduct disorder, unspecified) is included on Line 420 only for children ages 5 and younger who cannot be diagnosed with a more specific mental health diagnosis. This diagnosis is included on Line 479 for older children and adolescents.

- 2) Effective 1/1/24
 - a. Delete line 479 CONDUCT DISORDER, AGE 18 OR UNDER

Behavioural and cognitive-behavioural group-based parenting programmes for early-onset conduct problems in children aged 3 to 12 years (Review)

Furlong M, McGilloway S, Bywater T, Hutchings J, Smith SM, Donnelly M



This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2012, Issue 2

http://www.thecochranelibrary.com



Behavioural and cognitive-behavioural group-based parenting programmes for early-onset conduct problems in children aged 3 to 12 years (Review)

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[Intervention Review]

Behavioural and cognitive-behavioural group-based parenting programmes for early-onset conduct problems in children aged 3 to 12 years

Mairead Furlong¹, Sinead McGilloway², Tracey Bywater³, Judy Hutchings⁴, Susan M Smith⁵, Michael Donnelly⁶

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ABSTRACT

Background

Early-onset child conduct problems are common and costly. A large number of studies and some previous reviews have focused on behavioural and cognitive-behavioural group-based parenting interventions, but methodological limitations are commonplace and evidence for the effectiveness and cost-effectiveness of these programmes has been unclear.

Objectives

To assess the effectiveness and cost-effectiveness of behavioural and cognitive-behavioural group-based parenting programmes for improving child conduct problems, parental mental health and parenting skills.

Search methods

We searched the following databases between 23 and 31 January 2011: CENTRAL (2011, Issue 1), MEDLINE (1950 to current), EMBASE (1980 to current), CINAHL (1982 to current), PsycINFO (1872 to current), Social Science Citation Index (1956 to current), ASSIA (1987 to current), ERIC (1966 to current), Sociological Abstracts (1963 to current), Academic Search Premier (1970 to current), Econlit (1969 to current), PEDE (1980 to current), Dissertations and Theses Abstracts (1980 to present), NHS EED (searched 31 January 2011), HEED (searched 31 January 2011), DARE (searched 31 January 2011), HTA (searched 31 January 2011), mRCT (searched 29 January 2011). We searched the following parent training websites on 31 January 2011: Triple P Library, Incredible Years Library and Parent Management Training. We also searched the reference lists of studies and reviews.

Selection criteria

We included studies if: (1) they involved randomised controlled trials (RCTs) or quasi-randomised controlled trials of behavioural and cognitive-behavioural group-based parenting interventions for parents of children aged 3 to 12 years with conduct problems, and (2) incorporated an intervention group versus a waiting list, no treatment or standard treatment control group. We only included studies that used at least one standardised instrument to measure child conduct problems.

Behavioural and cognitive-behavioural group-based parenting programmes for early-onset conduct problems in children aged 3 to 12 years (Review)

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Data collection and analysis

Two authors independently assessed the risk of bias in the trials and the methodological quality of health economic studies. Two authors also independently extracted data. We contacted study authors for additional information.

Main results

This review includes 13 trials (10 RCTs and three quasi-randomised trials), as well as two economic evaluations based on two of the trials. Overall, there were 1078 participants (646 in the intervention group; 432 in the control group). The results indicate that parent training produced a statistically significant reduction in child conduct problems, whether assessed by parents (standardised mean difference (SMD) -0.53; 95% confidence interval (CI) -0.72 to -0.34) or independently assessed (SMD -0.44; 95% CI -0.77 to -0.11). The intervention led to statistically significant improvements in parental mental health (SMD -0.36; 95% CI -0.52 to -0.20) and positive parenting skills, based on both parent reports (SMD -0.53; 95% CI -0.90 to -0.16) and independent reports (SMD - 0.47; 95% CI -0.65 to -0.29). Parent training also produced a statistically significant reduction in negative or harsh parenting practices according to both parent reports (SMD -0.77; 95% CI -0.96 to -0.59) and independent assessments (SMD -0.42; 95% CI -0.67 to -0.16). Moreover, the intervention demonstrated evidence of cost-effectiveness. When compared to a waiting list control group, there was a cost of approximately \$2500 (GBP 1712; EUR 2217) per family to bring the average child with clinical levels of conduct problems into the non-clinical range. These costs of programme delivery are modest when compared with the long-term health, social, educational and legal costs associated with childhood conduct problems.

Authors' conclusions

Behavioural and cognitive-behavioural group-based parenting interventions are effective and cost-effective for improving child conduct problems, parental mental health and parenting skills in the short term. The cost of programme delivery was modest when compared with the long-term health, social, educational and legal costs associated with childhood conduct problems. Further research is needed on the long-term assessment of outcomes.

PLAIN LANGUAGE SUMMARY

Group parenting programmes for improving behavioural problems in children aged 3 to 12 years

Parenting programmes that are delivered in group settings have the potential to help parents develop parenting skills that improve the behaviour of their young children. This review provides evidence that group-based parenting programmes improve childhood behaviour problems and the development of positive parenting skills in the short-term, whilst also reducing parental anxiety, stress and depression. Evidence for the longer-term effects of these programmes is unavailable. These group-based parenting programmes achieve good results at a cost of approximately \$2500 (£1712 or EURO2217) per family. These costs are modest when compared with the long-term social, educational and legal costs associated with childhood conduct problems.

BACKGROUND

Description of the condition

Conduct problems in children are common and costly. In the UK and the USA, approximately 5% to 10% of children between five and 15 years of age present with clinically significant conduct problems (Offord 1989; Loeber 2001; Task Force 2006). In Western countries, there has been a steady increase in the incidence of such problems since the 1930s (Robins 1999). Conduct problems are

the most common reason for referral to psychological and psychiatric services in childhood (NICE 2006). They typically include troublesome, disruptive and aggressive behaviour; an unwillingness or inability to perform school work; few positive interactions with adults; poor social skills; low self-esteem; non-compliance with instructions; and emotional volatility (Loeber 2000; Scottish Executive 2001; Task Force 2006). These kinds of problems tend to exist on a continuum of severity (Burke 2002; Dretzke 2009). Children with the most severe disruptive behaviours may be diagnosed with Conduct Disorder (CD) or Oppositional Defiant

2



Cochrane Database of Systematic Reviews

Family and parenting interventions in children and adolescents with conduct disorder and delinquency aged 10-17 (Review)

Woolfenden S, Williams KJ, Peat J

Woolfenden S, Williams KJ, Peat J. Family and parenting interventions in children and adolescents with conduct disorder and delinquency aged 10-17. *Cochrane Database of Systematic Reviews* 2001, Issue 2. Art. No.: CD003015. DOI: 10.1002/14651858.CD003015.

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Trusted evidence. Informed decisions. Better health.

[Intervention Review]

Family and parenting interventions in children and adolescents with conduct disorder and delinquency aged 10-17

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Citation: Woolfenden S, Williams KJ, Peat J. Family and parenting interventions in children and adolescents with conduct disorder and delinquency aged 10-17. *Cochrane Database of Systematic Reviews* 2001, Issue 2. Art. No.: CD003015. DOI: 10.1002/14651858.CD003015.

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ABSTRACT

Background

Conduct disorder and delinquency are significant problems for children and adolescents and their families, with the potential to consume much of the resources of the health, social care and juvenile justice systems. A number of family and parenting interventions have been recommended and are used for these conditions. The aim of this review was to determine if these interventions are effective in the management of conduct disorder and delinquency in children and adolescents, aged 10-17.

Objectives

To determine if family and parenting interventions improve the child/adolescent's behaviour; parenting and parental mental health; family functioning and relations; and have an effect on the long term psychosocial outcomes for the child/adolescent.

Search methods

Randomised controlled trials were identified in September 1999 through searching the Cochrane Controlled Trial Register (CCTR), databases (MEDLINE, EMBASE, PsycINFO, CINAHL, Sociofile, ERIC, Healthstar), reference lists of articles and contact with authors.

Selection criteria

Randomised controlled trials with a major focus on parenting and/or family functioning were eligible for inclusion in the review. Trials needed to include at least one objective outcome measure (e.g. arrest rates) or have used a measure that had been published in peer review publications and validated for the relevant purpose. Studies were required to have a control group, which could be a no intervention group, a wait list group or a usual intervention group (e.g. probation).

Trials in children and adolescents aged 10 to 17 years with conduct disorder and/or delinquency and their families were considered. Conduct disorder was defined by a standardised psychological assessment (for example, using a child behaviour checklist), or a psychiatric diagnosis. Delinquency was defined by a referral from a juvenile justice or another legal system for a child/adolescent who has committed a serious crime e.g assault and/or offended on at least two occasions.

Data collection and analysis

Two reviewers independently reviewed all eligible studies for inclusion, assessed study quality (allocation concealment, blinding, follow up, clinically important outcomes) and extracted data. Heterogeneity was assessed using the Chi squared test of heterogeneity along with visual inspection of the data. A significance level less than 0.1 was interpreted as evidence of statistically significant heterogeneity. For data where heterogeneity was found the reviewers looked for an explanation. If studies with heterogeneous results were thought to be



comparable the statistical synthesis of the results was done using a random effects model. This model takes into account within-study sampling error and between-studies variation in the assessment of uncertainty and will give wider confidence intervals to the effect size and hence a more conservative result.

Sensitivity analysis was performed to explore the effects of the varying quality of the studies included on the results.

Main results

Of the nine hundred and seventy titles initially identified through the search strategy, eight trials met the inclusion criteria. A total of 749 children and their families were randomised to receive a family and parenting intervention or to be in a control group. In seven of these studies the participants were juvenile delinquents and their families and in only one the participants were children/adolescents with conduct disorder who had not yet had contact with the juvenile justice system.

At follow up, family and parenting interventions significantly reduced the time spent by juvenile delinquents in institutions (WMD 51.34 days, 95%CI 72.52 to 30.16). There was also a significant reduction in the risk of a juvenile delinquent being re arrested (RR 0.66, 95%CI 0.44 to 0.98) and in their rate of subsequent arrests at 1-3 years (SMD -0.56, 95% CI -1.100 to - 0.03). For both of these outcomes there was substantial heterogeneity in the results suggesting a need for caution in interpretation. At present there is insufficient evidence that family and parenting interventions reduce the risk of being incarcerated (RR=0.50, 95% CI 0.20 to 1.21). No significant difference was found for psychosocial outcomes such as family functioning, and child/adolescent behaviour.

Authors' conclusions

The evidence suggests that family and parenting interventions for juvenile delinquents and their families have beneficial effects on reducing time spent in institutions. This has an obvious benefit to the participant and their family and may result in a cost saving for society. These interventions may also reduce rates of subsequent arrest but at present these results need to be interpreted with caution due to the heterogeneity of the results.

PLAIN LANGUAGE SUMMARY

Family and parenting interventions in children and adolescents with conduct disorder and delinquency aged 10-17

Conduct disorder and delinquency are significant problems for children and adolescents and their families, with the potential to consume much of the resources of the health, social care and juvenile justice systems. A number of family and parenting interventions have been recommended and are used for these conditions. The aim of this review was to determine if these interventions are effective in the management of conduct disorder and delinquency in children and adolescents, aged 10-17. Current evidence suggests that family and parenting interventions for juvenile delinquents and their families have beneficial effects on reducing time spent in institutions. This has an obvious benefit to the participant and their family and may result in a cost saving for society. These interventions may also reduce rates of later arrest, but at present these results need to be interpreted with caution, because of diversity in the results of studies.

Question: Should insomnia be moved to a covered line?

Question source: Several HERC members as part of the Below the Line Review

<u>Issue:</u> Line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA contains multiple diagnoses, including the ICD-10-CM F51.0 family (Insomnia) and the G47.0 family (other insomnia). Insomnia involves dissatisfaction with sleep quantity or quality and is associated with difficulty initiating sleep, maintaining sleep, returning to sleep after early morning waking, or a combination thereof It can be related to other mental health disorders such as anxiety or depression or can exist as an independent condition. Diagnostic criteria for insomnia disorder require that sleep symptoms cause clinically significant distress or impairment in functioning, occur despite adequate opportunity for sleep, and are experienced on a chronic basis (at least 3 nights per week for at least 3 months).

Many treatments are available for insomnia symptoms, including sleep hygiene education, cognitive behavioral therapy, prescription medications (for example, benzodiazepines or zolpidem), over-the-counter medications and supplements (such as melatonin or diphenhydramine), and complementary and alternative medicine (CAM) treatments.

This condition has not been reviewed or discussed in over 10 years. This is part of a biennial review and any changes would take effect for the January 1, 2024, Prioritized List.

Current Prioritized List status

Line 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER Line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA F51.01 Primary insomnia F51.02 Adjustment insomnia F51.03 Paradoxical insomnia F51.04 Psychophysiologic insomnia F51.05 Insomnia due to other mental disorder F51.09 Other insomnia not due to a substance or known physiological condition G47.00 Insomnia, unspecified G47.01 Insomnia due to medical condition G47.09 Other insomnia Evidence review

- 1) AHRQ 2017: Management of Insomnia Disorder in Adults: Current State of the Evidence
 - a. Psychological and Behavioral Therapy:
 - i. Effectiveness
 - CBT-I improved global and sleep outcomes in the general adult population (low to moderate strength of evidence [SOE]). Effectiveness was demonstrated across modes of delivery [CBT-I, multicomponent behavioral therapy, relaxation training, stimulus control or sleep restriction] and was sustained in the long term (at least 6 months) for some outcomes (low to moderate SOE). CBT-I also appeared to improve global and some sleep outcomes in older adults and in patients with pain conditions and insomnia (low SOE for most outcomes).
 - ii. Adverse Effects
 - 1. Evidence was insufficient regarding the adverse effects of psychological and behavioral interventions.
 - b. Pharmacological Therapy:
 - i. Effectiveness
 - Nonbenzodiazepine hypnotics (eszopiclone and zolpidem) and an orexin receptor antagonist (suvorexant) improved some outcomes among the general adult population in primarily short-term (up to 3 months) studies (low to moderate SOE). The antidepressant doxepin improved global and some sleep outcomes, primarily in older patients (low to moderate SOE). Evidence regarding the long-term efficacy of pharmacological therapies for insomnia disorder is very limited.
 - ii. Adverse Effects
 - Evidence regarding the long-term (more than 3 months) safety of pharmacological therapies for insomnia disorder is limited. Nevertheless, observational studies suggest a possible association between hypnotics and fractures, head injuries, dementia, and cancer. FDA labels warn of several potential severe adverse effects for all insomnia medications.
- 2) **Brasure 2016**, Psychological and Behavioral Interventions for Insomnia: Evidence Report for the ACP Clinical Practice Guideline
 - a. N=60 trials
 - i. Compared psychological and behavioral interventions with inactive controls or other psychological and behavioral interventions
 - ii. Mean duration of insomnia was several years
 - b. CBT-I
 - i. N=22 trials comparing CBT-I with inactive control
 - 7 delivered CBT-I individually in person; 5 in groups; 1 by phone; and 10 by books, handouts, or electronic resources as self-help
 - 2. Low risk of bias
 - 3. CBT-I improved post-treatment global and most sleep outcomes across several delivery modes and inactive control types (moderate-strength evidence).
 - Evidence on adverse effects and withdrawals was insufficient for all comparisons; however, psychological and behavioral interventions are low-harm

- 3) Wilt 2016, pharmacologic treatment of insomnia: evidence report for the ACP clinical practice guideline
 - a. N=35 RCTs for efficacy, 11 observational studies for data on long term harms
 - i. Most studies were industry sponsored
 - ii. Trials rarely assessed treatments for longer than 4 weeks
 - b. General harms: FDA labeling warns of daytime memory and psychomotor impairment and behavioral changes; observational studies indicated that hypnotic drugs were associated with dementia
 - c. Escopiclone
 - i. N=3 RCTs (N=1929) with moderate risk of bias
 - Pooled results showed that escopiclone reduced sleep onset latency (SOL) by 19 minutes and increased total sleep time (TSTO by 45 minutes compared to placebo (moderate strength evidence)
 - d. Zaleplon
 - i. N=2 four week RCTs (N=973) with moderate risk of bias
 - 1. No clinically significant improvement in SOL or TST (Moderate strength evidence)
 - e. Zolpidem
 - i. N=6 RCTs (N=859) with moderate risk of bias
 - ii. Pooled trials showed that zolpidem, 5 to 10 mg, increased TST by 23 minutes compared with placebo
 - f. Melatonin
 - i. N=1 RCT (N=791) with moderate risk of bias
 - ii. Evidence on global and sleep outcomes was insufficient
 - g. Benzodiazepines
 - i. Only small trials found; evidence was insufficient for all outcomes
 - h. Conclusions: eszopiclone, zolpidem, and suvorexant improved global outcomes and sleep variables for carefully selected adults with insomnia disorder. The clinical significance and general applicability of beneficial effects, the comparative effectiveness and long-term efficacy of agents, and the frequency and severity of adverse effects, especially among older adults, are not clearly established. A large placebo response was reported. Observational studies, including FDA data, suggest an association between hypnotics with infrequent but serious harms. Evidence for benzodiazepine hypnotics, melatonin agonists, and antidepressants in general populations and for most interventions in older adults was insufficient or low strength

Expert guidelines

- 1) Choosing Wisely 2021:
 - a. https://www.choosingwisely.org/clinician-lists/aasm-hypnotics-for-chronic-insomnia/
 - b. Don't offer hypnotics as the only initial therapy for chronic insomnia in adults. Use cognitive-behavioral therapy for insomnia (CBT-I), whenever possible, and use medications only when necessary.
- 2) **Qaseem 2016**: Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline From the American College of Physicians
 - a. Recommendation 1: ACP recommends that all adult patients receive cognitive behavioral therapy for insomnia (CBT-I) as the initial treatment for chronic insomnia disorder. (Grade: strong recommendation, moderate-quality evidence)
 - i. There are various delivery methods for CBT-I, such as individual or group therapy, telephone or Web-based modules, or self-help books. Most studies focused on in-person CBT-I; however, the data suggest that other delivery methods are also effective
 - b. Recommendation 2: ACP recommends that clinicians use a shared decision-making approach, including a discussion of the benefits, harms, and costs of short-term use of medications, to decide whether to add pharmacological therapy in adults with chronic insomnia disorder in whom cognitive behavioral therapy for insomnia (CBT-I) alone was unsuccessful. (Grade: weak recommendation, low-quality evidence)
- 3) **Sateia 2017**, Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline
 - a. The following recommendations are intended as a guideline for clinicians in choosing a specific pharmacological agent for treatment of chronic insomnia in adults, when such treatment is indicated. Under GRADE, a STRONG recommendation is one that clinicians should, under most circumstances, follow. A WEAK recommendation reflects a lower degree of certainty in the outcome and appropriateness of the patient-care strategy for all patients, but should not be construed as an indication of ineffectiveness. [medication recommendation updates of 2008 guideline below]
 - i. We suggest that clinicians use suvorexant as a treatment for sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
 - ii. We suggest that clinicians use eszopiclone as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
 - iii. We suggest that clinicians use zaleplon as a treatment for sleep onset insomnia (versus no treatment) in adults. (WEAK)
 - iv. We suggest that clinicians use zolpidem as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
 - v. We suggest that clinicians use triazolam as a treatment for sleep onset insomnia (versus no treatment) in adults. (WEAK)
 - vi. We suggest that clinicians use temazepam as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
 - vii. We suggest that clinicians use ramelteon as a treatment for sleep onset insomnia (versus no treatment) in adults. (WEAK)
 - viii. We suggest that clinicians use doxepin as a treatment for sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
 - ix. We suggest that clinicians not use trazodone as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK)

Biennial Review: Insomnia

- x. We suggest that clinicians not use tiagabine as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- xi. We suggest that clinicians not use diphenhydramine as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- xii. We suggest that clinicians not use melatonin as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- xiii. We suggest that clinicians not use tryptophan as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- xiv. We suggest that clinicians not use valerian as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 4) Schutte-Rodin 2008: Clinical Guideline for the Evaluation and Management of Chronic Insomnia in Adults
 - a. Note: the pharmacologic guidelines were updated in Sateia 2017 above
 - b. Psychological and behavioral interventions are effective and recommended in the treatment of chronic primary and comorbid (secondary) insomnia. (Standard)
 - i. These treatments are effective for adults of all ages, including older adults, and chronic hypnotic users. (Standard)
 - ii. These treatments should be utilized as an initial intervention when appropriate and when conditions permit. (Consensus)
 - c. Although all patients with chronic insomnia should adhere to rules of good sleep hygiene, there is insufficient evidence to indicate that sleep hygiene alone is effective in the treatment of chronic insomnia. It should be used in combination with other therapies. (Consensus)

Current OHP coverage:

- 1) Cognitive behavioral therapy is not paired with insomnia
- 2) P&T PA criteria allow up to a prescription for up to 12 months of sedative hypnotics (both over the counter and prescription) with comorbid anxiety, depression, or bipolar disorder (with evidence of other medications being prescribed) and for sleep apnea for patients on CPAP

BHAP input:

Members were strongly in favor of coverage of insomnia.

HERC staff summary:

High quality reviews have found moderate evidence the cognitive behavioral therapy (CBT) is effective for treating insomnia. Pharmacologic treatments have low quality evidence that they are effective in the short term (less than 3 months), but there is evidence of harm with long term use based on observational data. Expert guidelines recommend using pharmacologic treatments only with CBT or when CBT is ineffective.

Modality of cognitive behavioral therapy can include in person, telemedicine, app, or book.

There is concern by HERC and OHA staff that addition of insomnia to a funded line would result in mainly increased sedative-hypnotic use (associated with significant harms), as cognitive behavioral therapy is currently difficult for patients to obtain in many areas of the state. A guideline should be adopted to ensure that CBT is tried concurrently or has not been effective before sedative-hypnotic medications are covered for insomnia.

HERC staff/BHAP recommendations (effective 1/1/2024 as part of biennial review):

- 1) Add the following ICD-10-CM codes to Line 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER and delete from Line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA
 - a. F51.01 Primary insomnia
 - b. F51.02 Adjustment insomnia
 - c. F51.03 Paradoxical insomnia
 - d. F51.04 Psychophysiologic insomnia
 - e. F51.05 Insomnia due to other mental disorder
 - f. F51.09 Other insomnia not due to a substance or known physiological condition
 - g. G47.00 Insomnia, unspecified
 - h. G47.01 Insomnia due to medical condition
 - i. G47.09 Other insomnia
- 2) Rename line 202 SLEEP APNEA, NARCOLEPSY, <u>INSOMNIA</u> AND REM BEHAVIORAL DISORDER for the January 1, 2024, Prioritized List
- 3) Add the CPT codes for cognitive behavioral therapy to line 202
 - a. 90785 Interactive complexity
 - b. 90832-90838 Psychotherapy
 - c. 90853 Group psychotherapy (other than of a multiple-family group)
- 4) Adopt a new guideline for line 202 as shown below:

GUIDELINE NOTE XXX INSOMNIA

Line 202

Insomnia is included on this line for pairing with cognitive behavioral therapy (CBT). Short term (up to 3 months) treatment with sedative-hypnotic medications is included on this line only if the patient is currently in CBT or has failed to respond to recent CBT (in the past year). Long-term (more than 3 months) treatment with sedative-hypnotic medications is included on this line only for patients with obstructive sleep apnea currently using continuous positive airway pressure and for patients with co-morbid psychiatric conditions (for example, depression, anxiety, bipolar disorder) who are being treated with psychiatric medications.

Clinician Summary

Management of Insomnia Disorder in Adults: Current State of the Evidence

Focus of This Summary

This is a summary of a systematic review that evaluated current evidence regarding the effectiveness, comparative effectiveness, and adverse effects of management strategies for insomnia disorder in adults. The systematic review synthesized evidence from 169 randomized controlled trials and 12 observational studies published through January 2015. The full report, listing all studies, is available at *www.effectivehealthcare.ahrq.gov/insomnia/*. This summary is provided to assist in informed clinical decisionmaking. However, reviews of evidence should not be construed to represent clinical recommendations or guidelines.

Background

Insomnia involves dissatisfaction with sleep quantity or quality and is associated with difficulty initiating sleep, maintaining sleep, returning to sleep after early morning waking, or a combination thereof. Diagnostic criteria for insomnia disorder require that sleep symptoms cause clinically significant distress or impairment in functioning, occur despite adequate opportunity for sleep, and are experienced on a chronic basis (at least 3 nights per week for at least 3 months).¹

Many treatments are available for insomnia symptoms, including sleep hygiene education, behavioral and psychological interventions, prescription medications, over-the-counter medications and supplements, and complementary and alternative medicine (CAM) treatments.

Psychological and behavioral interventions include cognitive behavioral therapy for insomnia (CBT-I), brief or multicomponent behavioral therapy, stimulus control, relaxation training, and sleep restriction (*see Appendix Table 1*). Guidelines^{2,3} recommend CBT-I as first-line treatment for all adults with chronic insomnia disorder.

The U.S. Food and Drug Administration (FDA) has approved several prescription drugs for insomnia, typically for short-term use. These include nonbenzodiazepine hypnotics (zaleplon, zolpidem, eszopiclone), an orexin receptor antagonist (suvorexant), a melatonin agonist (ramelteon), some benzodiazepines (e.g., triazolam, temazepam), and an antidepressant (doxepin).

The systematic review assessed the efficacy, comparative effectiveness, and adverse effects of a broad range of management strategies for insomnia disorder in adults.

- 1. American Psychiatric Association. Sleep-wake disorders. In: Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Arlington, VA: American Psychiatric Publishing; 2013:chapter 15.
- 2. Qaseem A, Kansagara D, Forciea MA, et al. Ann Intern Med. 2016 Jul 19;165(2):125-33. PMID: 27136449.
- 3. Morgenthaler T, Kramer M, Alessi C, et al. Sleep. 2006 Nov;29(11)1415-9. PMID: 17162987.



Conclusions

Psychological and Behavioral Therapy: Effectiveness (See Table 1)

- CBT-I improved global and sleep outcomes in the general adult population (low to moderate strength of evidence [SOE]). Effectiveness was demonstrated across modes of delivery and was sustained in the long term (at least 6 months) for some outcomes (low to moderate SOE).
- CBT-I also appeared to improve global and some sleep outcomes in older adults and in patients with pain conditions and insomnia (low SOE for most outcomes).

Psychological and Behavioral Therapy: Adverse Effects

• Evidence was insufficient regarding the adverse effects of psychological and behavioral interventions.

Pharmacological Therapy: Effectiveness (See Table 2)

- Nonbenzodiazepine hypnotics (eszopiclone and zolpidem) and an orexin receptor antagonist (suvorexant) improved some outcomes among the general adult population in primarily short-term (up to 3 months) studies (low to moderate SOE).
- The antidepressant doxepin improved global and some sleep outcomes, primarily in older patients (low to moderate SOE).
- Evidence regarding the long-term efficacy of pharmacological therapies for insomnia disorder is very limited.

Pharmacological Therapy: Adverse Effects (See Table 3)

- Evidence regarding the long-term (more than 3 months) safety of pharmacological therapies for insomnia disorder is limited. Nevertheless, observational studies suggest a possible association between hypnotics and fractures, head injuries, dementia, and cancer.
- FDA labels warn of several potential severe adverse effects for all insomnia medications.

Overview of Clinical Research Evidence

The effects of insomnia treatment can be assessed in various ways. Outcome measures include:

- Sleep outcome measures: These assess specific sleep parameters (sleep-onset latency, time awake after sleep onset, total sleep time, and sleep efficiency) or sleep quality.
- Global outcome measures: These assess improvements in both sleep and accompanying daytime dysfunction or distress (e.g., fatigue or sleepiness, depressed mood, reduced quality of life). The Insomnia Severity Index (ISI) and the Pittsburgh Sleep Quality Index (PSQI) are common global outcome instruments.

Table 1: Effectiveness of Psychological and Behavioral Interventions for Insomnia Disorder When Compared With a Control^a: Main Findings

	General Adult Population		Adults 55 Years of Age and Older		Adults With Pain Conditions	
Intervention	Global Outcomes	Sleep Outcomes	Global Outcomes	Sleep Outcomes	Global Outcomes	Sleep Outcomes
CBT-I ^b	Improves (●○○ to ●●○)	Improves (●●○)	May improve (●○○)	Reduces awake time after sleep onset (●●○) May improve other outcomes (●○○)	May improve (●○○)	May improve some outcomes (•০০)
CBT-I (studies lasting ≥ 6 months)	May improve (●○○)	Improves sleep efficiency (••○) May improve other outcomes (•○○)	(000)	(000)	(000)	(000)
Stimulus Control ^c	(000)	May improve some outcomes (•○○)	(000)	May improve total sleep time (●○○)	(000)	(000)
MBT or BBT	(000)	(000)	(000)	May improve some outcomes (•০০)	(000)	(000)

BBT = brief behavioral therapy; CBT-I = cognitive behavioral therapy for insomnia; MBT = multicomponent behavioral therapy

^a Controls included treatment as usual, attention control (i.e., sleep hygiene or sleep education), "wait-list" management, placebo or sham treatment, or no treatment.

^b The effectiveness of CBT-I was demonstrated across modes of delivery: in-person as an individual, in-person as a group, telephone, Web-based, and based on a self-help book.

^c These results refer to stimulus control alone. Stimulus control is also often a component of CBT-I, MBT, and BBT.

Strength of Evidence Scale [†]							
High:	•••	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimat of effect.	te				
Moderate:		Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.					
Low:	•00	Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.					
Insufficient:	000	Evidence either is unavailable or does not permit a conclusion.					

[†] The overall evidence grade was assessed based on the ratings for the following domains: study limitations, directness, consistency, precision, and reporting bias. Other domains were considered, as appropriate: dose-response association, plausible confounding, and strength of association (i.e., magnitude of effect). For additional details on the methodology used to assess strength of evidence, please refer to: Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions—Agency for Healthcare Research and Quality and the Effective Health-Care Program. J Clin Epidemiol. 2010 May;63(5):513-23. PMID: 19595577.

Overview of Clinical Research Evidence (*Continued***)**

Table 2: Effectiveness of Pharmacological Interventions for Insomnia Disorder When Compared With Placebo: Main Findings

Note: Most studies of pharmacological interventions were small and of short duration (less than 3 months).

	General Adult Population		Adults 55 Years of Age and Older				
Drua	Global Outcomes	Sleen Outcomes ^a	Global Outcomes	Sleen Outcomes ^a			
Nonbenzodiazenine Hypno	tics	Sicepouttomes	clobal outcomes	Sicepoutcomes			
Eszopiclone	May improve (•00)	Improves sleep onset latency and total sleep time (•••) May reduce time awake after sleep onset (•••)	May improve (●○○)	May improve some outcomes (●○○)			
Zolpidem ^b	May improve (●○○)	Improves latency, total sleep time, and sleep quality (•••) May reduce time awake after sleep onset (•••)	(000)	May improve sleep onset latency (●○○)			
Zolpidem ER	May improve (•০০)	May improve some outcomes (•00)	(000)	(000)			
Zaleplon	(000)	Improves sleep quality (●●○) Probably has no effect on total sleep time (●○○)	(000)	(000)			
Orexin Receptor Antagonist	s						
Suvorexant	Improves (●●○)	Improves latency and total sleep time (•••) Reduces time awake after sleep onset (•••)	(000)	(000)			
Melatonin Agonists							
Ramelteon	(000)	May improve sleep quality (••••) Probably has no effect on other outcomes (••••)	(000)	May improve sleep onset latency (●○○)			
Antidepressants							
Doxepin	(000)	May improve some outcomes (●○○)	May improve (●○○)	Improves total sleep time (••○) May improve other outcomes (•○○)			
Others ^c	(000)	(000)	(000)	(000)			
Benzodiazepines							
Temazepam	(000)	(000)	(000)	(000)			
Others ^d	(000)	(000)	(000)	(000)			
Over-the-Counter Sleep Medications and Supplements							
Diphenhydramine, doxylamine, melatonin	(000)	(000)	(000)	(000)			

ER = extended release

^a Sleep outcomes include sleep onset latency, total sleep time, time awake after sleep onset, sleep efficiency, and sleep quality.

^b Data are from studies of routine use of zolpidem 10 mg or 15 mg or as-needed use of zolpidem 10 mg for the general adult population and zolpidem 5 mg for the older adult population.

^c Other antidepressants include trazodone, amitriptyline, and mirtazapine, none of which are approved by the U.S. Food and Drug Administration (FDA) for insomnia.

^d Other benzodiazepines include drugs approved by the FDA for insomnia (estazolam, flurazepam, lorazepam, quazepam, and triazolam) and drugs not approved by the FDA for insomnia (alprazolam and clonazepam).
Overview of Clinical Research Evidence (*Continued***)**

Table 3: Adverse Effects of Pharmacological Interventions for Insomnia Disorder: Systematic Review Findings and U.S. Food and Drug Administration Label Information

Drug Class	Drug	Common Effects ^a	Serious Effects ^b
Nonbenzo- diazepine Hypnotics	Eszopiclone	Somnolence, unpleasant taste in the mouth, headache, dizziness, dry mouth, rash, anxiety, hallucinations, respiratory infection	 CNS depressant effects and next-day psychomotor impairment Increased CNS effects in older adults Sleep-driving and other complex behaviors while not fully awake Worsening depression or suicidal thoughts Falls and severe injuries because of drowsiness Savara anaphylactic or anaphylactoid reactions
	Zolpidem	Somnolence, headache, malaise, vertigo, dizziness, diarrhea	 Possible respiratory depression in people with severe lung disease or sleep apnea Withdrawal symptoms if abrupt dose reduction or discontinuation
	Zaleplon	Headache, drowsiness, dizziness, paresthesias, difficulty with coordination	
Benzodiazepines	Temazepam	Drowsiness, dizziness, headache, nervousness, nausea	 Abnormal thinking, behavioral changes, complex behaviors (including sleep-driving, hallucinations) Worsening depression or suicidal thoughts in people with primary depression Severe anaphylactic or anaphylactoid reactions Possible profound sedation, respiratory depression, coma, and death with concomitant opioid use Possible adverse effects in people with severe lung disease or sleep apnea
Orexin Receptor Antagonists	Suvorexant	Somnolence, fatigue, dry mouth	 CNS depressant effects and next-day psychomotor impairment Sleep-driving and other complex behaviors while not fully awake Sleep paralysis, hypnagogic or hypnopompic hallucinations, cataplexy-like symptoms Worsening depression or suicidal thoughts Possible respiratory depression in people with severe lung disease or sleep apnea
Melatonin Agonists	Ramelteon	Somnolence, fatigue, headache, dizziness, worsened insomnia, nausea	 Potential impairment of activities requiring complete mental alertness after drug ingestion Abnormal thinking, behavioral changes, complex behaviors (including sleep-driving, hallucinations) Worsening depression or suicidal thoughts Severe anaphylactic or anaphylactoid reactions Decreased testosterone and increased prolactin levels Possible adverse effects in people with severe sleep apnea
Antidepressants	Doxepin	Drowsiness, nausea, upper respiratory tract infection	 CNS depressant effects, with impaired alertness and motor coordination that may persist the next day Abnormal thinking, behavioral changes, complex behaviors (including sleep-driving, hallucinations) Potential addictive effects when combined with CNS depressants or sedating antihistamines Worsening depression or suicidal thoughts Possible respiratory depression in people with severe lung disease or sleep apnea

CNS = central nervous system

^a Adverse effects reported in randomized controlled trials and observational studies in the systematic review, as well as common side effects listed in the FDA labels for each drug. ^b Adverse effects accompanied by warnings or precautions statements in the FDA labels.

Other Findings

- Observational studies of long-term harms of pharmacological agents showed possible increased risks of the following:
 - » Hypnotics in general: dementia, cancer
 - » **Zolpidem:** head injury or fracture requiring hospitalization, hip fracture, cancer
 - » Ramelteon: prolactinoma
 - » Temazepam: death, cancer
- In observational studies, the effects of hypnotics on mortality were mixed.

Gaps in Knowledge and Other Issues

- Evidence regarding the effects of insomnia interventions in most patient subgroups was limited. Participants in general adult population trials were predominantly middle-aged, healthy, female, and white.
- Reporting on quality of life and functioning was very limited.
- Evidence for comparative effectiveness evaluations was low or insufficient.
- Evidence was insufficient regarding the effectiveness of most single behavioral interventions, such as sleep hygiene education, relaxation techniques, and sleep restriction.
- Evidence was insufficient regarding the adverse effects of psychological and behavioral interventions. Some studies reported participant withdrawals, which may reflect feasibility issues (e.g., treatments are time-consuming) rather than physical or psychological harms.
- Studies of pharmacological interventions rarely lasted more than 6 weeks. Evidence regarding their longer-term efficacy and safety is limited or lacking.
- Outcome reporting and intervention effect sizes varied among studies of pharmacological therapy, and a large placebo response was observed in some studies.
- Evidence was insufficient to assess the efficacy or comparative effectiveness of CAM interventions.

Companion Resource for Patients



Key Points for Clinician and Patient and Caregiver Discussions

- CBT-I appears to be effective and safe as treatment for insomnia disorder.
 - » Guidelines from professional organizations such as the American College of Physicians and the American Academy of Sleep Medicine recommend CBT-I as the first-line treatment for all adults with chronic insomnia disorder.
 - » Web-based CBT-I may be an option for individuals without access to a therapist trained in CBT-I techniques.
 - » Additional resources for CBT-I information include the American Academy of Sleep Medicine (www.sleepeducation.org/treatment-therapy/ cognitive-behavioral-therapy) and the National Sleep Foundation (sleepfoundation.org/sleep-news/ cognitive-behavioral-therapy-insomnia/page/0/4).
 - » A list of specialists certified by the American Board of Sleep Medicine in behavioral sleep medicine (including CBT-I) is available at *www.absm.org/bsmspecialists.aspx*.
- Some medications appear to be effective for insomnia in the short term (e.g., up to 3 months), but they have numerous potential side effects, some of which are serious.
- In light of the limited evidence regarding long-term benefits and the potential for serious adverse effects, medications should be used for insomnia disorder with caution.

Ordering Information

For electronic copies of this clinician research summary, the companion patient resource, and the full systematic review, visit *www.effectivehealthcare.ahrq.gov/insomnia/*. To order free print copies of the patient resource, call the AHRQ Publications Clearinghouse at 800-358-9295.

Source

The information in this summary is based on *Management* of *Insomnia Disorder*, Comparative Effectiveness Review No. 159, prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2012-00016-I for the Agency of Healthcare Research and Quality, December 2015. Available at *www.effectivehealthcare.ahrq.gov/insomnia/*. This summary was prepared by the John M. Eisenberg Center for Clinical Decisions and Communications Science at Baylor College of Medicine, Houston, TX.

Appendix Table 1: Psychological and Behavioral Interventions for Insomnia Disorder

Treatment	Definition		
Sleep Hygiene Education	Education of patients about health and environmental factors to improve sleep (e.g., avoiding/ limiting caffeine, nicotine, and alcohol; maintaining a regular sleep schedule; avoiding napping; exercising regularly; maintaining a quiet and dark bedroom).		
Stimulus Control	Therapy to change behaviors associated with bed or the bedroom and to establish consistent sleep patterns (e.g., using the bedroom for sleep only; going to bed only when tired).		
Sleep Restriction	Interventions to limit time in bed to sleep time and to gradually increase time in bed as sleep efficiency improves.		
Relaxation Training	Training to reduce somatic tension and to control bedtime thoughts that impair sleep.		
Brief Behavioral Therapy (BBT)	Therapy that combines stimulus control and sleep restriction strategies.		
Multicomponent Behavioral Therapy (MBT)	Therapy combining various behavioral interventions but not cognitive therapy.		
Cognitive Therapy	Interventions to change patients' thinking about sleep by identifying, challenging, and replacing dysfunctional beliefs and attitudes (e.g., challenging notions about requisite amounts of sleep and about how sleep is out of their control; thought journaling).		
Cognitive Behavioral Therapy for Insomnia (CBT-I)	Multimodal combination of treatments, including cognitive therapy, behavioral interventions (sleep restriction, stimulus control, or both), and education (sleep hygiene).		

Table adapted from: Morgenthaler T, Kramer M, Alessi C, et al.; American Academy of Sleep Medicine. Practice parameters for the psychological and behavioral treatment of insomnia: an update. An American Academy of Sleep Medicine report. Sleep. 2006 Nov;29(11):1415-9. PMID: 17162987; and Buysse DJ. Insomnia. JAMA. 2013 Feb 20;309(7):706-16. PMID: 23423416.



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Management of Insomnia Disorder



Management of Insomnia Disorder

Structured Abstract

Objective. To assess the efficacy, comparative effectiveness, and harms of treatments for insomnia disorder in the general adult population and older adults.

Data sources. Ovid MEDLINE[®], the Cochrane Central Register of Controlled Trials, Embase[®], and PsycINFO[®] bibliographic databases; hand searches of references of relevant studies.

Review methods. Two investigators screened abstracts and full-text articles of identified references for eligibility. Eligible studies included systematic reviews, randomized controlled trials (RCTs), and long-term observational pharmacologic studies enrolling participants with insomnia disorder. We analyzed data for global outcomes (measures that assess both sleep and daytime functioning associated with sleep), sleep parameters, and harms. We assessed risk of bias for RCTs, extracted data, assessed quality of relevant systematic reviews, and evaluated strength of evidence for comparisons and outcomes. Pooled estimates were analyzed to assess the efficacy and comparative effectiveness of treatments.

Results. We searched bibliographic databases through January 2015 for studies evaluating psychological, pharmacologic, and complementary and alternative medicine interventions for insomnia disorder. We synthesized evidence from 181 unique studies (data from 128 unique RCTs and 3 systematic reviews that synthesize data from 42 unique RCTs) and 12 observational studies. Sample sizes and enrollment criteria varied; most trials were short in duration. Outcome reporting and intervention effect sizes varied, and a large placebo response was often observed. Cognitive behavioral therapy for insomnia (CBT-I) improved global outcomes and nearly all sleep parameters in the general adult population, older adults, and adults with pain. We found insufficient evidence on adverse effects of these interventions. Evidence was less robust for psychological interventions other than CBT-I, but low-strength evidence shows that some interventions improve some sleep outcomes. Low- to moderate-strength evidence indicated that the nonbenzodiazepine hypnotics eszopiclone and zolpidem, and the orexin receptor antagonist suvorexant, improved short-term global and sleep outcomes in general adult populations. Doxepin improved sleep outcomes. The absolute mean effect was small. Evidence for benzodiazepine hypnotics, melatonin agonists, and antidepressants in general populations and for most pharmacologic interventions in older adults was generally insufficient. Evidence on adverse effects from RCT data was generally insufficient or low strength. Observational studies suggest that hypnotics may be associated with dementia, fractures, and major injury. Food and Drug Administration (FDA) labels warn about cognitive and behavioral changes, including driving impairment, and other harms, and advise lower doses for females and older/debilitated adults. Evidence on complementary and alternative medicine was insufficient. Evidence was insufficient to compare hypnotic medications within or across classes or versus CBT-I.

Conclusions. CBT-I or medical therapy with eszopiclone, zolpidem, and suvorexant improve global and sleep outcomes for insomnia disorder. Clinical significance, applicability, comparative effectiveness, and long-term efficacy, especially among older adults, are less well known. Effect sizes vary, and a large placebo response is sometimes observed. Observational

studies suggest an association of hypnotics with infrequent but serious harms. FDA labels provide specific warnings and precautions for drugs approved for insomnia.

Annals of Internal Medicine

REVIEW

Psychological and Behavioral Interventions for Managing Insomnia Disorder: An Evidence Report for a Clinical Practice Guideline by the American College of Physicians

Michelle Brasure, PhD, MSPH, MLIS; Erika Fuchs, MPH, PhD; Roderick MacDonald, MS; Victoria A. Nelson, MSc; Erin Koffel, PhD; Carin M. Olson, MD, MS; Imran S. Khawaja, MD; Susan Diem, MD, MPH; Maureen Carlyle, MPH; Timothy J. Wilt, MD, MPH; Jeannine Ouellette; Mary Butler, PhD; and Robert L. Kane, MD

Background: Psychological and behavioral interventions are frequently used for insomnia disorder.

Purpose: To assess benefits and harms of psychological and behavioral interventions for insomnia disorder in adults.

Data Sources: Ovid MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, and PsycINFO through September 2015, supplemented with hand-searching.

Study Selection: Randomized, controlled trials of psychological or behavioral interventions that were published in English and enrolled adults with insomnia disorder lasting 4 or more weeks.

Data Extraction: Data extraction by single investigator confirmed by a second reviewer; dual investigator assessment of risk of bias; consensus determination of strength of evidence.

Data Synthesis: Sixty trials with low to moderate risk of bias compared psychological and behavioral interventions with inactive controls or other psychological and behavioral interventions. Cognitive behavioral therapy for insomnia (CBT-I) improved posttreatment global and most sleep outcomes, often compared with information or waitlist controls (moderate-strength evidence). Use of CBT-I improved several sleep outcomes in

Cleep difficulties, including the inability to initiate or **O**maintain sleep, are common in adults. Sleep difficulties are typically transient; however, when they become chronic and cause distress or daytime dysfunction, insomnia disorder may be present. The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, defines insomnia disorder as a predominant symptom of difficulty with sleep initiation, difficulty maintaining sleep, or earlymorning waking with inability to return to sleep causing clinically significant distress or impairment in activities, occurring at least 3 nights per week for 3 months or more (1). Furthermore, individuals must have adequate opportunity for sleep and the symptoms cannot be better explained by medical or mental conditions, including another sleep disorder (such as breathing-related sleep disorder), or medication or substance use. The term previously used for insomnia disorder is chronic insomnia (1-4), for which diagnostic criteria required sleep problems lasting from weeks to months. These criteria are empirically similar to current criteria for insomnia disorder. We use the term insomnia disorder even though much of the primary research has used other terminology (such as chronic insomnia and persistent insomnia).

older adults (low- to moderate-strength evidence). Multicomponent behavioral therapy improved several sleep outcomes in older adults (low- to moderate-strength evidence). Stimulus control improved 1 or 2 sleep outcomes (low-strength evidence). Evidence for other comparisons and for harms was insufficient to permit conclusions.

Limitations: A wide variety of comparisons limited the ability to pool data. Trials did not always report global outcomes and infrequently conducted remitter or responder analysis. Comparisons were often information or waitlist groups, and publication bias was possible.

Conclusion: Use of CBT-I improves most outcomes compared with inactive controls. Multicomponent behavioral therapy and stimulus control may improve some sleep outcomes. Evidence on other outcomes, comparisons, and long-term efficacy were limited.

Primary Funding Source: Agency for Healthcare Research and Quality. (PROSPERO: CRD42014009908)

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Between 6% and 10% of adults meet the diagnostic

criteria for insomnia disorder (4). Duration ranges from 1 to 20 years across longitudinal studies (5). Insomnia disorder is more common in female patients and older adults (6, 7). Older adults typically report difficulty maintaining sleep as opposed to initiating sleep, which is common in younger adults (8).

Many treatment types are available once insomnia disorder is accurately diagnosed by using established diagnostic criteria (4, 9). These include psychological and behavioral treatments, pharmacologic therapies, and complementary and alternative medicine. The American Academy of Sleep Medicine recommends psychological and behavioral interventions and supports short-term supplementary medication (9, 10). Psychological and behavioral interventions include

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Annals of Internal Medicine • Vol. 165 No. 2 • 19 July 2016 113

Annals of Internal Medicine

REVIEW

Pharmacologic Treatment of Insomnia Disorder: An Evidence Report for a Clinical Practice Guideline by the American College of Physicians

Timothy J. Wilt, MD, MPH; Roderick MacDonald, MS; Michelle Brasure, PhD, MSPH, MLIS; Carin M. Olson, MD, MS; Maureen Carlyle, MPH; Erika Fuchs, PhD, MPH; Imran S. Khawaja, MD; Susan Diem, MD, MPH; Erin Koffel, PhD; Jeannine Ouellette; Mary Butler, PhD; and Robert L. Kane, MD

Background: Pharmacologic interventions are often prescribed for insomnia disorder.

Purpose: To assess the benefits, harms, and comparative effectiveness of pharmacologic treatments for adults with insomnia disorder.

Data Sources: Several electronic databases (2004-September 2015), reference lists, and U.S. Food and Drug Administration (FDA) documents.

Study Selection: 35 randomized, controlled trials of at least 4 weeks' duration that evaluated pharmacotherapies available in the United States and that reported global or sleep outcomes; 11 long-term observational studies that reported harm information; FDA review data for nonbenzodiazepine hypnotics and orexin receptor antagonists; and product labels for all agents.

Data Extraction: Data extraction by single investigator confirmed by a second reviewer; dual-investigator assessment of risk of bias; consensus determination of strength of evidence.

Data Synthesis: Eszopiclone, zolpidem, and suvorexant improved short-term global and sleep outcomes compared with placebo, although absolute effect sizes were small (low- to moderate-strength evidence). Evidence for benzodiazepine hypnotics, melatonin agonists, and antidepressants, and for most pharmacologic interventions in older adults, was insufficient or low strength. Evidence was also insufficient to compare efficacy

Sleep problems are common and associated with a decline in overall and sleep-related health (1-3). Insomnia is more common in women and older adults (4). Aging is often accompanied by disrupted sleep and frequent and early waking (5, 6). Other conditions coexist with, are due to, or lead to poor sleep (7).

Insomnia symptoms are typically transient and may not cause distress or impaired activity. However, insomnia disorder as defined by the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, requires sleep problems that are chronic, persistent, and associated with daytime dysfunction. Insomnia disorder includes a predominant symptom of difficulty with sleep initiation, difficulty maintaining sleep, or early-morning waking with inability to return to sleep causing clinically significant distress or impairment in activities, occurring at least 3 nights per week. Current definitions require insomnia symptoms to have persisted for 3 months or more (8). Individuals must have adequate opportunity for sleep, and symptoms must not be better explained by another sleep disorder, effects of a substance, or other medical or mental conditions.

within or across pharmacotherapy classes or versus behavioral therapy. Harms evidence reported in trials was judged insufficient or low strength; observational studies suggested that use of hypnotics for insomnia was associated with increased risk for dementia, fractures, and major injury. The FDA documents reported that most pharmacotherapies had risks for cognitive and behavioral changes, including driving impairment, and other adverse effects, and they advised dose reduction in women and in older adults.

Limitations: Most trials were small and short term and enrolled individuals meeting stringent criteria. Minimum important differences in outcomes were often not established or reported. Data were scant for many treatments.

Conclusion: Eszopiclone, zolpidem, and suvorexant may improve short-term global and sleep outcomes for adults with insomnia disorder, but the comparative effectiveness and long-term efficacy of pharmacotherapies for insomnia are not known. Pharmacotherapies for insomnia may cause cognitive and behavioral changes and may be associated with infrequent but serious harms.

Primary Funding Source: Agency for Healthcare Research and Quality. (PROSPERO: CRD42014009908)

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Treatment goals include meaningful improvements in sleep-associated distress or dysfunction (global outcomes). The Insomnia Severity Index (ISI) and the Pittsburgh Sleep Quality Index measure both problems and worry about sleep and accompanying distress or dysfunction. Sleep measures are based on specific sleep variables that can be assessed in a sleep laboratory with polysomnography or actigraphy or subjectively with patient-reported sleep diaries. These include sleep-onset latency (SOL), wake after sleep onset (WASO), total sleep time (TST), and sleep efficiency (percentage of time in bed sleeping). In general, insomnia disorder is treated by clinicians on the basis of patient-reported sleep-associated distress, not laboratory assessment. Additionally, polysomnography is not

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American Academy of Sleep Medicine

New Guideline

February 2017

The AASM has published a new clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults. These new recommendations are based on a systematic review of the literature on individual drugs commonly used to treat insomnia, and were developed using the GRADE methodology. The recommendations in this guideline define principles of practice that should meet the needs of most adult patients, when pharmacologic treatment of chronic insomnia is indicated. The clinical practice guideline is an essential update to the clinical guideline document:

Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. <u>Clinical practice guideline for the</u> pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep <u>Medicine clinical practice guideline</u>. J Clin Sleep Med. 2017;13(2):307–349.

Journal of Clinical Sleep Medicine

SPECIAL ARTICLE

Clinical Guideline for the Evaluation and Management of Chronic Insomnia in Adults

Sharon Schutte-Rodin, M.D.¹; Lauren Broch, Ph.D.²; Daniel Buysse, M.D.³; Cynthia Dorsey, Ph.D.⁴; Michael Sateia, M.D.⁵

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Insomnia is the most prevalent sleep disorder in the general population, and is commonly encountered in medical practices. Insomnia is defined as the subjective perception of difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity for sleep, and that results in some form of daytime impairment.¹ Insomnia may present with a variety of specific complaints and etiologies, making the evaluation and management of chronic insomnia demanding on a clinician's time. The purpose of this clinical guideline is to provide clinicians with a practical framework for the assessment and disease management of chronic adult insomnia, using existing evidence-based insomnia practice parameters where available, and consensus-based recommendations to bridge areas where such parameters do not exist. Unless otherwise stated, "insomnia" refers to chronic insomnia, which is present for at least a month, as opposed to acute or transient insomnia, which may last days to weeks.

Citation: Schutte-Rodin S; Broch L; Buysse D; Dorsey C; Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med* 2008;4(5):487-504.

SUMMARY RECOMMENDATIONS

General:

- Insomnia is an important public health problem that requires accurate diagnosis and effective treatment. (Standard)
- An insomnia diagnosis requires associated daytime dysfunction in addition to appropriate insomnia symptomatology. (ICSD-2 definition)

Evaluation:

- Insomnia is primarily diagnosed by clinical evaluation through a thorough sleep history and detailed medical, substance, and psychiatric history. (Standard)
 - The sleep history should cover specific insomnia complaints, pre-sleep conditions, sleep-wake patterns, other sleep-related symptoms, and daytime consequences. (Consensus)
 - The history helps to establish the type and evolution of insomnia, perpetuating factors, and identification of comorbid medical, substance, and/or psychiatric conditions. (Consensus)
- Instruments which are helpful in the evaluation and differential diagnosis of insomnia include self-administered

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questionnaires, at-home sleep logs, symptom checklists, psychological screening tests, and bed partner interviews. (Guideline)

- At minimum, the patient should complete: (1) A general medical/psychiatric questionnaire to identify comorbid disorders (2) The Epworth Sleepiness Scale or other sleepiness assessment to identify sleepy patients and comorbid disorders of sleepiness (3) A two-week sleep log to identify general patterns of sleep-wake times and day-to-day variability. (Consensus)
- Sleep diary data should be collected prior to and during the course of active treatment and in the case of relapse or reevaluation in the long-term. (Consensus)
- Additional assessment instruments that may aid in the baseline evaluation and outcomes follow-up of patients with chronic insomnia include measures of subjective sleep quality, psychological assessment scales, daytime function, quality of life, and dysfunctional beliefs and attitudes. (Consensus)
- Physical and mental status examination may provide important information regarding comorbid conditions and differential diagnosis. (Standard)
- Polysomnography and daytime multiple sleep latency testing (MSLT) are not indicated in the routine evaluation of chronic insomnia, including insomnia due to psychiatric or neuropsychiatric disorders. (Standard)
 - Polysomnography is indicated when there is reasonable clinical suspicion of breathing (sleep apnea) or movement disorders, when initial diagnosis is uncertain, treatment fails (behavioral or pharmacologic), or precipitous arousals occur with violent or injurious behavior. (Guideline)

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Eading Internal Medicine, Improving Lives

CLINICAL GUIDELINE

Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline From the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Devan Kansagara, MD, MCR; Mary Ann Forciea, MD; Molly Cooke, MD; and Thomas D. Denberg, MD, PhD; for the Clinical Guidelines Committee of the American College of Physicians*

Description: The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on the management of chronic insomnia disorder in adults.

Methods: This guideline is based on a systematic review of randomized, controlled trials published in English from 2004 through September 2015. Evaluated outcomes included global outcomes assessed by questionnaires, patient-reported sleep outcomes, and harms. The target audience for this guideline includes all clinicians, and the target patient population includes adults with chronic insomnia disorder. This guideline grades the evidence and recommendations by using the ACP grading system, which is based on the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. **Recommendation 1:** ACP recommends that all adult patients receive cognitive behavioral therapy for insomnia (CBT-I) as the initial treatment for chronic insomnia disorder. (Grade: strong recommendation, moderate-quality evidence)

Recommendation 2: ACP recommends that clinicians use a shared decision-making approach, including a discussion of the benefits, harms, and costs of short-term use of medications, to decide whether to add pharmacological therapy in adults with chronic insomnia disorder in whom cognitive behavioral therapy for insomnia (CBT-I) alone was unsuccessful. (Grade: weak recommendation, low-quality evidence)

Ann Intern Med. 2016;165:125-133. doi:10.7326/M15-2175 www.annals.org For author affiliations, see end of text. This article was published at www.annals.org on 3 May 2016.

nsomnia is a major health care problem in the United States. It is defined as dissatisfaction with sleep quantity or quality and is associated with difficulty initiating or maintaining sleep and early-morning waking with inability to return to sleep (1). Approximately 6% to 10% of adults have insomnia that meets diagnostic criteria (1-4). Insomnia is more common in women and older adults (5, 6) and can occur independently or be caused by another disease. People with the disorder often experience fatigue, poor cognitive function, mood disturbance, and distress or interference with personal functioning (2, 4). An estimated \$30 billion to \$107 billion is spent on insomnia in the United States each year (7). Insomnia also takes a toll on the economy in terms of loss of workplace productivity, estimated at \$63.2 billion in the United States in 2009 (8).

Chronic insomnia, also referred to as "chronic insomnia disorder" in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5), is diagnosed according to the DSM-5 (9) and the International Classification of Sleep Disorders (10), which have similar criteria for making the diagnosis. These criteria specify that symptoms must cause clinically significant functional distress or impairment; be present for at least 3 nights per week for at least 3 months; and not be linked to other sleep, medical, or mental disorders (1). Symptoms of insomnia differ between older adults and the younger population. Older adults are more likely to report problems with waking after sleep onset (difficulty maintaining sleep) than they are to report problems with sleep onset latency (time to fall asleep).

The goal of treatment for insomnia is to improve sleep and alleviate distress or dysfunction caused by the disorder. Insomnia can be managed with psychological therapy, pharmacologic therapy, or a combination of both. Psychological therapy options include cognitive behavioral therapy for insomnia (CBT-I); multicomponent behavioral therapy or brief behavioral therapy (BBT) for insomnia; and other interventions, such as stimulus control, relaxation strategies, and sleep restriction (see **Appendix Table 1**, available at

See also:

Related articles.103, 113Editorial comment149	
Summary for Patients	

† Author (participated in discussion and voting).

‡ Nonauthor contributor (participated in discussion but excluded from voting).

^{*} This paper, written by Amir Qaseem, MD, PhD, MHA; Devan Kansagara, MD, MCR; Mary Ann Forciea, MD; Molly Cooke, MD; and Thomas D. Denberg, MD, PhD, was developed for the Clinical Guidelines Committee of the American College of Physicians. Individuals who served on the Clinical Guidelines Committee from initiation of the project until its approval were Mary Ann Forciea, MD† (*Chair*); Thomas D. Denberg, MD, PhD† (*Immediate Past Chair*); Michael J. Barry, MD†; Cynthia Boyd, MD, MPH‡; R. Dobbin Chow, MD, MBA†; Molly Cooke, MD†; Nick Fitterman, MD†; Russell P. Harris, MD, MPH‡; Linda L. Humphrey, MD, MPH†; Devan Kansagara, MD, MCR†; Scott Manaker, MD, PhD†; Robert McLean, MD†; Tanveer P. Mir, MD‡; Holger J. Schünemann, MD, PhD‡; Sandeep Vijan, MD, MS†; and Timothy Wilt, MD, MPH‡. Approved by the ACP Board of Regents on 25 July 2015.

Journal of Clinical Sleep Medicine

SPECIAL ARTICLES

Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline

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Introduction: The purpose of this guideline is to establish clinical practice recommendations for the pharmacologic treatment of chronic insomnia in adults, when such treatment is clinically indicated. Unlike previous meta-analyses, which focused on broad classes of drugs, this guideline focuses on individual drugs commonly used to treat insomnia. It includes drugs that are FDA-approved for the treatment of insomnia, as well as several drugs commonly used to treat insomnia without an FDA indication for this condition. This guideline should be used in conjunction with other AASM guidelines on the evaluation and treatment of chronic insomnia in adults.

Methods: The American Academy of Sleep Medicine commissioned a task force of four experts in sleep medicine. A systematic review was conducted to identify randomized controlled trials, and the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) process was used to assess the evidence. The task force developed recommendations and assigned strengths based on the quality of evidence, the balance of benefits and harms, and patient values and preferences. Literature reviews are provided for those pharmacologic agents for which sufficient evidence was available to establish recommendations. The AASM Board of Directors approved the final recommendations.

Recommendations: The following recommendations are intended as a guideline for clinicians in choosing a specific pharmacological agent for treatment of chronic insomnia in adults, when such treatment is indicated. Under GRADE, a STRONG recommendation is one that clinicians should, under most circumstances, follow. A WEAK recommendation reflects a lower degree of certainty in the outcome and appropriateness of the patient-care strategy for all patients, but should not be construed as an indication of ineffectiveness. GRADE recommendation strengths do not refer to the magnitude of treatment effects in a particular patient, but rather, to the strength of evidence in published data. Downgrading the quality of evidence for these treatments is predictable in GRADE, due to the funding source for most pharmacological clinical trials and the attendant risk of publication bias; the relatively small number of eligible trials for each individual agent; and the observed heterogeneity in the data. The ultimate judgment regarding propriety of any specific care must be made by the clinician in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.

- 1. We suggest that clinicians use suvorexant as a treatment for sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 2. We suggest that clinicians use eszopiclone as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 3. We suggest that clinicians use zaleplon as a treatment for sleep onset insomnia (versus no treatment) in adults. (WEAK)
- 4. We suggest that clinicians use zolpidem as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 5. We suggest that clinicians use triazolam as a treatment for sleep onset insomnia (versus no treatment) in adults. (WEAK)
- 6. We suggest that clinicians use temazepam as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 7. We suggest that clinicians use ramelteon as a treatment for sleep onset insomnia (versus no treatment) in adults. (WEAK)
- 8. We suggest that clinicians use doxepin as a treatment for sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 9. We suggest that clinicians not use trazodone as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 10. We suggest that clinicians not use tiagabine as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- We suggest that clinicians not use diphenhydramine as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 12. We suggest that clinicians not use melatonin as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 13. We suggest that clinicians not use tryptophan as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK)
- 14. We suggest that clinicians not use valerian as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults. (WEAK) **Keywords:** insomnia, treatment, pharmacologic, guideline

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Sedatives

Goals:

- Restrict use of sedatives to OHP-funded conditions. Treatment of uncomplicated insomnia is not funded; insomnia contributing to covered co-morbid conditions is funded.
- Prevent concomitant use of sedatives, including concomitant use with benzodiazepines or opioids.
- Limit daily zolpidem dose to the maximum recommended daily dose by the FDA.
- Permit use of melatonin in children and adolescents 18 years of age or younger.

Length of Authorization:

• Up to 12 months or lifetime (criteria-specific)

Requires PA:

• All sedatives (e.g., sedative hypnotics, hypnotics-melatonin agonists) except melatonin in children and adolescents. Melatonin is not covered for adults over 18 years of age.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at <u>www.orpdl.org</u>
- Searchable site for Oregon FFS Drug Class listed at <u>www.orpdl.org/drugs/</u>

Zolpidem Daily Quantity Limits

Generic	Brand	Max Daily Dose
Zolpidem	Ambien	10 mg
Zolpidem ER	Ambien CR	12.5 mg

Approval Criteria				
1. What diagnosis is being treated? Record ICD10 code.				
 Is the request for melatonin in an adult over 18 years of age? 	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #3		
3. Is the request for zolpidem at a higher dose than listed in the quantity limit chart?	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #4		
 4. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product? Message: Preferred products are evidence- based and reviewed for comparative effectiveness and safety by the P&T 	Yes: Inform prescriber of preferred alternatives in class.	No: Go to #5		
Committee.				
5. Is the patient being treated under palliative care services (ICD10 Z51.5) with a life-threatening illness or severe advanced illness expected to progress toward dying?	Yes: Approve for lifetime.	No: Go to #6		

Approval Criteria				
 Has the patient been treated with another non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days? 	Yes: Go to #7	No: Go to #8		
7. Is this a switch in sedative therapy due to intolerance, allergy or ineffectiveness?	Yes: Document reason for switch and approve duplication for 30 days.	No: Pass to RPh. Deny; medical appropriateness.		
8. Does the patient have a diagnosis of insomnia with obstructive sleep apnea?	Yes: Go to #9	No: Go to #10		
9. Is patient on CPAP?	Yes: Approve for up to 12 months.	No: Pass to RPh. Deny; medical appropriateness. Sedative/hypnotics are contraindicated due to depressant effect.		
 10. Is the patient being treated for co-morbid: Depression; Anxiety or panic disorder; or Bipolar disorder? AND Is there an existing claim history for treatment of the co-morbid condition (e.g., antidepressant, lithium, lamotrigine, antipsychotic, or other appropriate mental health drug)? 	Yes: Approve for up to 12 months.	No: Pass to RPh; Go to #11		
11. RPh only: Is diagnosis being treated a funded condition and is there medical evidence of benefit for the prescribed sedative?	Funded: Document supporting literature and approve up to 6 months with subsequent approvals dependent on follow-up and documented response.	Not Funded: Go to #12		
12. RPh only: Is this a request for continuation therapy for a patient with a history of chronic benzodiazepine use where discontinuation would be difficult or unadvisable?	Yes: Document length of treatment and last follow-up date. Approve for up to 12 months.	No: Deny; medical appropriateness		

P&T/DUR Review: Implementation: 12/20 (AG); 7/18 (JP); 3/17; 11/20/14, 3/27/14, 5/18/06, 2/23/06, 11/10/05, 9/15/05, 2/24/04, 2/5/02, 9/7/01 1/1/21; 8/15/18; 1/1/15, 7/1/14; 1/1/07, 7/1/06, 11/15/05

Section 9.0 New Discussion Items

Plain Language Summary:

<u>Background:</u> Clarify coding related to a type of brain inflammation where the body's immune system attacks healthy cells and tissues in the brain or spinal cord. People with this condition may have various neurologic and/or psychiatric symptoms. Left untreated, the illness can quickly become serious. It may lead to coma or permanent brain injury. In rare cases, it may cause death.

<u>Should OHP cover this treatment?</u> Staff recommends covering this treatment because the evidence shows benefit from the treatments.

Question: Where should autoimmune encephalitis be prioritized and what treatments should be paired?

Question source: EbGS

<u>Issue:</u> EbGS recently reviewed pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute-onset neuropsychiatric syndrome (PANS). Autoimmune encephalitis (AE) was initially included as part of this larger review. However, it became clear to EbGS and HERC staff that AE was a distinct and different diagnosis, with established diagnostic criteria and accepted treatment modalities. HERC staff was instructed to ensure that the diagnosis and appropriate treatments were in correct locations on the Prioritized List.

Autoimmune encephalitis refers to a group of conditions that occur when the body's immune system mistakenly attacks healthy brain cells, leading to inflammation of the brain. People with autoimmune encephalitis may have various neurologic and/or psychiatric symptoms. Autoimmune encephalitis may be associated with antibodies to proteins on the surface of nerve cells, or within nerve cells. Some of these proteins are involved in passing signals between nerve cells. In some cases, it occurs in association with cancer (a paraneoplastic syndrome). Left untreated, autoimmune encephalitis can lead to coma or permanent brain injury. In rare cases, it can be fatal.

Per the NIH (<u>https://rarediseases.info.nih.gov/diseases/11979/autoimmune-encephalitis</u>): Diagnosis of autoimmune encephalitis can be made when all three of the following criteria have been met:

1. Subacute onset (rapid progression of less than 3 months) of working memory deficits (short-term memory loss), altered mental status, or psychiatric symptoms

- 2. At least one of the following:
 - New focal CNS findings
 - Seizures not explained by a previously known seizure disorder
 - CSF pleocytosis (white blood cell count of more than five cells per mm3)
 - MRI features suggestive of encephalitis
- 3. Reasonable exclusion of alternative causes

Per expert guidelines, first line treatment of AE is intravenous immunoglobulins (IVIG), steroids and plasmapheresis. Second line treatment is rituximab or cyclophosphamide.

Current Prioritized List status

ICD-10-CM G04.81 (Other encephalitis and encephalomyelitis) is on the dysfunction lines (lines 71, 292, 345, 377) and line 536 VIRAL, SELF-LIMITING ENCEPHALITIS, MYELITIS AND ENCEPHALOMYELITIS.

Note 1: Subdiagnoses of this code include paraneoplastic encephalitis, limbic encephalitis and Bickerstaff encephalitis

Note 2: Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) is included under ICD-10-CM D89.89 (Other specified disorders involving the immune mechanism, not elsewhere classified)

CPT 90283 (Immune globulin (IgIV), human, for intravenous use) is Ancillary

CPT 36514 (Therapeutic apheresis; for plasma pheresis) is on lines 90,106,124,126,129,131,140,141, 148, 159, 175, 194, 212, 234, 285, 313, 339, 456

Expert guidelines

- 1) Abboud 2021, Best practice recommendations for diagnosis and management of autoimmune encephalitis
 - a. First line therapy: high dose corticosteroids (or IVIG or plasmapheresis [PLEX] if steroids are not preferred or contraindicated)
 - b. If there is no clinical, radiological or electrophysiological improvement by the end of the initial treatment cycle, add IVIG or PLEX. Consider IVIG first in agitated patients and in those with bleeding disorders. Consider PLEX first in patients with severe hyponatremia, high thromboembolic (or cancer) risk, and if there is associated brain or spinal demyelination.
 - c. Consider starting with a combination therapy of steroids/ IVIG or steroids/PLEX from the beginning (as opposed to sequentially) in patients with severe initial presentation (e.g., severe NMDAR-antibody presentation, new onset refractory status epilepticus, severe dysautonomia, etc.).
 - d. If there is no clinical or radiological improvement 2–4 weeks after completion of combined acute therapy, consider starting a second-line agent when the clinical suspicion is high and/or a clinically relevant antibody is present.
 - e. Consider rituximab in known or highly suspected antibody-mediated autoimmunity (e.g., NMDAR-antibody encephalitis) and consider cyclophosphamide in known or highly suspected cell-mediated autoimmunity (eg, classical paraneoplastic syndrome).
 - f. If no clear objective or subjective evidence of improvement with conventional secondline therapies, consider novel approaches such as tocilizumab or bortezomib although there is only minimal evidence to support their use.

HERC staff recommendation:

- 1) Add ICD-10-CM G04.81 (Other encephalitis and encephalomyelitis) to line 313 DISORDERS INVOLVING THE IMMUNE SYSTEM
 - a. Remove G04.81 from line 536 VIRAL, SELF-LIMITING ENCEPHALITIS, MYELITIS AND ENCEPHALOMYELITIS.
 - b. Will pair with plasmapheresis (CPT 36514) and will have medications such as IVIG and corticosteroids available as Ancillary
- 2) Modify the new guideline regarding PANDAS and PANS as shown below

GUIDELINE NOTE XXX PANDAS, PANS AND AUTOIMMUNE ENCEPHALITIS

Line 313

ICD-10-CM G04.81 (Other encephalitis and encephalomyelitis) is only included on this line for autoimmune encephalitis and related non-PANDAS/PANS conditions and is not included in this guideline. Autoimmune encephalitis must meet established diagnostic criteria (for example, the International Encephalitis Consortium 2013 diagnostic criteria).

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

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

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

A reevaluation at 3 months by both the primary care provider and pediatric expert is required for continued therapy of IVIG. This evaluation must include clinical testing with a validated instrument, which must be performed pretreatment and posttreatment to demonstrate clinically meaningful improvement. Long term antibiotic therapy is not included on this line for treatment of PANDAS/PANS. Therapeutic plasma exchange (CPT 36514) does not pair with PANDAS or PANS (ICD-10-CM D89.89 or D89.9).



Autoimmune encephalitis: proposed best practice recommendations for diagnosis and acute management

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ABSTRACT

Review

The objective of this paper is to evaluate available evidence for each step in autoimmune encephalitis management and provide expert opinion when evidence is lacking. The paper approaches autoimmune encephalitis as a broad category rather than focusing on individual antibody syndromes. Core authors from the Autoimmune Encephalitis Alliance Clinicians Network reviewed literature and developed the first draft. Where evidence was lacking or controversial, an electronic survey was distributed to all members to solicit individual responses. Sixty-eight members from 17 countries answered the survey. Corticosteroids alone or combined with other agents (intravenous IG or plasmapheresis) were selected as a first-line therapy by 84% of responders for patients with a general presentation, 74% for patients presenting with faciobrachial dystonic seizures, 63% for NMDAR-IgG encephalitis and 48.5% for classical paraneoplastic encephalitis. Half the responders indicated they would add a second-line agent only if there was no response to more than one first-line agent, 32% indicated adding a second-line agent if there was no response to one first-line agent, while only 15% indicated using a second-line agent in all patients. As for the preferred second-line agent, 80% of responders chose rituximab while only 10% chose cyclophosphamide in a clinical scenario with unknown antibodies. Detailed survey results are presented in the manuscript and a summary of the diagnostic and therapeutic recommendations is presented at the conclusion.

INTRODUCTION

Autoimmune encephalitis (AE) comprises a group of non-infectious immune-mediated inflammatory disorders of the brain parenchyma often involving the cortical or deep grey matter with or without involvement of the white matter, meninges or the spinal cord.^{1–4} The original description of AE was based on paraneoplastic conditions related to antibodies against intracellular onconeuronal antigens such asANNA-1/anti-Hu.5 6 These 'classical' antibodies are non-pathogenic but represent markers of T-cell-mediated immunity against the neoplasm with secondary response against the nervous system. In recent years, an increasing number of antibodies targeting neuronal surface or synaptic antigens have been recognised such as N-MethylD-Aspartate Receptor (NMDAR)-antibody and Leucine-richglioma inactivated (LGI1)-antibody.¹ Most of these surface antibodies have been shown to be likely pathogenic and are thought to mediate more immunotherapy-responsive forms of AE and have less association with tumours. Specific types of encephalitis can occur in the setting of antibodies against oligodendrocytes (eg, anti-myelin oligodendrocyte glycoprotein (MOG) brainstem encephalitis) or astrocytes (eg, anti-aquaporin-4 (AQP4) diencephalic encephalitis, anti-glial fibrillary acidic protein (GFAP) meningoencephalitis). In addition, some AE patients do not have any identifiable antibodies (seronegative) representing a disease category with novel, yet to be identified antibodies or T-cell mediated disease. Online supplemental appendix S1 contains a list of the commercially available neuronal autoantibodies (NAAs).

Recent epidemiological studies suggest that AE is possibly as common as infectious encephalitis with an estimated prevalence rate of 13.7/100 000.⁷ The rapidly advancing knowledge of new antibodies and their associated syndromes has created a new and growing field of autoimmune neurology.⁸ However, advances from the laboratory bench have not been paralleled by advancement in clinical practice, leading to a large knowledge gap and many unanswered questions regarding the acute and long-term management of AE. The heterogeneity of AE presentation and findings on ancillary testing hinder large-scale clinical trials and limit the quality of evidence behind AE management.

The objective of this paper is to evaluate available evidence for each step in AE management and

Clinical approach to the diagnosis of autoimmune encephalitis in the pediatric patient

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Abstract

Objective

Autoimmune encephalitis (AE) is an important and treatable cause of acute encephalitis. Diagnosis of AE in a developing child is challenging because of overlap in clinical presentations with other diseases and complexity of normal behavior changes. Existing diagnostic criteria for adult AE require modification to be applied to children, who differ from adults in their clinical presentations, paraclinical findings, autoantibody profiles, treatment response, and long-term outcomes.

Methods

A subcommittee of the Autoimmune Encephalitis International Working Group collaborated through conference calls and email correspondence to consider the pediatric-specific approach to AE. The subcommittee reviewed the literature of relevant AE studies and sought additional input from other expert clinicians and researchers.

Results

Existing consensus criteria for adult AE were refined for use in children. Provisional pediatric AE classification criteria and an algorithm to facilitate early diagnosis are proposed. There is also discussion about how to distinguish pediatric AE from conditions within the differential diagnosis.

Conclusions

Diagnosing AE is based on the combination of a clinical history consistent with pediatric AE and supportive diagnostic testing, which includes but is not dependent on antibody testing. The proposed criteria and algorithm require validation in prospective pediatric cohorts.

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Go to Neurology.org/NN for full disclosures. Funding information is provided at the end of the article.

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Plain Language Summary:

<u>Background:</u> The staff of the OHA Pharmacy and Therapeutics (P&T) committee requested that language related to drug treatment be removed from the guideline about inflammatory skin diseases. The current language is out of date and the P&T already has guidelines regarding use of these drugs.

<u>Should OHP change this guideline?</u> Staff recommends HERC delete the wording regarding medication use from this guideline.

<u>Question</u>: should the severe inflammatory skin disease guideline be modified to remove mentions of drug tiers?

Question source: Pharmacy and Therapeutics Committee (P&T) staff

<u>Issue</u>: P&T recently reviewed treatments for atopic dermatitis and updated their prior authorization (PA) criteria for targeted immune modulators. Some of the working in current GN21 is out of date and/or does not reflect the current state of the evidence for targeted immune modulators. P&T regularly reviews these medications and new medications are coming to market on a regular basis. P&T staff are requesting that the HERC remove wording regarding these drugs to prevent internal conflicts between the Prioritized List guideline and P&T PA criteria. PA criteria can and do change at more regular intervals than Prioritized Lists can be published.

Specific issues:

- 1) The current guideline uses the term "biologics" when the correct term currently is "targeted immune modulators (TIMs)."
- 2) In the guideline, atopic dermatitis has step therapy with oral immunomodulator therapy listed as second line therapy. Based on the P&T review, oral immunomodulator therapy is third line therapy for this condition. From the P&T report: "Current therapies for atopic dermatitis include a variety of pharmaceutical agents and treatment modalities, including orally administered products, topical creams, and subcutaneous injections. Older therapies such as azathioprine and cyclosporine are effective, but carry the risks of significant side effects (e.g., systemic immunosuppression)." P&T requested that failure of these more high risk medications be removed from the requirement of being failed prior to targeted immune modulators.
- 3) New medications are regularly being released
 - a. From P&T staff: "In the past year, 3 new TIMs received FDA-approval for AD [atopic dermatitis] management. A topical JAK inhibitor, ruxolitinib (OPZELURA) was approved in September 2021. A new injectable IL-13 antagonist, tralokinumab (ADBRY), was approved in December 2021. A new oral JAK inhibitor, abrocitinib (CIBINQO) was approved in January 2022. In addition, upadacitinib (RINVOQ), an oral JAK inhibitor originally approved for rheumatoid arthritis (RA), received expanded approval for AD management in January 2022. Additional TIMs currently under investigation for AD include the oral JAK inhibitor baricitinib (OLUMIANT), currently approved for RA treatment, and 2 new injectable IL-13 antagonists, lebrikizumab and nemolizuamb. Lastly, a novel neurokinin-1 receptor antagonist, tradipitant, is being studied for AD. In all the trials for these drugs, patients were either naïve to therapy, or had failed topical

Modifications to the Severe Inflammatory Skin Disease Guideline

corticosteroids or calcineurin inhibitors (e.g., tacrolimus). Oral immunosuppressants were not included as step therapy."

HERC staff recommendation:

1) Modify GN 21 as shown below

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

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

Inflammatory skin conditions included in this guideline are:

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

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

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

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

For severe psoriasis, first line agents include topical agents, phototherapy and methotrexate. Second line agents include other systemic agents and oral retinoids and should be limited to those who fail, or have contraindications to, or do not have access to first line agents. Biologics are included on this line only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.

For severe atopic dermatitis/eczema, first-line agents include topical moderate- to high-potency corticosteroids and narrowband UVB. Second line agents include topical calcineurin inhibitors (e.g. pimecrolimus, tacrolimus), topical phosphodiesterase (PDE)-4 inhibitors (e.g. crisaborole), and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, or oral corticosteroids). Use of the topical second line agents (e.g. calcineurin inhibitors and phosphodiesterase (PDE)-4 inhibitors) should be limited to those who fail or have contraindications to first line agents. Biologic agents are included on this line for atopic dermatitis only after failure of or contraindications to at least one agent from each of the following three classes: 1) moderate to high potency topical corticosteroids, 2) topical calcineurin inhibitors or topical phosphodiesterase (PDE)-4 inhibitors, and 3) oral immunomodulator therapy.

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

Plain Language Summary:

Background: This is a test used to decide colon cancer treatments.

<u>Should OHP cover this test?</u> Staff recommends OHP cover this test because this has become a standard test and is required for doctors to decide a treatment path in many cases.

Question: Should microsatellite instability analysis (MSI) be covered for patients with colon cancer?

Question source: Jeanne Savage, CCO medical director

<u>Issue</u>: Microsatellites, also known as Short Tandem Repeats (STRs) are small (1-6 base pairs) repeating stretches of DNA scattered throughout the entire genome and account for approximately 3 % of the human genome. Due to their repeated structure, microsatellites are prone to high mutation rate. Microsatellite instability (MSI) is a unique molecular alteration and hyper-mutable phenotype, which is the result of a defective DNA mismatch repair (MMR) system. The presence of MSI is found in sporadic colon, gastric, sporadic endometrial and the majority of other cancers. Approximately, 15-20 % of colorectal cancers display MSI. Determination of MSI status in CRC has prognostic and therapeutic implications. Microsatellite instability (MSI) analysis of colorectal cancers is clinically useful to identify patients with hereditary nonpolyposis colorectal cancer (HNPCC) caused by germline mutations of mismatch repair genes. MSI status may also predict cancer response/resistance to certain chemotherapies.

MSI was last reviewed as part of the 2015 coverage guidance on biomarkers for cancer. That coverage guidance concluded: "Evidence from multiple studies supports clinical validity, with added value beyond traditional prognostic factors, for MammaPrint[®], Oncotype DX Breast[®], KRAS mutation testing for lung cancer, BRAF mutation testing for CRC, KRAS mutation testing for CRC, and MSI for CRC for at least one outcome [risk of recurrence (RR), cancer-specific survival (CSS), or overall survival (OS)]." MSI was given a 1B rating for screening and prognostic value and a IIB rating for predictive value. The final recommendation of the coverage guidance was a weak recommendation against coverage. The CPT code for MSI was added to line 662/GN173 and an entry was included in the new guideline "Biomarkers Tests of Cancer Tissue" which read "Microsatellite instability (MSI) is included on the Services recommended for noncoverage table."

Dr. Savage is requesting a re-review of MSI coverage. Per Dr. Savage: "In order for oncologists to determine appropriate adjuvant treatment (Chemo or Immunotherapy) they need the testing and we require it for some medications."

Of note, MSI testing is included in multiple colon cancer testing panels, usually coded with generic CPT codes such as CPT 88342 (Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure).

Current Prioritized List status

On line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

CPT 81301 Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed

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.

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

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
81301	Microsatellite instability (MSI) for colorectal cancer	Unproven intervention	August, 2015

Expert recommendations

- 1) NCCN Guideline 1.2022 for Colon Cancer treatment
 - a. Microsatellite Instability or Mismatch Repair Testing
 - i. Universal MMR or MSI testing is recommended in all newly diagnosed patients with colon cancer.
 - b. MSI testing is included in the workup algorithms for all colon cancer and is a branchpoint in several chemotherapy algorithms and adjuvant treatment algorithms
 - c. Note: MMR and MSI testing use the same CPT code
 - d. "The panel recommends universal MMR or MSI testing for all patients with a personal history of colon or rectal cancer to identify individuals with Lynch syndrome, to inform use of immunotherapy in patients with metastatic disease, and to inform decisions for patients with stage II disease."

<u>Other payer policies</u>: All major insurers are covering MSI testing/CPT 81301 HERC staff summary

Since the 2015 coverage guidance review, MSI testing has become standard of care in colon cancer, and is required to determination of treatment pathway in many NCCN algorithms.

HERC staff wish to discuss whether coverage guidance on <u>Biomarkers Tests of Cancer Tissue for</u> <u>Prognosis and Potential Response to Treatment</u> from 2015 should be updated by EbGS or retired and testing decisions be made following NCCN guidelines.

HERC staff recommendation:

- Remove CPT 81301 (Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed) from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
 - a. Advise HSD to add CPT 81302 to the DIAGNOSTIC PROCEDURES file
- 2) Modify GN 148 as shown below
- 3) Remove the entry for CPT 81301 from GN 173

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.
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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.

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

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
81301	Microsatellite instability (MSI) for colorectal cancer	Unproven intervention	August, 2015

Plain Language Summary:

<u>Background</u>: Clarify treatment for adults who have a sideways curvature of the spine; current surgical coverage is only for persons under 20 years of age. A spine surgeon is asking for this to be changed.

<u>Should OHP cover this treatment?</u> Staff recommends covering this treatment because of good evidence of effectiveness of treating adolescent (the phase of life between childhood and adulthood) scoliosis of unknown origin into adulthood; other payers are covering this surgery for adults.

Question: Should the scoliosis guideline be modified to remove age as a criteria for surgical treatment?

Question source: Dr. Joseph Orina, OHSU neurosurgery

<u>Issue</u>: Scoliosis is a sideways curvature of the spine that most often is diagnosed in adolescents. Most cases of scoliosis are mild, but some curves worsen as children grow. Severe scoliosis can be disabling. Scoliosis is treated with back bracing, and when bracing is not effective, spinal fusion surgery.

The current scoliosis guideline restricts scoliosis surgery to age 20 and younger. This guideline was written by the Back Pain Taskforce and adopted in 2015. Dr. Orina is requesting that the age restriction be removed and that surgery coverage be based on clinical criteria.

From Dr. Orina:

As a spine surgeon, I am a member of the Scoliosis Research Society and multiple national spine organizations. I am also the Head of the Neurosurgery Spine Division at OHSU.

I have never heard of an arbitrary age cutoff for adolescent scoliosis, and certainly not 20 years of age. We make decisions on surgery based on the patient's symptoms, curve magnitude, curve progression, and failure of non-operative management.

Recommendations for treatment focus on the curve magnitude, patient symptoms, and evidence of curve progression not on age. It would make much more clinical sense to draft guidelines based on these criteria as Cigna has done. Aetna's cutoff of 25 years old is also not consistent with any national guidelines.

Criteria I would recommend for surgery:

- Patients with adolescent idiopathic scoliosis curve greater than 45 degrees
- Intractable pain and documented failure of non-operative management
- Patients with adolescent idiopathic scoliosis whose curves progress despite nonoperative management.

Current Prioritized List status: Line 361 SCOLIOSIS Treatment: MEDICAL AND SURGICAL THERAPY

GUIDELINE NOTE 41, SCOLIOSIS

Line 361

Non-surgical treatments of scoliosis (ICD-10-CM M41) are included on Line 361 when

- 1) the scoliosis is considered clinically significant, defined as curvature greater than or equal to 25 degrees, or
- 2) there is curvature with a documented rapid progression.

Surgical treatments of scoliosis are included on Line 361

- 1) only for children and adolescents (age 20 and younger) with
- 2) a spinal curvature of greater than 45 degrees

<u>Evidence</u>

- 1) Hresko 2013: review of idiopathic scoliosis in adolescents
 - a) Operative treatment is indicated when progressive scoliosis exceeds 45 degrees in patients with an immature skeleton or when progression or associated pain occurs after skeletal maturity
 - b) Ten years after initial surgery for idiopathic scoliosis, 3 to 10% of patients undergo subsequent surgery
 - c) The role of surgery is controversial in patients with a mature skeleton and a curvature greater than 50 degrees but without pain or appreciable progression.

Specialty guidelines

1) American Association of Neurological Surgeons

- a) Accessed April 20, 2022: <u>https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Scoliosis</u>
 - i) Surgery in children: Most experts would recommend surgery only when the spinal curve is greater than 40 degrees and there are signs of progression.
 - ii) In general, surgery in adults may be recommended when the spinal curve is greater than 50 degrees and the patient has nerve damage to their legs and/or is experiencing bowel or bladder symptoms.

Other payer policies:

- 1) Aetna 2021: Aetna considers surgery (e.g., spinal fusion with instrumentation and bone grafting) for the treatment of idiopathic scoliosis medically necessary for *any* of the following conditions:
 - a) Idiopathic scoliosis with curve greater than or equal to 40 degrees in an adolescent younger than age 18; *or*
 - b) Idiopathic scoliosis with curve greater than or equal to 50 degrees in a young adult age 18 to 25.
- 2) Cigna 2022
 - a) Single or multilevel lumbar fusion is considered medically necessary for idiopathic adolescent scoliosis over 40°

HERC staff summary

Idiopathic adolescent scoliosis may require surgical intervention age ages above 20 if there is a curve greater than or equal to 40 to 50 degrees with pain or other symptoms, based on expert opinion.

HERC staff recommendation

1) Modify GN 41 as shown below

GUIDELINE NOTE 41, SCOLIOSIS

Line 361

Non-surgical treatments of scoliosis (ICD-10-CM M41) are included on Line 361 when

- 1) the scoliosis is considered clinically significant, defined as curvature greater than or equal to 25 degrees, or
- 2) there is curvature with a documented rapid progression.

Surgical treatments of <u>adolescent idiopathic</u> scoliosis (<u>ICD-10-CM M41.1 family</u>) are included on Line 361 <u>only for</u>

1) only for children and adolescents (age 20 and younger) with

- 2) patients with documented failure of non-operative management; AND
- 3) a spinal curvature of greater than 45 degrees

Transluminal Dilation of Aqueous Outflow Canal

Plain Language Summary:

<u>Background:</u> A non-penetrating surgical technique for glaucoma. Last reviewed in 2010, a physician asked for the technique to be re-reviewed considering its improved evidence for treatment of a type of glaucoma called "open-angle" which leads to progressive eye damage and, if untreated, blindness.

<u>Should OHP cover this treatment?</u> Staff recommends covering this treatment because of the evidence of effectiveness and a good safety profile.

Question: Should transluminal dilation of aqueous outflow canal be moved to a covered line?

Question source: Dr. Max Kaiser, medical director, Samaritan Health Plans

<u>Issue</u>: Transluminal dilation of aqueous outflow canal (also known as canaloplasty) is a non-penetrating surgical technique for glaucoma which aims to restore the natural drainage of fluid from the eye. This procedure was last reviewed as a new CPT code in December, 2010. At that time, a NICE 2008 review found insufficient evidence of effectiveness, and the procedure was placed on the Excluded File. It was later moved to line 662/GN173. Dr. Kaiser is requesting re-review of this procedure as it appears to have improved evidence of effectiveness for treatment of open angle glaucoma.

Primary open-angle glaucoma is a chronic condition associated with elevated intraocular pressure. It leads to progressive damage to the optic nerve. Early stages are usually asymptomatic but as the condition progresses it causes visual impairment and, if untreated, blindness. Treatment is usually eye drops containing drugs that either reduce the production of aqueous humor [fluid inside the eye] or increase its drainage. Surgical procedures such as trabeculectomy [creating a new drainage pathway for aqueous fluid], drainage tubes, deep sclerectomy, viscocanalostomy, or laser trabeculoplasty may also be used.

Ab externo canaloplasty is a surgical technique that aims to reduce intraocular pressure by improving drainage of aqueous fluid from the eye. It is done under local or general anesthetic. A superficial hinged flap of sclera is made and a deeper flap excised, exposing the Schlemm's canal. An ultrasound imaging system is used to identify the canal and to visualize the surgical instruments when they are in the canal. A microcatheter with an illuminated tip is introduced into the canal and advanced around its entire circumference. As the catheter tip advances, viscoelastic fluid is injected into the canal to dilate it. When catheterization of the entire canal is complete a suture is tied to the tip of the microcatheter and it is withdrawn, pulling the suture into the canal. The suture is cut, tied in a loop encircling the inner wall of the canal and tightened. This widens the canal.

Current Prioritized List status

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

CPT **66174** Transluminal dilation of aqueous outflow canal; without retention of device or stent CPT **66175** Transluminal dilation of aqueous outflow canal; with retention of device or stent

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
66174-66175	Transluminal dilation of aqueous outflow canal	Insufficient evidence of effectiveness	<u>December,</u> <u>2010</u>

Trabeculectomy (CPT 66170) is on lines 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE and 336 RUBEOSIS AND OTHER DISORDERS OF THE IRIS. Trabeculectomy with previously scarring (CPT 66172) is only on line 139.

Open angle glaucoma is on line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE

Updated evidence review

- 1) **NICE 2017** Interventional procedure overview of ab externo canaloplasty for primary open-angle glaucoma <u>https://www.nice.org.uk/guidance/ipg591/evidence/overview-final-pdf-4597394077</u>
 - a. This IP overview is based on approximately 2,000 patients who had canaloplasty from 1 review, 2 randomized controlled trials, 3 retrospective comparative studies, 1 case series, 1 case report and 1 systematic review and meta-analysis
 - b. In a systematic review and meta-analysis of 1,498 eyes, comparing canaloplasty with trabeculectomy, there was no statistically significant difference between groups for complete success rates (maximum postoperative intraocular pressure [IOP] of 18 mmHg without medication) and qualified success rates (maximum IOP of 18 mmHg with or without medication) after the procedure.
 - c. In the systematic review and meta-analysis of 1,498 eyes, the mean IOP reduction was 9.94 mmHg (95% confidence interval [CI] 8.42 to 11.45) and was statistically significantly lower in the canaloplasty group (mean difference between groups −3.61, 95% CI −5.53 to −1.69 mmHg) at 1-year follow-up
 - d. In the systematic review and meta-analysis of 1,498 eyes, the mean reduction in antiglaucoma medication use was 2.11 (95% CI 1.80 to 2.42) 1 year after canaloplasty, and there was no statistically significant difference in medication reduction between groups (mean difference –0.37, 95% CI –0.83 to 0.08).
 - e. Safety
 - i. Intraocular pressure (IOP) of more than 30 mmHg after the procedure was reported in 2% to 9% of eyes in a review of 914 eyes treated by canaloplasty alone (n=777 eyes) or by canaloplasty with phacoemulsification (n=137 eyes) at a maximum of 36 months' follow-up.
 - ii. Hyphema (greater than 1 mm layered blood) was statistically significantly more frequent in the canaloplasty group than in the trabeculectomy group at 1-year follow-up, in a systematic review and meta-analysis of 1,498 eyes (odds ratio [OR] 9.24, 95% confidence interval [CI] 3.09 to 27.60)
 - iii. Hypotony was statistically significantly less frequent after canaloplasty than after trabeculectomy at 1-year follow-up, in the systematic review and meta-

analysis of 1,498 eyes (OR 0.32, 95% CI 0.13 to 0.80). The incidence of hypotony in the canaloplasty group was 9% (94/1091)

- 2) **Gabai 2019**, safety and efficacy of trabeculectomy vs nonpenetrating surgeries open-angle glaucoma: a meta-analysis
 - a. N=5 studies comparing trabeculectomy (TE) with canaloplasty (CP)
 i. 1 RCT and 4 observational studies
 - b. IOP-lowering capacity of TE was superior to CP (WMD =2.32 mm Hg, 95% CI: 0.55 to 4.82, I2=0.0%, P=0.610) at 6 months and CP (WMD =2.99 mm Hg, 95% CI: 1.31 to 4.67, I2=66.6%, P=0.018) at 12 months
 - c. Hypotony (OR = 2.7, 95% CI: 1.01 to 7.3), choroidals (OR = 19.6, 95% CI: 2.6 to 149.2), and shallow or flat anterior chamber (OR = 4.1, 95% CI: 0.4 to 37.3) were more associated with TE when compared with CP
 - d. The meta-analysis of glaucoma medications after TE and NPGSs showed a lower medications' number after TE when compared with CP (WMD = -0.38, 95% CI: -0.66 to-0.11, I2=0.00%, P=0.856)
 - e. Four studies comparing TE to CP found that best corrected visual acuity was not significantly different between the groups during follow-up
 - f. Conclusions: TE is more effective in reducing IOP. TE presents a higher risk of complications as compared with NPGS, except for hyphema

Other payer policies

- 1) NICE 2021
 - **a.** Current evidence on the safety and efficacy of ab externo canaloplasty for primary open-angle glaucoma is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
 - **b.** Ab externo canaloplasty for primary open-angle glaucoma should only be done by clinicians with specific training in the procedure.

2) BCBS 2022

- a. Canaloplasty may be considered medically necessary as a method to reduce intraocular pressure in patients with chronic primary open-angle glaucoma under the following conditions:
 - i. Medical therapy has failed to adequately control intraocular pressure, AND
 - ii. The patient is not a candidate for any other intraocular pressure–lowering procedure (e.g., trabeculectomy or glaucoma drainage implant) due to a high risk for complications.
- b. Canaloplasty is considered not medically necessary under all other conditions, including angle-closure glaucoma, due to a lack of peer-reviewed scientific literature demonstrating the efficacy of the procedure.

3) Aetna 2022

a. Aetna considers canaloplasty medically necessary for the treatment of primary openangle glaucoma (POAG), including normal-tension glaucoma, and for pseudoexfoliation glaucoma.

Expert input

Dr. Aiyin Chen, a glaucoma specialist at Casey Eye Institute, recommended addition of coverage for canaloplasty.

HERC staff summary

Canaloplasty appears to have similar or slightly inferior outcomes to trabeculectomy and appears to have a similar or better safety profile for treatment of open angle glaucoma.

HERC staff recommendation:

- Add CPT 66174 Transluminal dilation of aqueous outflow canal; without retention of device or stent and CPT 66175 Transluminal dilation of aqueous outflow canal; with retention of device or stent to line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
 - a. Remove CPT 66174 and 66175 from line 662
- 2) Remove the entry from 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
66174-66175	Transluminal dilation of aqueous	Insufficient evidence of	December,
	outflow canal	effectiveness	2010

Efficacy and Safety of Trabeculectomy Versus Nonpenetrating Surgeries in Open-angle Glaucoma: A Meta-analysis

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Purpose: The purpose of this study was to conduct a meta-analysis on the efficacy and safety of trabeculectomy (TE) and nonpenetrating glaucoma surgery (NPGS) techniques in patients with primary open-angle glaucoma, pseudoexfoliation glaucoma, pigmentary glaucoma, and normal-tension glaucoma.

Methods: All studies were identified by searching electronic sources (PubMed, Medline, Scopus, and Embase) until February 5, 2018. Primary outcome was mean intraocular pressure (IOP) reduction at 6, 12, and 24 months. Complications, number of antiglaucomatous medications, and visual outcomes were also evaluated.

Results: Twenty-one studies were included. Ten studies compared TE with deep sclerectomy (DS), 5 with viscocanalostomy (VC), 1 study with both DS and VC, and 5 with canaloplasty (CP). TE was superior to DS, VC, and CP in reducing IOP at 6 and 12 months, and to DS at 24 months. When comparing TE to VC and to CP at 24 months, there was no significant difference in IOP reduction. Hypotony, choroidals, anterior chamber shallowing or flattening, and cataract formation or progression were more associated with TE than with NPGSs. TE was more effective in reducing anti-glaucomatous medications than VC and CP.

Conclusions: TE is more effective in reducing IOP. TE presents a higher risk of complications as compared with NPGS, except for hyphema.

Key Words: deep sclerectomy, viscocanalostomy, canaloplasty, trabeculectomy

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DESCRIPTION OF THE DISEASE

Glaucomatous optic neuropathy, commonly referred to as glaucoma, represents a group of heterogeneous conditions characterized by progressive damage of the neuro-retinal fibers and progressive visual field restriction.^{1,2}

Its diagnosis relies on clinical findings that include optic disc excavation, corresponding to ganglionar cell loss with thinning of the retinal nerve fiber layer and the optic neural rim, and specific glaucomatous visual field defects. The 2 major types of glaucoma are open-angle glaucoma,

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where the iridocorneal angle is open, and angle-closure glaucoma (ACG). Primary open-angle glaucoma (POAG) is the most common form.³ Although most POAG patients exhibit high intraocular pressure (IOP), due to a hindered aqueous outflow through the trabecular meshwork, the disease can occur with normal IOP values, being diagnosed as normal-tension glaucoma (NTG). This particular form of POAG presents with cupped optic disc and/or glaucomatous visual field defects, absence of gonioscopic alterations, and normal IOP values.⁴

Open-angle glaucoma can also be a consequence of specific syndromes. Pseudoexfoliation syndrome (PEX) and pigment dispersion syndrome (PDS) are the causes of the 2 main forms of secondary open-angle glaucoma, pseudoexfoliation glaucoma (PEG), and pigmentary glaucoma (PG). In PEX, there is a gradual accumulation of proteic material (pseudoexfoliation material), deriving from basal membranes, on the anterior segment structures such as corneal endothelium, lens, zonular fibers, and trabecular meshwork.⁵ In PDS, pigment granules, coming from the iris epithelium, deposit on the same structures. In both cases, over a period of time, deposition of material on the trabecular meshwork leads to its dysfunction, with a subsequent IOP raise causing glaucomatous neuropathy.⁶

EPIDEMIOLOGY

According to a review on blindness causes conducted by the World Health Organization, glaucoma is the first cause of nonreversible blindness and the second overall, after cataract.⁷ A review by Vajaranant et al⁸ reported that women are at higher risk for ACG but that there is no clear sex predilection for open-angle glaucoma.

Glaucoma risk increases with age, and the prolonged survival expectancy will make its prevalence to grow in the near future, passing from an estimated number of 64.3 million in 2013 to 111.8 million in 2040.^{9–11}

POAG accounts for three quarters of all glaucomas,³ with higher prevalence in dark races but steeper increase with age in the white population.^{9,12,13} NTG accounts for 20% to 40% of POAG cases, whereas ~25% of all open-angle glaucomas are secondary to PEX. PEG can present either bilaterally or monolaterally, usually in elderly patients, with visual field defects already present at the time of diagnosis at least in 1 eye.^{12,14,15}

PDS is the most common nontraumatic cause of glaucoma in young adults, with an onset in the third to fourth decade, and a risk to develop glaucoma of 10% to 50% in patients with PDS.^{16–21} Male sex, black race, severe myopia, and Krükenberg spindles have been identified as possible risk factors.^{16–21}

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Section 10.0 Coverage Guidances

Health Evidence Review Commission (HERC) Coverage Guidance: High-Frequency Chest Wall Oscillation Devices

DRAFT for HERC meeting 8/11/2022

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 such therapies are not tolerated, contraindicated, not effective, or not available (for example, inability of a caregiver to perform chest physiotherapy).

High-frequency chest wall oscillation devices are recommended for coverage for patients with noncystic fibrosis bronchiectasis (*weak recommendation*) when the 3 criteria below are met:

- A) The bronchiectasis is confirmed by computed tomography (CT) scan, AND
- B) 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
- C) The patient has received mucolytics and less costly airway clearance treatments (for example, chest physiotherapy, positive expiratory pressure therapy, self-management techniques) OR such therapies are not tolerated, contraindicated, not effective, or not available (for example, 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 such therapies are not tolerated, contraindicated, not effective, or not available (for example, 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.



Table of Contents

Coverage Guidance: High-Frequency Chest Wall Oscillation Devices1
Rationale for development of coverage guidances and multisector intervention reports
GRADE Tables5
Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with cystic fibrosis?
Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with non–cystic fibrosis bronchiectasis?
Should high-frequency chest wall oscillation devices be recommended for coverage for children and adults with chronic obstructive pulmonary disease?
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?13
Background
Indications17
Technology Description
Evidence Review
Cystic Fibrosis
Bronchiectasis
COPD
Pulmonary Complications from Neuromuscular Disease22
Harms of HFCWO Devices
Comparative Cost Effectiveness of HFCWO Devices
Ongoing Studies for HFCWO Devices24
Evidence Summary
Policy Landscape
Payer Coverage Policies
Evidence-based Guidelines and Recommendations
Recommendations and Guidelines from Professional Societies
Recommendations From Advocacy Organizations
References
Appendix A. GRADE Table Element Descriptions
Appendix B. GRADE Evidence Profile
Appendix C. Methods
Appendix D. Applicable Codes

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	Compared to chest physiotherapy:	Coverage of high-	Patients may prefer	Some patients may
(Critical outcome)	No significant difference in mean days of	frequency chest wall	treatment options	not be able to
	hospitalization (mean difference, -0.20; 95% Cl, -	oscillation would add	that can be self-	tolerate chest
	2.32 to 1.92; <i>P</i> > .05).	significant cost	administered,	physiotherapy or
	● ○ (very low confidence, based on 1 RCT,	compared to chest	confer greater	positive expiratory
	n = 50)	physiotherapy or	independence, and	pressure devices.
Mortality	No evidence	positive expiratory	ensure reliable and	
(Critical outcome)		pressure devices.		

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

Outcomes	Estimate of Effect for Outcome/	Resource Allocation	values and	Other
	Confidence in Estimate		Preferences	Considerations
Pulmonary	Mixed results	However, in situations	consistent	Some patients may
Exacerbations	Compared to positive expiratory pressure:	in which chest	treatment.	not have caregivers
Requiring	Significantly more exacerbations requiring	physiotherapy is not		who are available or
Antibiotics	antibiotics (median, 2.0; interquartile range, 1.0 to	consistently available		physically able to
(Important	3.0) than the positive expiratory pressure therapy	or tolerated and		administer daily
outcome)	group (median, 1.14; interquartile range, 0.0 to	positive expiratory		chest
	2.0; odds ratio, 4.10; 95% CI, 1.42 to 11.84; P =	pressure devices are		physiotherapy.
	.007)	not effective or		
		tolerated, the		
	No significant difference when limited to IV	additional cost of the		
	antibiotics (OR, 2.36; 95% Cl, 0.81 to 6.94)	high-frequency chest		
	●○○ (very low confidence, based on 1 RCT,	wall oscillation device		
	n = 107)	would be offset to the		
	Compared to chest physiotherapy:	extent that it reduces		
	No significant difference in time to nulmonary	hospitalizations and		
	exacerbation requiring antibiotics ($P > .05$).	exacerbations.		
	• • • (very low confidence, based on 1 RCT,	Chest physiotherapy		
	n = 115)	must be provided by a		
	Compared to other and an outernal assillatory	trained caregiver for 20		
	devices:	to 40 minutes, one or		
	<u>No significant difference</u>	more times per day;		
	• · · · · · · · · · · · · · · · · · · ·	could be provided by a		
	n = 16	paid or unpaid		
Exercise Canacity	No evidence	caregiver.		
(Important				
outcome)				
Exercise Capacity (Important outcome)	2.0; odds ratio, 4.10; 95% Cl, 1.42 to 11.84; $P = .007$) No significant difference when limited to IV antibiotics (OR, 2.36; 95% Cl, 0.81 to 6.94) •••• (very low confidence, based on 1 RCT, n = 107) <u>Compared to chest physiotherapy</u> : No significant difference in time to pulmonary exacerbation requiring antibiotics ($P > .05$). ••• (very low confidence, based on 1 RCT, n = 115) <u>Compared to other oral or external oscillatory</u> <u>devices</u> : No significant difference ••• (very low confidence, based on 1 RCT, n = 16) No evidence	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. 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.		priysiotnerapy.

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
Breathlessness or	No evidence			
Cough				
(Important				
outcome)				

Balance of benefits and harms: Based on very low-confidence evidence, high-frequency chest wall oscillation devices have similar outcomes to chest physiotherapy for reducing hospitalizations. There is mixed evidence compared to positive expiratory pressure, chest physiotherapy, and other oscillating devices for reducing exacerbations in patients with cystic fibrosis. There are few device-related harms found for high-frequency chest wall oscillation devices.

Rationale: High-frequency chest wall oscillation devices are not inferior to other alternatives based on very low certainty evidence, and have a low rate of device-related harms, but much higher cost. However, we recommend coverage because some patients may need other treatment options and due to the small size of the population affected. The recommendation is weak because of the very 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/	Resource Allocation	Values and	Other
	Confidence in Estimate		Preferences	Considerations
Hospitalizations	No evidence	Coverage of high-	Patients may	Appointed expert
(Critical outcome)		frequency chest wall	prefer	opinion
Mortality	No evidence	oscillation would	treatment	supported
(Critical outcome)		add significant cost	options that can	coverage of high-
Pulmonary	Respin11 HFCWO device compared to standard	compared to chest	be self-	frequency chest
Exacerbations	pharmacological therapy alone:	physiotherapy or	administered,	wall oscillation
Requiring	Significantly fewer exacerbations over 12 months on	positive expiratory	confer greater	devices for
Antibiotics	average for 1 group that used high-frequency chest wall	pressure devices.	independence,	bronchiectasis,
(Important	oscillation devices:	However, in	and ensure	due to the
outcome)	• Respin11 group (mean, 0.52 exacerbations; SD, 0.14)	situations in which	reliable and	pathophysiologic
	Pharmacological therapy with other device-delivered	cnest physiotherapy	consistent	similarities of this
	interventions (mean, 0.96 exacerbations; SD, 0.40)	is not consistently	treatment.	condition to
	• Between-group difference, <i>P</i> < .001	available of		Cystic fibrosis
		tolerated and		bronchiectasis,
	Smartvest AFCWO device compared to standard	positive expiratory		there is evidence
	pharmacological therapy alone.	pressure devices are		of chronic
	did not have significantly fewer exacerbations when	tolerated the		infection
	compared to the group that received standard	additional cost of		intection.
	nharmacological therapy	the high-frequency		
	SmartVest group (mean not reported: SD not	chest wall oscillation		
	 Smartvest group (mean, not reported, 3D, not reported) 	device would be		
	 Pharmacological therapy with other device-delivered 	offset to the extent		
	interventions (mean 0.96 exacerbations: SD 0.40)	that it reduces		
	• Between-group difference $P > 05$	hospitalizations and		
	• Detween-group unterence, r > .05	exacerbations.		
	● ○ (very low confidence, based on 1 RCT, n = 42)			

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/	Resource Allocation	Values and Preferences	Other Considerations
Exercise Capacity (Important outcome) Breathlessness or	No evidence Compared to chest physiotherapy:		Treferences	
Cough (Important outcome)	Significant reduction in symptoms as measured by the 12- point Breathlessness Cough Sputum Score scale (mean difference, -5.8; 95% Cl, -7.21 to -4.39; N = 20; P < .05) • • • (very low confidence, based on 1 RCT, n = 20)			
	 <u>Respin11 HFCWO device compared to standard</u> <u>pharmacological therapy alone</u>: 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) 			
	 <u>SmartVest HFCWO device compared to standard</u> <u>pharmacological therapy alone</u>: 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) 			

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
	 Pharmacological therapy with other device-delivered interventions group (mean at 12 months postbaseline, 6.1; SD, not reported) Between-group difference, P > .05 (very low confidence, based on 1 RCT, n = 42) 			

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 device-related 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 3 criteria below are met:

- A) The bronchiectasis is confirmed by computed tomography (CT) scan, AND
- B) 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
- C) The patient has received mucolytics and less costly airway clearance treatments (for example, chest physiotherapy, positive expiratory pressure therapy, self-management techniques) OR such therapies are not tolerated, contraindicated, not effective, or not available (for example, 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/	Resource Allocation	Values and Preferences	Other Considerations
Outcomes Hospitalizations (Critical outcome) Mortality (Critical outcome) Pulmonary Exacerbations Requiring Antibiotics (Important outcome) Exercise Capacity (Important outcome) Breathlessness or Cough (Important outcome)	Estimate of Effect for Outcome/ Confidence in Estimate No evidence No evidence No evidence No evidence No evidence 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)	Resource Allocation 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.	Values and Preferences Patients may prefer treatment options that can be self- administered, confer greater independence, and ensure reliable and consistent treatment.	Other Considerations Appointed expert did not recommend high-frequency chest wall oscillation devices for this population.
	 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 device-related 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/	Resource Allocation	Values and	Other
Outcomes Hospitalizations (Critical outcome) Mortality (Critical outcome) Pulmonary Exacerbations Requiring Antibiotics (Important outcome)	Estimate of Effect for Outcome/ Confidence in Estimate 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; $P > .05$) ••••••••••••••••••••••••••••••••••••	Resource Allocation 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	Values and Preferences 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	Other Considerations 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
Exercise Capacity (Important	 device group (2/7; P > .05) (very low confidence, based on 1 RCT, n = 14) No evidence 	additional cost of the high-frequency chest wall oscillation device would be offset to	condition.	(defined as persistent culture positivity of organisms known to
outcomer				

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 $\bullet \circ \circ$ (very low confidence, based on 1 RCT, $n = 35$)	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 device-related 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.

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
Recommendation: High-frequency chest wall oscillation devices are recommended for coverage for patients with neuromuscular disease resulting in chronic lung disease (<i>weak recommendation</i>) when there is evidence of chronic lung infection, despite either:				
a) having received chest physiotherapy and positive expiratory pressure therapy, OR				
 b) documentation that such therapies are not tolerated, contraindicated, not effective, or not available (for example, 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 claimsdata 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 selfadministered.⁶
- Positive expiratory pressure devices
 - o 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.

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

Table 1. HFCWO Device Descriptions

Device Name FDA Approval Date	Manufacturer	Features	Indications
SmartVest SQL System ⁹ December 19, 2013 ¹⁰	Electromed	 Portable Wearable & 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 	 Bronchiectasis COPD Cystic fibrosis Neuromuscular conditions Emphysema
InCourage Vest ¹⁵ June 17, 2005 ¹⁶	Philips, via RespirTech	 state 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 RCT²² 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, 1.14; interquartile range, 0.0 to 2.0; Odds Ratio [OR] 4.10; 95% Cl, 1.42 to 11.84; P = .007).⁶ However, this result was no longer significant when limited to exacerbations requiring treatment with intravenous antibiotics (OR, 2.36; 95% Cl, 0.81 to 6.94, P > .05).⁶

Two RCTs compared HFCWO devices to conventional physiotherapy for patients with cystic fibrosis. In 1 RCT (N = 50) of patients with cystic fibrosis admitted to a hospital for an acute exacerbation, there was no significant difference between the study groups for days of hospitalization (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 The second RCT (N = 115) reported no

significant between-group difference in time to pulmonary exacerbations requiring antibiotics in children, adolescents, and adults with cystic fibrosis.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 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% Cl, -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% Cl, -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 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

22 | High-Frequency Chest Wall Oscillation Devices DRAFT for 8/11/2022 HERC meeting materials

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 device-related 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.

Device Name FDA Approval Date	Manufacturer	Adverse Event(s)
Frequencer V2 and V2x ⁷	Dymedso	No records
January 26, 2011 ⁸		
SmartVest SQL System ⁹	Electromed	No records
December 19, 2013 ¹⁰		
The Vest Airway Clearance System Model 105 ¹¹	Hill-Rom	No records
Cohrugny 21, 2002 ¹²		
repruary 21, 2003		
Respin11 ¹³	RespInnovation	No records
July 13, 2012 ¹⁴	SAS	
InCourage Vest ¹⁵	Philips, via	 8 reports identified classified under injury event type
June 17, 2005 ¹⁶	RespirTech	 Rib bone fractures in 3 different patients
		\circ 1 electromagnetic interference problem with a
		pacemaker
		o 1 hematoma
		o 1 pneumothorax
		 1 pressure problem with co-occurring mastitis
AffloVest ¹⁷	International	• 1 report identified
March 27, 2013 ¹²	Biophysics	Fractured ribs
,	Corporation	

Table 2. Adverse Events Reported in MAUDE by HFCWO Device

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 pulmonary exacerbations and quality of life.²⁵ The anticipated study completion date was November 2020.²⁵

Evidence Summary

For patients with cystic fibrosis, we have very low confidence that HCWFO device therapy is equivalent to conventional chest physiotherapy for reducing hospitalizations. There is mixed evidence for

24 | High-Frequency Chest Wall Oscillation Devices

DRAFT for 8/11/2022 HERC meeting materials

prevention of exacerbations requiring antibiotics compared to positive expiratory pressure, conventional chest physiotherapy, and other oscillating devices. 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 device-related 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 necessity²⁸:

- 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 necessity²⁹:

- 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 necessity³⁰:

- 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 necessity³¹:

- 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 devices³²:

- 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 inperson 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 suggestions³⁶:

- 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 populations³⁷:

- 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

References

- 1. Rogers DF, Barnes PJ. Treatment of airway mucus hypersecretion. *Ann Med.* 2006;38(2):116-125. doi: 10.1080/07853890600585795.
- 2. Centers for Disease Control and Prevention. Chronic obstructive pulmonary disease (COPD). 2021; https://www.cdc.gov/copd/index.html. Accessed May 3, 2021.
- Centers for Disease Control and Prevention. Cystic fibrosis. 2021; https://www.cdc.gov/genomics/disease/cystic_fibrosis.htm. Accessed May 3, 2021.
- 4. Weycker D, Hansen GL, Seifer FD. Prevalence and incidence of noncystic fibrosis bronchiectasis among US adults in 2013. *Chron Respir Dis.* 2017;14(4):377-384. doi: 10.1177/1479972317709649.
- 5. Konstan M, Berger M. Current understanding of the inflammatory process in cystic fibrosis: onset and etiology. *Pediatr Pulmonol.* 1997;24(2):137-142.
- 6. Morrison L, Milroy S. Oscillating devices for airway clearance in people with cystic fibrosis. *The Cochrane database of systematic reviews.* 2020;4:CD006842. doi: https://dx.doi.org/10.1002/14651858.CD006842.pub5.
- 7. Dymedso. Frequencer. 2021; https://dymedso.com/frequencer/. Accessed April 21, 2021.
- 8. US Food and Drug Administration. Dymedso Frequencer V2 and Frequencer V2x airway clearance device. 2011; https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103176.pdf. Accessed April 22, 2021.
- 9. Electromed Inc. The smart shoice for HFCWO therapy. 2021; https://smartvest.com/smartchoice-for-hfcwo-therapy/?gclid=EAIaIQobChMIz92Cqb-K7gIV2zizAB01yAGgEAAYASAAEgJoaPD_BwE. Accessed April 21, 2021.
- 10. US Food and Drug Administration. Special 510(k) summary. 2013; https://www.accessdata.fda.gov/cdrh_docs/pdf13/K132794.pdf. Accessed April 22, 2021.
- 11. Hill-Rom Inc. The Vest airway clearance system, model 105. 2021. Accessed April 21, 2021.
- 12. US Food and Drug Administration. 510(k) summary of safety and effetiveness. 2013; https://www.accessdata.fda.gov/cdrh_docs/pdf12/K122480.pdf. Accessed April 22, 2021.
- 13. respInnovation. RespIn 11 bronical clearance system. 2021; http://respin11.com/index.php/respin/respin-11. Accessed April 21, 2021.
- 14. US Food and Drug Administration. Premarket notification 510(k). 2012; https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121170.pdf. Accessed April 22, 2021.
- 15. Philips, RespirTech. InCourage system airway clearance device. 2021; https://www.usa.philips.com/healthcare/product/HC500055/incourage-system-airwayclearance-device. Accessed April 22, 2021.
- 16. US Food and Drug Administration. 510(k) summary of safety and effectiveness. 2005; https://www.accessdata.fda.gov/cdrh_docs/pdf5/K051383.pdf. Accessed April 22, 2021.
- 17. International Biophysics Corportation. AffloVest mobile mechanial HFCWO vest therapy. 2020; https://www.afflovest.com/. Accessed Aprik 22, 2021.
- 18. Lee AL, Burge AT, Holland AE. Airway clearance techniques for bronchiectasis. *Cochrane Database Syst Revs.* 2015(11):CD008351. doi: 10.1002/14651858.CD008351.pub3.
- 19. Nicolini A, Grecchi B, Banfi P. Effectiveness of two high frequency chest wall oscillation techniques in patients with bronchiectasis: a randomized controlled preliminary study. *Panminerva Med.* 2020. doi: 10.23736/S0031-0808.20.03735-0.
- 20. Nicolini A, Grecchi B, Ferrari-Bravo M, Barlascini C. Safety and effectiveness of the highfrequency chest wall oscillation vs intrapulmonary percussive ventilation in patients with severe COPD. *International journal of chronic obstructive pulmonary disease*. 2018;13:617-625. doi: 10.2147/COPD.S145440.
- 31 | High-Frequency Chest Wall Oscillation Devices

- 21. Lange DJ, Lechtzin N, Davey C, et al. High-frequency chest wall oscillation in ALS: an exploratory randomized, controlled trial. *Neurology*. 2006;67(6):991-997.
- 22. Clinical Trials Registry. Clinical effectiveness of high frequency chest wall oscillation (HFCWO) in a bronchiectasis population. 2021; https://clinicaltrials.gov/ct2/show/NCT04271969. Accessed April 23, 2021.
- 23. 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.
- 24. McIlwaine MP, Alarie N, Davidson GF, et al. Long-term multicentre randomised controlled study of high frequency chest wall oscillation versus positive expiratory pressure mask in cystic fibrosis. *Thorax.* 2013;68(8):746-751. doi: 10.1136/thoraxjnl-2012-202915.
- 25. Clinical Trials Registry. A pilot study to evaluate the use of the Vest system for treatment of bronchiectasis patients in the home setting. 2020; https://clinicaltrials.gov/ct2/show/NCT04017312. Accessed April 23, 2021.
- 26. Washington Apple Health (Medicaid). Respiratory care billing guide. 2019; https://www.hca.wa.gov/assets/billers-and-providers/Respiratory-care-bi-20190101.pdf.
- 27. Washington Health Care Authority. Provider billing guides and fee schedules. 2021; https://www.hca.wa.gov/billers-providers-partners/prior-authorization-claims-andbilling/provider-billing-guides-and-fee-schedules. Accessed April 30, 2021.
- 28. Centers for Medicare & Medicaid Services. Local coverage determination: high frequency chest wall oscillation devices (L33785). 2020; https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33785. Accessed Arpil 22, 2021.
- 29. Aetna. Chest physiotheray and airway clearance devices. 2021; http://www.aetna.com/cpb/medical/data/1_99/0067.html. Accessed April 22, 2021.
- 30. Cigna. Airway clearance devices in the ambulatory setting. 2021; https://chk.static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_Future/mm_0069_ coveragepositioncriteria_airway_clearance_devices.pdf. Accessed April 22, 2021.
- 31. Moda. High frequency chest wall oscillation devices (HFCWO). 2021; https://www.modahealth.com/pdfs/med_criteria/HighFrequencyChestWallOscillationDevices.p df. Accessed April 22, 2021.
- 32. Regence BlueCross BlueShield. Oscillatory devices for the treatment of cystic fibrosis and other respiratory conditions. 2020; http://blue.regence.com/trgmedpol/dme/dme45.pdf. Accessed April 22, 2021.
- 33. National Institute for Health and Care Excellence. Cystic fibrosis: diagnosis and management NG78. 2017; https://www.nice.org.uk/guidance/ng78/chapter/Recommendations#pulmonary-monitoring-assessment-and-management. Accessed April 30, 2021.
- 34. Polverino E, Goeminne PC, McDonnell MJ, et al. European Respiratory Society guidelines for the management of adult bronchiectasis. *Eur Respir J.* 2017;50(3). doi: 10.1183/13993003.00629-2017.
- Chatwin M, Toussaint M, Goncalves MR, et al. Airway clearance techniques in neuromuscular disorders: a state of the art review. *Respir Med.* 2018;136:98-110. doi: 10.1016/j.rmed.2018.01.012.
- 36. Hill AT, Barker AF, Bolser DC, et al. Treating cough due to non-CF and CF bronchiectasis with nonpharmacological airway clearance: CHEST expert panel report. *Chest.* 2018;153(4):986-993. doi: 10.1016/j.chest.2018.01.014.
- Strickland SL, Rubin BK, Drescher GS, et al. AARC clinical practice guideline: effectiveness of nonpharmacologic airway clearance therapies in hospitalized patients. *Respir Care*. 2013;58(12):2187-2193. doi: 10.4187/respcare.02925.
- **32** | High-Frequency Chest Wall Oscillation Devices

- 38. Qaseem A, Wilt T, Weinberger S, et al. Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline update from the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society. *Ann Intern Med.* 2011;155:179-191. doi: 10.7326/0003-4819-155-3-201108020-00008.
- 39. American Lung Association. Treating COPD. 2021; https://www.lung.org/lung-healthdiseases/lung-disease-lookup/copd/treating. Accessed April 30, 2021.
- 40. American Lung Association. Treating and managing bronchiectasis. 2021; https://www.lung.org/lung-health-diseases/lung-disease-lookup/bronchiectasis/treating-andmanaging. Accessed April 30, 2021.
- 41. American Lung Association. Treating and managing cystic fibrosis. 2021; https://www.lung.org/lung-health-diseases/lung-disease-lookup/cystic-fibrosis/treating-and-managing. Accessed April 30, 2021.
- 42. O'Conner M, O'Sullivan B, Cystic Fibrosis Foundation. Cystic fibrosis airway clearance therapies clinical care guidelines. 2019; https://www.cff.org/Care/Clinical-Care-Guidelines/Respiratory-Clinical-Care-Guidelines/CF-Airway-Clearance-Therapies-Clinical-Care-Guidelines/. Accessed April 19, 2021.
- 43. Flume PA, Robinson KA, O'Sullivan BP, et al. Cystic fibrosis pulmonary guidelines: airway clearance therapies. Respir Care. 2009;54(4):522-537.
- 44. Yuan N, Kane P, Shelton K, Matel J, Becker BC, Moss RB. Safety, tolerability, and efficacy of highfrequency 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. doi: https://dx.doi.org/10.1177/0883073809350223.

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The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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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.
Certainty Assessment (Confidence in Estimate of Effect) for Cystic Fibrosis No. of Study **Risk of** Other Inconsistency Indirectness Imprecision Certainty **Studies** Design(s) Bias Factors Hospitalizations 1 RCT Small Serious Not serious Serious Serious Very low samples, •000 short follow-up Mortality 0 **Pulmonary Exacerbations Requiring Antibiotics** 3 RCTs Serious Not serious Serious Serious Small Very low samples, •000 short follow-up **Exercise Capacity** 0 **Breathlessness or Cough**

Appendix B. GRADE Evidence Profile

Abbreviation. RCT: randomized controlled trial.

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Certainty Assessment (Confidence in Estimate of Effect) for Bronchiectasis							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Certainty
Hospitali	zations						
0							
Mortality	1						
0							
Pulmona	ry Exacerbatio	ons Requirin	g Antibiotics				
1	RCT	Serious	Unable to rate	Not serious	Serious		Very low
			(single study)				●000
Exercise	Capacity						
0							
Breathlessness or Cough							
1	RCT	Serious	Unable to rate	Not serious	Serious		Very low
			(single study)				•000

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
Hospitali	zations						
0							
Mortality	1						
0							
Pulmona	ry Exacerbat	ions Requiring	g 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.

Certain	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
Hospitali	zations			•	•		
0							
Mortality							
0							
Pulmona	ry Exacerbatio	ons Requiring	g Antibiotics				
0							
Exercise	Exercise Capacity						
0							
Breathles	Breathlessness or Cough						
1	RCT	Serious	Unable to rate	Serious	Serious	Small	Very low
			(single study)			sample,	● ○○○
						short	
						follow-up	

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?

40 | High-Frequency Chest Wall Oscillation Devices

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 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					
47025	High frequency chest wall oscillation system vest, replacement for use with				
A7025	patient owned equipment, each				
A7026	High frequency chest wall oscillation system hose, replacement for use with				
A7020	patient owned equipment, each				
	Home ventilator, multi-function respiratory device, also performs any or all of the additional				
E0467	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				
СРТ					
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-	Drimary disorders of muscles				
G71.1	Filling 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.

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

Question source: EbGS

<u>Issue</u>: EbGS re-assessed and modified a coverage guidance regarding High-Frequency Chest Wall Oscillation Devices at their June 2, 2022 meeting. The "blue box" wording was modified at that meeting. Base don previous discussion at VBBS and HERC, the December 2021 "blue box" wording was modified to remove coverage for non-cystic fibrosis bronchiectasis based on the low level of supporting evidence. Based on expert comment and testimony, EbGS has proposed re-adding coverage for non-cystic fibrosis bronchiectasis in certain clinical situations.

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).

<u>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:</u>

- A) <u>The bronchiectasis is confirmed by computed tomography (CT) scan, AND</u>
- B) 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
- C) <u>The patient has received chest physiotherapy and positive expiratory pressure therapy OR such</u> <u>therapies are not tolerated, contraindicated, not effective, or not available (for example,</u> <u>inability of a caregiver to perform chest physiotherapy).</u>

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
A 7025	High frequency chest wall oscillation system vest,	Never reviewed
A7025	replacement for use with patient owned equipment, each	
17026	High frequency chest wall oscillation system hose,	Never reviewed
A7026	replacement for use with patient owned equipment, each	
50402	High frequency chest wall oscillation system, includes all	Never reviewed
EU465	accessories and supplies, each	
СРТ		Placement
		502 CONDITIONS FOR WHICH
94669	Mechanical chest wall oscillation to facilitate lung	INTERVENTIONS RESULT IN
	function, per session	MARGINAL CLINICAL BENEFIT
		OR LOW COST-EFFECTIVENESS

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

HERC staff recommendations:

 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 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), and 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) receiving 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 all 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

Coverage Guidance – High-Frequency Chest Wall Oscillation Devices

- C) The patient has neuromuscular disease resulting in chronic lung disease when there is evidence of chronic lung infection, despite either:
 - 1) receiving 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).

Table of Contents

Discussion Table		
Commenters		
Public Comments		3
References Provided by Commenters		16
References Provided by commenters	•••••••••••••••••••••••••••••••••••••••	

Discussion Table

IDs/#s	Summary of Issue	Subcommittee Response
A3, A4, A6,	Evidence not included in this review shows	Most of the data submitted from commenters were not published in peer-reviewed
В2—В8,	effectiveness of HFCWO for COPD, bronchiectasis,	journals (e.g., posters and conference abstracts) or used noncomparative before-after
C3–C6, C8	neuromuscular disease, and cystic fibrosis.	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,	The state of the evidence for HFCWO therapy is	Although observational before-and-after studies (like those submitted by commenters),
C3	sparse given the rare diseases it treats, lack of	do appear to show benefit, the study designs do not permit us to determine whether
	consensus on study endpoints, and inability to use	the effect was caused by HFCWO devices; these study designs cannot control for
	blinding. Lower-quality evidence obtained from real-	confounding factors. More robust study designs exist, such as the randomized trial, or if
	world data (claims databases) shows this therapy is	that is not feasible, a matched-cohort or interrupted-time-series study.
effective and cost-effective. This lower-quality evidence should be considered, and coverage should be recommended for other conditions.		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.



Commenters

Identification	Stakeholder
A	David Chandler, Senior Director of Payer Relations at American Association for Homecare [Submitted July 2, 2021]
В	Gary Hansen, Director of Scientific Affairs at RespirTech [Submitted June 29, 2021]
С	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,	Thank you for your comments. We have written specific
	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.	responses to individual sections of your letter in the rows that follow.
	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	



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	Our background section acknowledges HFCWO device
	patients for decades and is considered the standard of care for cystic fibrosis	therapy is a commonly used treatment option for cystic
	patients with an estimated 76% of the US CF population using the therapy for	fibrosis.
	airway clearance, according to the 2019 CF Foundation Patient Registry Annual Data	
	Report.	
A3	2) Respiratory complications are the leading cause of morbidity and mortality for	Our review found insufficient evidence that HFCWO device
	patients with NMD, and HFCWO has been shown to reduce these complications.	therapy reduces exacerbations and hospitalizations for
	Some NMD patients are not able to tolerate manual CPT or be put in all of the	conditions other than cystic fibrosis.
	required positions to receive the treatment.	
A4	3) For patients with non-cystic fibrosis bronchiectasis, HFCWO therapy reduces the	For bronchiectasis, our review found very-low-confidence
	frequency of acute exacerbations, hospitalizations, antibiotic use and costs.	evidence that HFCWO device therapy improves key
		outcomes.
A5	4) Medicare, most state Medicaid programs, and nearly all commercial payers,	Our policy is to report coverage for Medicare,
	provide HFCWO coverage for CF, NMD and bronchiectasis patients.	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.	We identified the meta-analysis that you refer to (Daynes
	According to a recent meta-analysis across 18 studies of airway clearance devices,	et al., 2021). The single included study of HFCWO devices
	future exacerbations were reduced by 50%. In addition, analysis of real-world data	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.,
A7 A8	 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. 7) It is in the best interest of the patient to give physicians access to all therapies 	2020), and is ineligible for inclusion. 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. Thank you for your comment.
A9	 and devices to address specific patient needs. 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.
Β1	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
	 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. 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. 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.
В4	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.
Β7	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,	Thank you for your comments. We have written responses
	Hillrom appreciates the opportunity to provide comment on the coverage	to specific individual sections of your comment in the rows
	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.	
C2	HFCWO coverage for patients with CF has expanded across the payer continuum	We recognize that HFCWO device therapy is a commonly
	such that at least 45 of the Medicaid fee-for-service plans cover HFCWO for CF	used treatment option for cystic fibrosis. Though the
	beneficiaries. HFCWO is considered standard of care for CF as evidenced by the CF	available evidence shows no difference in hospitalizations
	foundation's estimate that 76% of the US CF population uses HFCWO for airway	compared to chest physiotherapy, we are recommending
	clearance. ¹ This is largely attributable to assurance or reliable and consistent	coverage because of patient preferences and because
	treatment, adherence to therapy, and patient preference. Accordingly, providing	chest physiotherapy may not be available or feasible for all
	HFCWO coverage for the CF population would ultimately offset costs through	patients.
	reduced exacerbations and hospitalizations.	
C3	Hillrom strongly encourages the committee also consider coverage for patients with	No economic studies met our inclusion criteria for this
	NMD. Respiratory complications are the leading cause of morbidity and mortality	coverage guidance.
	for patients with NMD and HFCWO has been shown to reduce these complications.	See response to comment A5 regarding other payer
	The rationale for the recommendation for coverage for patients with NMD starts	coverage.
	that there is no evidence that HFCWO devices improve key outcomes compared to	



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	The Yuan et al., 2010 reference has been added to the
	physiotherapy (CPT). Both studies demonstrated significantly decreased rates of	coverage guidance since the submission of this comment.
	hospitalization for intravenous antibiotics and superior oxygenation for patients	The Landon et al., 2022 reference was excluded because it
	using HFCWO as well as superior adherence to the therapy. The investigator-	was a conference abstract. The Fitzgerald et al., 2014
	initiated Fitzgerald study demonstrated a 32% reduction in hospitalizations (P<.01)	reference reported a before-after study. Although
	in neurologically impaired children with respiratory symptoms. These studies	observational before-and-after studies, such as the real-
	provide sufficient comparative evidence of the superior benefits of HFCWO over	world studies you refer to, do appear to show benefit, this
	standard treatment for this population.	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	This reference was excluded because the cost effectiveness
	of HFCWO therapy on healthcare costs for neuromuscular disorders, which supports	estimates produced for the health system in the UK are not
	the efficacy of HFCWO when compared to standard treatment. Most notable is the	directly related to cost effectiveness estimates for the
	2019 research article published by the National Institute for Health Care Excellence	health system in the US (Javanbakht et al., 2019).
	(NICE) which analysed the cost-effectiveness of HFCWO compared to CPT in	Additionally, this study included information from a
	patients with complex neurological disorders, including neuromuscular disease and	before-after study and from the Yuan et al., 2010 study
	cerebral palsy. ⁵ This analysis revealed that per 1000 patients, the Vest System	that we have incorporated into the coverage guidance.
	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	



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%	The Pandya et al., 2020 reference was a conference presentation of a before-after study; the other 2 references also utilized a before-after desian.
	(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	
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	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	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 winterwe 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 	
D2	lung and respiratory-related incidents that were not considered 'disease'? 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.



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



References Provided by Commenters

ID	References
А	Excluded from the coverage guidance
	Berry JG, Goodman DM, Coller RJ, et al. Association of home respiratory equipment and supply use with health care resource utilization in children.
	J Pediat. 2019;207:169-175.e162. doi: 10.1016/j.jpeds.2018.11.046.
	A systematic review and meta-analysis of randomized controlled trials. Ann Am Thoras Soc. 2021;18(2):308-320
	doi: 10.1513/AnnalsATS 202005-4820C
	McEvoy C, Pandya P, Weycker D, Hanson GL. Outcomes with high-frequency chest wall oscillation among patients with COPD using a large claims
	database. Presented at: CHEST 2020 Annual Meeting; October 18-21, 2020; Online. P1468.
В	Excluded from the coverage guidance
	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 #4)
	Barto T, Maselli DJ, Daignault S, Hansen G. Outcomes of high frequency chest wall oscillation (HFCWO) in COPD patients without bronchiectasis.
	Presented at: CHEST 2019 Annual Meeting; October 19-23, 2019; New Orleans, LA. E1080. (letter reference #11)
	registry of non-CE bronchiectasis nations. Presented at: American Thoracic Society Conference: May 21, 2019. (letter reference #5)
	Basavarai A. Choate R. Addrizzo-Harris D. et al. Airway clearance techniques in bronchiectasis: analysis from the United States bronchiectasis and
	non-TB mycobacteria research registry. CHEST. 2020;158(4):1376-1384. (letter reference #3)
	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 #7)
	Daynes E, Jones AW, Greening NJ, Singh SJ. The use of airway clearance devices in the management of chronic obstructive pulmonary disease: a
	systematic review and meta-analysis of randomized controlled trials. Ann Am Thorac Soc. 2021;18(2):308-320. doi:10.1513/AnnalsATS.202005-
	4820C (letter reference #10)
	Am Thorac Soc. 2016:13(6):904-909 (letter reference #9)
	McEvoy C, Pandya P, Weycker D, Hansen G. A Retrospective Real-World Cohort Study Demonstrating the Impact of HFCWO Therapy on Patients with
	Neuromuscular Disorders. Presented at: CHEST 2020 Annual Meeting; October 18-21, 2020; Online.P1943. (letter reference #8)
	McEvoy C, Pandya P, Weycker D, Hansen G. Outcomes with high-frequency chest wall oscillation among patients with COPD using a large claims
	database. Presented at: CHEST 2020 Annual Meeting; October 18-21, 2020; Online. P1468. (letter reference #12)
	Mikesell CL, Kempainen RR, Laguna TA, et al. Objective measurement of adherence to out-patient airway clearance therapy by high-frequency chest
	wall compression in cystic fibrosis. Respir Care. 2017;62(7):920-927. doi: 10.4187/respcare.05349 (letter reference #2)





ID	References
	Rubin BK. Designing clinical trials to evaluate mucus clearance therapy. <i>Respir Care</i> . 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)
С	Newly included in the coverage guidance 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, <i>J. Child Neurol</i> . 2010;25(7):815–821. (letter reference #2)
	Already included in coverage guidance
	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)
	Excluded from the coverage guidance
	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. <i>Ther Adv Respir Dis.</i> 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. <i>Respir Care.</i> 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. <i>Open Pharmacoeconomics Health Econ J.</i> 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. <i>CHEST</i> . 2020;156(4Suppl):A2292. doi: 10.1016/j.chest.2020.08.1943



ID	References
	Sievert C, Beaner C. Incidence of bronchiectasis-related exacerbation rates after high frequency chest wall oscillation (HFCWO) treatment — a longitudinal outcome-based study. <i>Respir Ther</i> . 2018;13(2):30-33. (letter reference #10)
	Sievert C, Beaner C. Cost-effective analysis of using high frequency chest wall oscillation (HFCWO) in patients with non-cystic fibrosis bronchiectasis. <i>Respir Ther</i> . 2017;12(1):45-49. (letter reference #11)
	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 #12)
	Winfield NR, Barker NJ, Turner ER, Quin GL. Non-pharmaceutical management of respiratory morbidity in children with severe global developmental delay. <i>Cochrane Database Syst Rev.</i> 2014;2014(10):CD010382. doi: 10.1002/14651858.CD010382.pub2. (no letter reference number provided)
D	None provided



Table of Contents

Discussion Table	 1
Commenters	 2
Public Comments	

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.





Commenters

Identification	Stakeholder	
А	Jenna Kelly, parent/caregiver of a child with non-CF bronchiectasis [Submitted September 24, 2021]	
В	Sharon Skidmore, PT, DPT Physical Therapy for Kids, LLC [Submitted September 28, 2021]	
С	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.





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).



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.
С9	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.





Table of Contents

Discussion Table	
Commenters	
Public Comments	3
References Provided by Commenters	11
References i forface by confinence since and a since a	 ***

Discussion Table

IDs/#s	Summary of Issue Raised by Commenters	Subcommittee Response
A3, A4	Bronchiectasis is a rare disease, resulting in low impact	Bronchiectasis is not a rare disease, although it is a heterogenous condition. Data for
	of adding coverage.	Oregon Health Plan (OHP) claims from 2018-2020 showed claims for nearly 1,500
		members which included a diagnosis of bronchiectasis. This number is likely an
		underestimate to the true bronchiectasis population in Oregon.
A1, A4-A9,	The nature of the very low quality evidence for	Although observational noncomparative studies (like those submitted by
B1, C2	bronchiectasis stems from lack of consensus on study	commenters), do appear to show benefit, the study designs do not permit us to
	endpoints and other factors, as well as lack of interest	determine whether the effect was caused by HFCWO devices; these study designs
	among independent researchers, making it difficult to	cannot control for confounding factors and more robust study designs exist. Further,
	conduct novel research for this population. This lower-	the size of the bronchiectasis population is large enough to feasibly conduct studies.
	quality evidence should be included in this review.	
A2, A10,	There is an equity consideration in noncoverage of	The subcommittee acknowledges that patients in these groups/areas may have more
A11, B8,	HFCWO devices, as patients may be located in more	limited access to care options. These contextual factors will inform subcommittee
C3	rural or economically disadvantaged areas, are from	deliberation.
	developing countries, have comorbidities, and/or have	For EbGS discussion.
	language or cultural barriers to care.	



IDs/#s	Summary of Issue Raised by Commenters	Subcommittee Response
B2, C1	Expert opinion supports the use of HFCWO in selected	For EbGS consideration:
	patients with bronchiectasis	Previous expert opinion-generated "blue box" language is shown below and can be included again if EbGS considers the expert recommendations to be strong enough to justify inclusion.
		 High-frequency chest wall oscillation devices are recommended for coverage for patients with non–cystic fibrosis bronchiectasis (<i>weak recommendation</i>) 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:
	D.	 Daily productive cough for at least 6 continuous months, OR Frequent (> 2 times a year) exacerbations requiring antibiotic therapy, AND 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).

Commenters

Identification	Stakeholder	
А	Gary Hansen, PhD, Director of Scientific Affairs, RespirTech [April 29, 2022]	
В	Alan Barker, MD, Professor of Medicine, Pulmonary and Critical Care, Oregon Health & Science University [May 4, 2022]	
C	Aaron Trimble, MD, Assistant Professor of Medicine, Pulmonary and Critical Care, Oregon Health & Science University [May 10, 2022]	





Public Comments

ID/#	Comment	Disposition
A1	We reviewed the revised draft guidance for coverage of high-frequency chest wall oscillation (HFCWO) and are pleased with the recommendation for coverage of cystic fibrosis (CF) and neuromuscular disorders. However, we strongly urge the EbGS and HERC committee to reconsider the recommendation for denial of coverage to the vulnerable and at-risk Oregonian patients with bronchiectasis (BE). Despite the lack of high-quality evidence, HFCWO has become well-established as an important means of airway clearance therapy for this population.	Thank you for your comments. We have written responses to specific individual sections of your letter in the rows that follow.
A2	Vest therapy has been clinically shown to be just as effective as other methods of airway clearance and does not depend on the user's skill or effort. ¹ This makes the device an important alternative for persons in disadvantaged socio-economic circumstances, or for persons who have not been successful with other methods.	The publication referenced here presents narrative summaries of published studies but does not include meta-analyses or present any original research findings.




ID/#	Comment				Disposition
A3	Accordingly, allo meeting. There seemed to the state who ar that the number reports the preve be extrapolated <u>Age Range</u> 35 to 44 years 45 to 54 years 55 to 64 years Total The roughly one- because not all of 65 have coverage studies for BE are As noted in prev (RCT) for BE has considerable and rationale in prior 12/1/2020 and 6	w me to address several points of the some uncertainty about a potential users of HFCWO was large. We have found in alence of diagnosed BE in the to the Oregonian under-65 of <u>Oregon Population</u> 568,712 568,712 510,127 538,950 1,617,789 -thousand BE cases in Oregon are airway clearance other than Medicaid. ⁴ A fee easier to conduct than for ious meetings, conducting a proven challenging and is urd well-intentioned efforts. We communications to this conto (25/2021). There are good to the several point and the several point and the several point of	ints raised in the mo the number of BE p , and a few member to be otherwise. A segeneral population population as follow <u>BE Prevalence Cases/100,000³</u> 18 43 122 183 on can be further rec ce and most patients w members suggest CF or neuromuscula randomized contro hlikely to occur desp /e provided consider mmittee (Submission reasons for this. ⁵	st recent batients in s suspected recent study n; this may s: <u>Estimated</u> <u>BE Cases</u> 102 219 658 979 Auced s below age ed that ar conditions. Iled trial ite rable ns dated	The Weycker et al., 2017 publication cited here used health-care claims data from 2009 to 2013 to estimate the prevalence and incidence of bronchiectasis in adults enrolled in multiple private health plans. Between 2018-2020, claims were submitted for nearly 1,500 OHP members showing a diagnosis of bronchiectasis, and this number is likely an underestimate of the true size of this population in Oregon. Furthermore, the Weycker et al., 2017 publication estimates that there has been an annual growth rate of 8% per year since 2001 of patients with newly diagnosed bronchiectasis, and further suggests that cases that were identified represented only a small part of the true population with bronchiectasis. This suggests that even their proposed method of estimating prevalence and incidence may provide underestimates. Responses to prior comments can be viewed <u>here</u> and <u>here</u> .
A4	First, HFCWO oft cohorts of adequ	en treats rare diseases whic uate size.	h makes it difficult t	o recruit	We understand that cystic fibrosis and many of the neuromuscular diseases in scope for this topic are rare, but chronic obstructive pulmonary disorder and non–cystic fibrosis bronchiectasis are not rare diseases. See response A3 regarding the population estimate for bronchiectasis in Oregon.



ID/#	Comment	Disposition
A5	Second, there is little agreement on study endpoints, and many older studies rely on problematical proxy measures such as sputum volume or changes in forced expiratory volume (FEV1).	Outcomes such as sputum volume or changes in volume were not selected as critical or important outcomes for this report.
A6	Third, past studies did not identify or control for machine power settings or adherence. ⁶	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.
A7	Fourth, airway clearance studies cannot be blinded, making it impossible to do a truly double-blind study.	The subcommittee does not require studies to have a double-blind design for inclusion in coverage guidance reports.
A8	Lastly, there has been little interest among independent researchers on this topic, perhaps because the therapy has been around for so long. We ask that you take these well-known difficulties into account.	Thank you for your comment. The EbGS does take these contextual factors into account in its decision-making.
A9	The Barto et al (2020) peer-reviewed publication ⁷ was unfortunately not among those included in the overall evidence evaluation by all members of the committee, yet it is among the most substantial pieces of contemporary evidence that supports the use of vest therapy in the BE patient population. This peer-reviewed outcomes publication has already been cited by several key thought leaders in the field of bronchiectasis as a positive contribution to the BE airway clearance literature – so we were naturally disappointed that the broader committee elected to not consider this data in their assessment.	The Barto et al., 2020 publication did not meet inclusion criteria for this coverage guidance because it used noncomparative observational data from a registry using patient-reported outcomes that they were asked to retrospectively recall.
A10	From a health equity perspective, the collective needs of these patients need to be considered. Patients with pulmonary diseases requiring airway clearance are likely to be located in areas where access to health care services may be limited. This situation is clear from the following map, which shows the high prevalence of COPD in rural and/or economically disadvantaged areas in Oregon. ⁸	Though we acknowledge that access to treatments may be more difficult to obtain in rural areas, any available treatment must still be evidence-based and be sufficiently effective at improving critical or important outcomes. Our review found insufficient evidence that HFCWO devices improve key outcomes for patients with chronic obstructive pulmonary disease compared to



ID/#	Comment	Disposition
	[Image of CDC model of COPD prevalence by census tract, 2018, retrieved from: https://www.cdc.gov/copd/data.html]	alternatives. Expert opinion does not recommend use in this population.
A11	Dr. Trimble stated, and medical literature concurs, that patients respond differently to different forms of airway clearance and a personalized approach to airway clearance is key to positive patient outcomes. ⁹ For various reasons, patients frequently fail their initial attempts at an airway clearance modality; this may be due to motivational issues, lack of social support, physical limitations, or improper use of devices. There is a high treatment burden for traditional chest physiotherapy and the number of personnel with appropriate training is limited. In addition, there is a tremendous amount of variability in the delivery of many of the manual airway clearance techniques that are offset/addressed by the standardization offered by HFCWO. Therefore, Medicare and most insurance payors in the US include HFCWO as an option for BE patients and specifically took into account a 'tried and failed criterion'. We respectfully request that the draft coverage be amended to include coverage for BE on a tried-and- failed basis. This would minimize confusion among patients and health care providers in Oregon and better align with Medicare, other state Medicaid programs, and most private insurance payors. By doing so, it would help Oregonians avoid having to pursue an arduous and time-consuming appeals process and would likely proactively reduce healthcare resource utilization from a population health perspective. We hope these comments are constructive to the committee as they make their final recommendations for coverage criteria to the HERC committee. Thank you for considering our request to include BE for the aforementioned reasons. Please let us know if we can answer any questions, and do not hesitate to contact me directly.	The Sontag et al., 2010 publication referenced here reports on lessons learned after a randomized trial of airway clearance techniques for patients with cystic fibrosis. This draft of the coverage guidance has a weak recommendation for covering HFCWO devices for patients with cystic fibrosis who have frequent exacerbations and for whom chest physiotherapy and positive expiratory pressure are not available, effective, or tolerated. The coverage criteria from Medicare, Aetna, Cigna, Moda, Regence BlueCross BlueShield, and the Washington Medicaid program are summarized in the coverage guidance. Thank you for your detailed comments and your interest in ensuring that Oregon Medicaid members have access to the best available treatment options.



ID/#	Comment	Disposition
B1	I would like to address and encourage consideration of coverage for HFCWO devices for (non-CF) bronchiectasis.	Thank you for your comments. We have written responses to specific individual sections of your letter in the rows that follow.
	The draft document on HFCWO is well studied and researched. Part of the problem acquiring evidence for HFCWO is the lack of endpoints for studies in bronchiectasis. Mortality over a few months is not an appropriate endpoint. Bronchiectasis patients have permanent structural airway damage that does not show improvement in pulmonary function after antibiotics or other therapies. In uncontrolled studies exacerbations are reduced and quality of life improved after airway clearance therapies (ACT). I would suggest several considerations for provision of HFCWO devices based on authoritative opinion:	
B2	Bronchiectasis is the prototypical condition for which ACT including HFCWO is therapeutic. The pathophysiology includes airway inflammation and infection leading to exceptional and tenacious mucus for which enhancing secretion removal is salutary (1).	The publication referenced here is for a nearly 200-page issue of the publication Clinics in Chest Medicine. This issue presented articles that summarize the current state of research related to bronchiectasis and future directions in research.
В3	International Guidelines for the diagnosis of bronchiectasis and for exacerbations can be utilized for clinical consideration and management as well as research studies (2,3).	The Aliberti et al., 2022 publication summarized consensus recommendations for establishing criteria and definitions for radiological and clinical diagnosis of bronchiectasis to improve patient recruitment for future clinical trials of treatments for bronchiectasis. Similarly, the Hill et al., 2017 publication summarized a consensus definition for pulmonary exacerbations in adults with bronchiectasis.
B4	Airway Clearance Therapies (ACT) are a well accepted part of the management of bronchiectasis, promoted strongly by Guidelines from Great Britain, Europe, Spain, Australia, and New Zealand. There are no US Guidelines, but the Bronchiectasis Research Registry (of which I am a board member and includes experts throughout the US) actively promotes ACT and further study of ACT.	For bronchiectasis, our review included evidence-based guidelines and recommendations from the European Respiratory Society and the American College of Chest Physicians.
OREGON HEALTH &SCIENC UNIVERS	Center for Evidence-based Policy	Comments received 4/13/2022 to 5/5/2022 Page 7

ID/#	Comment	Disposition
В5	In US bronchiectasis centers, HFCWO is the 2 nd most utilized ACT modality. Chest physical therapy (CPT) is rarely practiced (4). The Guidelines from abroad do not focus on HFCWO because they have a long tradition of encouraging traditional CPT (patient positioning and chest percussion) through specialized physiatry services. CPT is labor intensive and the positioning can be uncomfortable for some patients. HFCWO mimics percussion in a more gentle and concerted fashion. Some types of HFCWO (battery generated) allow movement away from a fixed source and patients do not need a companion or professional assistant (Respiratory or Physical Therapist).	The Basavaraj et al., 2020 publication cited here was not eligible for inclusion in the coverage guidance due to the study's noncomparative observational retrospective design. Additionally, very few of the participants in this study ($N = 51$) used HFCWO devices and only two-thirds of those participants were included in the follow-up ($N = 34$). 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.
B6	HFCWO is approved for cystic fibrosis (CF). The airway condition in CF IS bronchiectasis. CF is now an adult disease and has many similarities to (non-CF) bronchiectasis	Our review found insufficient evidence that HFCWO device therapy reduces exacerbations and hospitalizations for conditions other than cystic fibrosis.
Β7	The FDA now promotes patient centered outcomes in diseases. There are well-studied and established HRQL instruments in bronchiectasis including SGRQ, QOL-B, LQ, and CAT. They have been used and can be followed during management including ACT in bronchiectasis (5).	The De la Rosa Carrillo et al., 2020 publication cited here did not meet inclusion criteria for the coverage guidance due to its noncomparative observational design. The primary purpose of the publication was to validate the COPD assessment tool (CAT) for use in patients with bronchiectasis, and this publication may be helpful for researchers planning clinical trials.





ID/#	Comment	Disposition
B8	Most importantly each patient adapts, finds efficacy, and tolerates various forms of ACT. Although many can utilize directed coughing, or positive expiratory pressure (PEP) devices, elderly patients (average age bronchiectasis patients-63) with substantial co-morbidities may not tolerate or even perform directed coughing or PEP. HFCWO may be more effective, comfortable, and tolerable. Use of HFCWO fits into the principle of personal and collaborative management and furthering education that include regular exercise, pulmonary rehabilitation, maintaining a healthy diet, and on-going learning that are key to chronic disease management including bronchiectasis (6).	Thank you for providing important context for the subcommittee's deliberation.
C1	I am a clinician with experience and expertise in the area of Cystic Fibrosis (CF) as well as non-CF bronchiectasis. I am concerned that Health Evidence Review Commission is proposing a guideline for patients with non-CF bronchiectasis involving High Frequency Chest Wall Oscillating Vests (HFCWO vests) for airway clearance therapy (ACT) which burdens patients with an appeals process to secure coverage for this therapy. While data supporting the use of ACT techniques and devices is better in CF than in non-CF bronchiectasis, even in CF, the data supporting its use is weak and of low quality. However, the use of ACT remains central to the treatment of both CF and non-CF bronchiectasis, and effective adherence to ACT is widely considered to be among the most important factors in patient outcomes, including exacerbation/hospitalization frequency and even mortality.	Thank you for providing your expertise for this coverage guidance report. The health equity concerns you outline will be important considerations for subcommittee discussion.
C2	The reasons for the low quality and quantity of data for ACT likely stem, at least in part, from need for personalization of ACT technique to the individual patient, as different methods of ACT may have variable efficacy for each patient. HFCWO vests are important tools as they do not require the use of a caregiver (manual chest PT requires 40-60 minutes a day of high-intensity manual therapy from a caregiver) and produce more force transmitted through the airway than active-ACT devices such as positive expiratory pressure devices and autogenic drainage.	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.



ID/#	Comment	Disposition
C3	I am particularly concerned that the current planned recommendation of the HERC places the burden of appeal on the individual patient, which will lead to disparities of care. The most common cause of clinically significant bronchiectasis is prior severe infection with organisms such as TB, which disproportionally affects vulnerable individuals, such as those with low socioeconomic status and/or those who have immigrated from developing countries. These individuals are more likely to have language and cultural barriers making it unacceptably difficult to obtain an exception to allow coverage for HFCWO devices. These individuals are also more likely to need access to effective independent ACT therapy options.	The health equity concerns you outline will be important considerations for subcommittee discussion.
C4	I urge the HERC to recommend that individuals with non-CF bronchiectasis with clinically active/severe disease (as defined by the HERC; i.e. frequent exacerbations, declining lung function, etc.) be allowed access to HFCWO devices. Note, the vast minority of individuals with the diagnosis of bronchiectasis have clinically active/severe disease. The diagnosis is frequently given to individuals based on imaging, but these clinical criteria are rarely met.	Thank you for providing important context for the subcommittee's deliberation.





References Provided by Commenters

ID	References
A	 Belli S, Prince I, Savio G, et al. Airway clearance techniques: the right choice for the right patient. <i>Front Med (Lausanne)</i>. 2021;8:544826. 2019 US Census Annual Estimate. https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-detail.html Weycker D, Hansen GL, Seifer FD. Prevalence and incidence of noncystic fibrosis bronchiectasis among US adults in 2013. <i>Chron Respir Dis</i>. 2017;14:377-384. Oregon Health Insurance Survey Early Release Results. 2019; https://www.oregon.gov/oha/ERD/Pages/2019-Oregon-Health-Insurance-Survey.aspx.
	 Rubin BK. Designing clinical trials to evaluate mucus clearance therapy. <i>Respir Care</i>. 2007;52(10):1348-1358; discussion 1358-1361. Mikesell CL, Kempainen RR, Laguna TA, et al. Objective measurement of adherence to out-patient airway clearance therapy by high-frequency chest wall compression in cystic fibrosis. <i>Respir Care</i>. 2017. 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. <i>Ther Adv Respir Dis</i>. 2020;14:1753466620932508. CDC 2019 COPD Data. https://www.cdc.gov/copd/data.html. Sontag MK, Quittner AL, Modi AC, et al. Lessons learned from a randomized trial of airway secretion clearance techniques in cystic fibrosis. <i>Pediatr Pulmonol.</i> 2010;45(3):291-300.
В	 Chalmers J, ed. Bronchiectasis. <i>Clin Chest Med.</i> 2022, March issue Aliberti S, Goeminne PC, O'Donnell AE, et al. Criteria and definitions for the radiological and clinical diagnosis of bronchiectasis in adults for use in clinical trials: international consensus recommendations. <i>Lancet Respir Med</i>, March, 2022. Hill AT, Haworth CS, Aliberti S, et al. Pulmonary exacerbation in adults with bronchiectasis: a consensus definition for clinical research. <i>Eur Respir J.</i> 2017;49. Basavaraj A, Choate R, Addrizzo-Harris D, et al. Airway clearance techniques in bronchiectasis: analysis from the United States Bronchiectasis and Non-TB Mycobacteria Research Registry. <i>CHEST.</i> 2020;158:1376 De la Rosa Carrillo D, Olveira C, García-Clemente M, et al. COPD assessment test in bronchiectasis: minimum clinically important difference and psychometric validation: a prospective study. <i>CHEST.</i> 2020;157:824. British Thoracic Society. Bronchiectasis self-management plan. https://www.brit-thoracic.org.uk/quality-improvement/quality-standards/bronchiectasis/.



