



**Health Evidence Review
Commission's**

**Evidence-based Guidelines
Subcommittee**

June 7, 2012

**Meridian Park Hospital
Community Health Education Center, Room 117B&C
19300 SW 65th Avenue, Tualatin, OR 97062**

**AGENDA
EVIDENCE-BASED GUIDELINES SUBCOMMITTEE (EbGS)**

June 7, 2012

2:00pm - 5:00pm

Meridian Park Room 117B&C

Community Health Education Center

19300 SW 65th Avenue, Tualatin, OR 97062

(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	2:00 PM	Call to Order	Wiley Chan	
2	2:05 PM	Review of May minutes	Wiley Chan	x
3	2:10 PM	Review public comment and finalize CGs: 1) Knee arthroscopy for osteoarthritis 2) Femoracetabular impingement syndrome surgery 3) Elective induction of labor 4) Ultrasound in pregnancy 5) Indications for planned cesarean section 6) Evaluation and management of low back pain – Pharmacologic interventions	Alison Little	x
4	3:20 PM	New Draft Coverage Guidances 1) Non-pharmacologic interventions for treatment resistant depression 2) Neuroimaging for headache 3) Imaging in dementia	Cat Livingston	x
5	4:40 PM	Confirmation of next meeting August 2, 2012	Wiley Chan	x
6	4:42 PM	Other business		
7	4:50 PM	Public Comment		
8	5:00 PM	Adjournment	Wiley Chan	

MINUTES

Evidence-based Guidelines Subcommittee

Meridian Park Hospital
Community Health Education Center, Room 117 B&C
19300 SW 65th Avenue, Tualatin, OR 97062
May 3, 2012
2:00pm - 5:00pm

Members Present: Steve Marks, MD, Vice-Chair Presiding; Wiley Chan, MD, Chair; Vern Saboe, DC; Beth Westbrook, PsyD; Irene Crosswell, RPh; Leda Garside, RN (arrived after roll call); Som Saha, MD, MPH (arrived after roll call).

Members Absent: None

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Dave Lenar.

Also Attending: Alison Little, MD and Shannon Vandegriff (CEbP); Jessie Little (ASU); Paul Nielsen (MedImmune); Kathy Kirk (OPMC).

CALL TO ORDER

Steve Marks called the meeting of the Evidence-based Guideline Subcommittee (EbGS) to order at 2:12 pm (after quorum achieved) and updated the agenda. Marks indicated a topic slated for today's discussion - nonpharmacologic interventions for treatment-resistant depression - will be addressed at the June meeting. In addition, some topics listed for next month's discussion, 1) early childhood caries treatment: stainless steel crowns vs other, 2) laser based treatment of venous disease and 3) evaluation and management of low backpain – pharmacologic interventions, will not be discussed in June.

REVIEW OF MARCH MINUTES

Motion: Approve minutes as written. Motion carries: 5-0 (Absent – Garside, Saha).

DIRECTOR UPDATES

Darren Coffman presented a revised [coverage guidance process](#). The new trusted sources that have been approved by HERC were reviewed. If possible, topics with public reports will be prioritized higher. The 30-day posting process was reviewed, as well as the 2-month time span between meetings the 30-day posting requires, so that public comment can be brought back to the subcommittee to review. Coffman reviewed the process for responding to studies that are submitted as part of public comment.

Coffman discussed the overall timeline of subcommittee's work. This subcommittee will now meet every other month. This new schedule will allow us to discuss topics continuously between meetings, incorporating a 30-day comment period. Meetings will be held in August, October and December. The September and November meetings are cancelled.

REVIEW OF THE PERCUTANEOUS INTERVENTIONS FOR LOW BACK PAIN GUIDELINE

Alison Little reviewed major points of the draft guideline included in the meeting materials ([pages 25-47](#)). There was no discussion.

Motion: To approve the guideline as written. Motion carries: 7-0

COVERAGE GUIDANCE PUBLIC COMMENT:

Nonpharmacological Treatments of Low Back Pain

Marks began a discussion about the approach to the public comment process. Wiley Chan mentioned it would be interesting to know why seemingly strong studies were rejected by trusted sources if it were easily identifiable. Som Saha affirmed the importance of not dismissing concerns about excluded studies. However, it was noted the HERC process is about evaluating guidelines that are already determined to be of high quality. The members agreed the trusted sources accomplish their work through a very well accepted method. If interested parties have a problem with how the guideline is developed, that should be addressed with the guideline makers themselves; there are not the resources nor is it efficient for the EbGS or staff to dig into primary sources. Knowledge of which specific studies have been used and cited is clearly listed and readily available.

There was a discussion about the role of the subcommittee in evaluating evidence excluded from the source report. The members agree if the studies have already been considered by a trusted source, the subcommittee will not evaluate further details about those studies. Further, if the evidence is already examined by a systematic review and/or trusted source, the Center for Evidence-based Policy (CEbP) does not need to reevaluate. If there is a review of systematic reviews, no searching is necessary. If source document has references included, then CEbP will check to see if those studies were included or excluded. HERC policy is to use systematic reviews or highly quality guidelines and to re-evaluate studies previously assessed for inclusion or exclusion by the systematic review is not warranted.

Little reviewed the public comments ([pages 62-70](#)) and the [CeBP's recommended responses](#). No changes were recommended to be made to the draft coverage guidance on Low Back Pain: Non-Pharmacologic/Non-Invasive Interventions after review of the public comments.

Motion: To approve the coverage guidance as written and forward to HERC. Motion carries: 7-0.

REVIEW OF NEW DRAFT COVERAGE GUIDANCES

Diagnosis and Treatment of Pediatric ADHD ([pages 71-79](#))

Livingston began the discussion, stating the term “preschoolers” should be replaced with the phrase “[children under 6](#)” with disruptive behavior disorders (including those at risk for ADHD), and parent behavior training should be covered as first-line therapy. It was suggested there may be a need to determine which subtypes of parent behavior trainings are more efficacious and if the elements of parent behavior training are known, whether those should be specified. Saha stated details such as to length, duration and frequency of trainings should be determined by the health plan’s coverage implementation teams and should not be included in the guidance.

The evidence suggests psychostimulant medication should be considered as a second line of therapy, weighing the benefits and harms to determine if it is appropriate for an individual child. Additional changes suggested included the following: For children ages [6 and over](#) with ADHD, psychostimulants alone or psychostimulants with [specific](#) behavioral treatment are considered first-line therapy and should be covered.

Action

- Change language to replace “preschoolers” with the statement “children 5 and under”
- Add into draft coverage guidance “specific* parent behavior treatment” : *Parent behavior therapies with evidence to support them include a), b), c),...x).

Motion: To conditionally approve the ADHD draft coverage guidance for public comment pending the ability to identify the parent behavior training therapies with supporting evidence. Motion carries: 7-0.

Advanced Imaging for Low Back Pain ([pages 89-95](#))

Livingston reiterated the proposed coverage guidance stemming from the recently approved HERC guideline. There was little substantial discussion.

Action

- Add red flags Table B (and add an asterix) into coverage guidance document
- Define persistent as (>1 month duration)

Motion: To approve the Advanced Imaging for Low Back Pain draft coverage guidance for public comment as amended. Motion carries: 7-0.

NEXT MONTHS TOPICS

- Review public comment and finalize coverage guidances on:
 - Knee arthroscopy for osteoarthritis
 - Femoracetabular impingement syndrome surgery
 - Elective induction of labor
 - Ultrasound in pregnancy
 - Indications for planned cesarean section

- New Draft Coverage Guidance Topics
 - Red flags and imaging in headache
 - Imaging in dementia
 - Nonpharmacologic interventions for treatment-resistant depression

Clarification about Studies with Insufficient Evidence

Livingston asked for a clarification about how the subcommittee views making recommendations based on studies when there is insufficient evidence. Saha pointed out there are many standardly practiced interventions which are never studied or are impossible to study with randomized trials. Marks agreed, stating lack of evidence does not necessarily mean lack of efficacy.

Chan held that if the subcommittee's charge is to give guidance on maximal cost-effective care and the studies cannot prove that fact, then we are unable to estimate cost-benefit and should not pay for it; the burden of proof is on the proponent of the intervention. Others wondered about factoring in provider and patient preferences, supposing it depends on the topic and if it is even possible to conduct randomized controlled trials. For example, it is *not* feasible to do a study of the efficacy for labor induction for pre-eclamptic pregnant women; however, low back pain studies are possible.

Consensus from the members was that if there are current proven interventions that work, then new therapies which do not have sufficient evidence should not be recommended for coverage. It becomes much more of an issue if there are no known effective treatments. At that point, a shared decision making process should occur.

CONFIRMATION OF NEXT MEETING

The next meeting is scheduled for June 7, 2012 from 2:00- 5:00 pm in Room 117B&C of the Meridian Park Hospital Health Education Center in Tualatin.

PUBLIC COMMENT

There was no public comment.

ADJOURNMENT

The meeting was adjourned at 3:53 pm.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: KNEE ARTHROSCOPY FOR OSTEOARTHRITIS

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

[Treatment of knee osteoarthritis with arthroscopic lavage and debridement](#) should not be covered.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Health Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2008). HTA evidence report: Arthroscopic surgery of the knee for osteoarthritis. Retrieved from http://www.hta.hca.wa.gov/documents/ka_final.pdf

National Institute for Health and Clinical Excellence. (2007). Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis: Guidance. London: NICE. Retrieved from <http://guidance.nice.org.uk/IPG230/Guidance/pdf/English>

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Osteoarthritis (OA) is a common orthopedic condition characterized by articular degeneration within a joint that is estimated to affect approximately 27 million people in the United States. The diagnosis of osteoarthritis of the knee is commonly based on a combination of symptoms and physical findings such as knee pain or stiffness and radiographic findings. Patients with knee osteoarthritis and symptoms that are refractory to medical management may receive arthroscopic interventions for diagnosis or treatment. Interventions such as debridement and lavage of the knee are carried out with the goal of delaying knee replacement arthroplasty. Although orthopedic guidelines list joint lavage and arthroscopic debridement as treatment options, their roles in managing OA of the knee remain controversial. In 1998, it was estimated that 650,000 knee arthroscopies were performed yearly (Moseley 2002). Arthroscopies are considered by many to be minimally invasive procedures, but clinically significant adverse events have been reported.

Evidence Review

The Washington HTA report utilized the 2007 systematic review conducted by AHRQ (Samson 2007) as the primary evidence base. That report stated that the evidence is insufficient to conclude that arthroscopy and lavage or debridement results in pain reduction or improved function for patients with osteoarthritis of the knee. Neither arthroscopic lavage nor debridement has been found to be superior to sham arthroscopy in well-designed and conducted randomized controlled trials (RCTs). A search of the literature identified no new studies since the AHRQ Publication that met inclusion criteria. Only one study (Moseley 2002), was included in the review, which evaluated the Knee-Specific-Pain Score (KSPS) at two years along with other measures of pain and function and determined that they did not include a clinically meaningful difference between either the debridement group and placebo or the lavage group and placebo group.

The WA HTA reported limited information on adverse effects from RCTs that evaluated arthroscopy with lavage and debridement for knee OA, primarily because the trials focused on efficacy and did not formally measure safety events. Observational data, however, provided useful indicators about safety concerns, including the following:

- Mortality has been reported to be from 0.1% to 0.5% ;
- A 0.3% rate of stroke or myocardial infarction has been reported;
- A hemarthrosis rate of nearly 25% was reported in one case series;
- Reports of infection have ranged from 0.5% to 2%;
- DVT has been reported to be from 0.6% to 17.9% in patients undergoing arthroscopy for any reason (not specifically for OA of the knee).

An economic model was provided by The Medical Advisory Secretariat Ministry of Health and Long-term Care, Toronto. The authors were unable to conduct a full economic analysis because effectiveness was not demonstrated in the literature.

[\[Evidence Source\]](#)

Overall Summary

There is no evidence that neither arthroscopic lavage nor debridement improves pain or functional outcomes in patients with osteoarthritis of the knee.

LIMITATIONS OF COVERAGE

Not applicable

PROCEDURE

Arthroscopy of the Knee

DIAGNOSES

Osteoarthritis of the knee

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
715.06	Osteoarthrosis, generalized, of lower leg
715.16	Osteoarthrosis, localized, primary of lower leg
715.26	Osteoarthrosis, localized, secondary, of lower leg
715.36	Osteoarthrosis, localized, not specified as primary or secondary, of lower leg
715.86	Osteoarthrosis, involving more than one site but not specified as generalized, of lower leg
715.96	Osteoarthrosis, unspecified as localized or generalized, of lower leg
716.66	Unspecified monoarthritis, lower leg
CPT codes	
29877	Arthroscopy, knee, surgical; debridement/shaving of articular cartilage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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.

DRAFT

HERC Coverage Guidance – Knee Arthroscopy For Osteoarthritis Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition																	
Industry Andover, MA	1	Smith & Nephew, Inc. is a global medical technology business specializing in Endoscopy, Orthopedics and Wound Management. We comment on the no coverage guidance recommendation for Knee Arthroscopy for Osteoarthritis. We concur with the HERC's assessment that at the present time evidence is insufficient to support routine use of knee arthroscopy solely for the purpose of lavage and debridement of knee osteoarthritis.	Thank you for your comment.																	
	2	However, any such guidance should clearly distinguish that this indication for knee arthroscopy is only one of several potential applications of knee arthroscopy in patients with or without knee osteoarthritis. Knee arthroscopy may be indicated for evaluation and repair of suspected or known meniscal tear or removal of loose bodies in patients with or without osteoarthritis. Such use for patients with osteoarthritis is identified in the American Association of Orthopedic Surgeons (AAOS) guidance 19. The publically available summary guidelines for the treatment of osteoarthritis of the knee are available as of May 21, 2012 on the AAOS website at http://www.aaos.org/research/guidelines/OAKrecommendations.pdf and are attached.	This coverage guidance does not address other indications for arthroscopy or treatment for OA of the knee other than lavage and debridement; coverage guidance modified to clarify this distinction.																	
	3	Furthermore, several additional Category Level 1 CPT codes have been approved by the American Medical Association for knee arthroscopy procedures. Criteria for Category Level 1 CPT codes includes "that the clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature." These are listed in the following table. <table border="1" style="margin-top: 10px;"> <thead> <tr> <th>CPT</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>29870</td> <td>Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)</td> </tr> <tr> <td>29871</td> <td>Arthroscopy, knee, surgical; for infection, lavage and drainage</td> </tr> <tr> <td>29873</td> <td>Arthroscopy, knee, surgical; with lateral release</td> </tr> <tr> <td>29874</td> <td>Arthroscopy, knee, surgical; for removal of loose body or foreign body (e.g., osteochondritis dissecans fragmentation, chondral fragmentation)</td> </tr> <tr> <td>29875</td> <td>Arthroscopy, knee, surgical; synovectomy, limited (e.g., plica or shelf resection) (separate procedure)</td> </tr> <tr> <td>29876</td> <td>Arthroscopy, knee, surgical; synovectomy, major, two or more compartments (e.g., medial or lateral)</td> </tr> <tr> <td>29879</td> <td>Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture</td> </tr> <tr> <td>29880</td> <td>Arthroscopy, knee, surgical; with meniscectomy (medial)</td> </tr> </tbody> </table>	CPT	Description	29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)	29871	Arthroscopy, knee, surgical; for infection, lavage and drainage	29873	Arthroscopy, knee, surgical; with lateral release	29874	Arthroscopy, knee, surgical; for removal of loose body or foreign body (e.g., osteochondritis dissecans fragmentation, chondral fragmentation)	29875	Arthroscopy, knee, surgical; synovectomy, limited (e.g., plica or shelf resection) (separate procedure)	29876	Arthroscopy, knee, surgical; synovectomy, major, two or more compartments (e.g., medial or lateral)	29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture	29880	Arthroscopy, knee, surgical; with meniscectomy (medial)
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Comment [a11]: Cat checking on coding

HERC Coverage Guidance – Knee Arthroscopy For Osteoarthritis Disposition of Public Comments

Stakeholder	#	Comment	Disposition
	4	Additionally, policies from numerous national commercial payers state that arthroscopic debridement may be considered medically necessary when preoperative imaging indicates that specific anatomic lesions other than osteoarthritis, e.g., large meniscal tears, loose bodies, are the cause of the patient’s symptoms regardless of the presence of osteoarthritis. They also state arthroscopic debridement may be medically necessary for persons presenting with mild-to-moderate (Outerbridge classification I and II) osteoarthritis with knee pain plus mechanical symptoms due to loose bodies and meniscal tears.	The EbGS agrees; see response to comment #2.
	5	We recommend that the HERC clarify that utilization of knee arthroscopy when applied for medically necessary and reasonable indications, regardless of the known or suspected presence or absence of osteoarthritis will be considered appropriate use of this important procedure and will be a covered benefit for its constituents.	See response to comment #2.
<i>Professional society</i> Washington, D.C.	6	Thank you for the opportunity to comment on the draft guidance regarding knee arthroscopy for osteoarthritis. The American Association of Orthopaedic Surgeons represents 98% of the orthopaedic surgeons practicing in the United States, 368 of who practice in Oregon. Orthopaedic surgeons are the preeminent physicians providing surgical treatment for musculoskeletal conditions and disease. I currently serve as the President of the AAOS and have practiced in Tualatin, Oregon for more than 30 years.	Thank you for this information.
	7	The AAOS firmly supports the incorporation of evidence into clinical practice, and is actively involved in developing and promoting Evidence Based Clinical Practice Guidelines for a number of musculoskeletal conditions, including OA of the knee (Available at: http://www.aaos.org/Research/guidelines/OAKguideline.pdf). The “Overall Summary” of your Draft Coverage Guidance is consistent with Recommendation 18 (Grade of Recommendation: A) of the AAOS December 6, 2008 Clinical Practice Guideline for the Treatment of Osteoarthritis of the Knee (non-arthroplasty), which “recommends against performing arthroscopy with debridement or lavage in patients with a primary diagnosis of symptomatic OA of the knee.” Your “Overall Summary” states: “There is no evidence that either arthroscopic lavage nor debridement improves pain or functional outcomes in patients with osteoarthritis of the knee.”	Thank you for your comment.
	8	However, your “HERC Coverage Guidance” at the beginning of the document lacks the necessary nuance found in the “Overall Summary.” There, you write: “Arthroscopic treatment of knee osteoarthritis (or osteoarthrosis) should not be covered.” This is a recommendation against ALL arthroscopy of the knee for OA of the knee. Arthroscopic debridement or lavage is one of several arthroscopic procedures done for OA of the knee and your “HERC Coverage Guidance” statement at the beginning of the document fails to recognize this distinction and recommends against coverage of any type of arthroscopic treatment. For example, the AAOS Clinical Practice Guideline also states in Recommendation 19 (Grade of Recommendation: C) that “arthroscopic partial meniscectomy or loose body removal is an option in patients with symptomatic OA of the knee who also have primary signs and symptoms of a torn meniscus or loose body.” This is one example of an arthroscopic treatment for OA that should be covered.	This coverage guidance does not address other indications for arthroscopy or treatment for OA of the knee other than lavage and debridement; coverage guidance modified to clarify this distinction.
	9	We believe that this drafting error may deprive Oregonians of necessary and efficacious care for knee pain. We also believe that this may lead to an increase in total costs to the State as patients who would otherwise be treated in a single operative session may	This coverage guidance does

HERC Coverage Guidance – Knee Arthroscopy For Osteoarthritis Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		instead seek treatment from a multitude of providers who will not fix the underlying mechanical problem of their knee or experience functional loss of mobility and independence—thus increasing total costs to the various state-funded programs. This could also lead to a disparity in treatment for those who are covered by a state-funded plan. Medicare and private insurers cover meniscectomy and loose body removal as a treatment for osteoarthritis.	not address other indications for arthroscopy or treatment for OA of the knee other than lavage and debridement; coverage guidance modified to clarify this distinction.
	10	We strongly urge the HERC to amend the “HERC Coverage Guidance” statement to mirror the “Overall Summary” so that it reads, “Arthroscopic lavage or debridement for patients with osteoarthritis of the knee should not be covered.”	Coverage guidance modified to reflect this change.
	11	In addition, you incorrectly cite CPT code “29877” as the applicable code. It should be CPT code “29871.” Thank you for your consideration of these amendments.	Thank you for this information.
<i>Professional society</i> Portland, OR	12	Our members are medical and osteopathic physicians specializing in orthopaedics and practicing throughout Oregon. I want to express our concern that the above-referenced Coverage Guidance is too broad. We agree, based on the published evidence, that neither arthroscopic lavage nor debridement improves pain or functional outcomes in patients with knee osteoarthritis.	Thank you for your comment.
	13	Our Clinical Practice Guidelines from the American Association of Orthopaedic Surgeons and published evidence support improved pain and functional outcomes in patients with osteoarthritis of the knee with other arthroscopic knee procedures. Arthroscopic partial meniscectomy or loose body removal is an option in patients with symptomatic OA of the knee who also have primary signs and symptoms of a torn meniscus of knee body. This is an example of an arthroscopic treatment for OA that we believe should be covered. It is a treatment that can relieve patients in pain and ultimately help hold down costs.	See comment #2
	14	We urge you to amend the Coverage Guidance to read: “Arthroscopic lavage or debridement for patients with osteoarthritis of the knee should not be covered.”	See comment #10

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: HIP SURGERY PROCEDURES FOR FEMOROACETABULAR IMPINGEMENT SYNDROME

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Hip surgeries for femoroacetabular impingement syndrome should *not* be covered.

RATIONALE FOR GUIDANCE DEVELOPMENT

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- Represents important uncertainty with regard to efficacy or harms
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EVIDENCE SOURCES

Washington State Health Care Authority Health Technology Assessment Program. (2011). *Hip surgery procedures for treatment of femoroacetabular impingement syndrome: Health technology assessment*. Retrieved from http://www.hta.hca.wa.gov/documents/fai_final_082611.pdf

National Institute for Health and Clinical Excellence. (2011). *Interventional Procedure Guidance 403: Open femoro–acetabular surgery for hip impingement syndrome*. London: National Institute for Health and Clinical Excellence. Retrieved from <http://www.nice.org.uk/nicemedia/live/11328/56416/56416.pdf>

National Institute for Health and Clinical Excellence. (2011). *Interventional Procedure Guidance 408: Arthroscopic femoro–acetabular surgery for hip impingement syndrome*. London: National Institute for Health and Clinical Excellence. Retrieved from <http://www.nice.org.uk/nicemedia/live/11181/55487/55487.pdf>

National Institute for Health and Clinical Excellence. (2011). *Interventional Procedure Programme IP 243_2: Open femoro–acetabular surgery for hip impingement syndrome*. London: National Institute for Health and Clinical Excellence. Retrieved from <http://www.nice.org.uk/nicemedia/live/11181/55772/55772.pdf>

National Institute for Health and Clinical Excellence. (2011). *Interventional Procedure Programme IP 365_2: Arthroscopic femoro–acetabular surgery for hip impingement syndrome*. London: National Institute for Health and Clinical Excellence. Retrieved from <http://www.nice.org.uk/nicemedia/live/11328/54753/54753.pdf>

SUMMARY OF EVIDENCE

Clinical Background

Femoroacetabular impingement (FAI) syndrome is a recently recognized diagnosis in primarily younger individuals where relatively minor abnormalities in the joint (orientation or morphology) are thought to cause friction/impingement and pain. It is theorized that FAI starts the breakdown of cartilage, leading to osteoarthritis. There are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in overcoverage of the femoral head). Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of osteoarthritis degeneration. Surgery to correct FAI includes arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur. The causes of hip pain, the natural history of FAI and its relationship to osteoarthritis are unclear, and the case definition and selection criterion of patients for this procedure is uncertain. Furthermore, questions remain about the efficacy and effectiveness, safety and cost effectiveness of hip surgery for FAI.

Evidence Review

The evidence review addressed questions concerning case definition, evaluation of treatment outcomes, effectiveness and safety of hip surgery for FAI. To address the question of case definition, the most consistent case definition of FAI (cam or mixed) includes hip/groin pain, positive clinical impingement test, and an α -angle >50 - 55° . There is no evidence that the diagnosis of FAI can be obtained from clinical exam. One clinical test, the impingement sign, had a positive and negative predictive value of 86% and 79% in one study where the prevalence of FAI was 50%; however, in another study, the reliability of the impingement sign was only moderate. Even though the α -angle showed moderate to high interobserver reliability in several studies, it had poor

diagnostic value in identifying FAI. Other imaging tests assessing abnormalities of the femur and acetabulum had variable degrees of reliability, but no others were tested for diagnostic validity.

Regarding outcome measures to evaluate the effectiveness of hip surgery for FAI, seven hip outcome measures were commonly used in the FAI patient population, but only three have undergone psychometric analysis in FAI (Hip Outcome Score, German version (HOS-D) and the modified Western Ontario and McMaster Universities Arthritis Index (M-WOMAC) or young hip-pain patients (Nonarthritic Hip Score (NAHS))). Reliability was inadequately tested for all three instruments. The minimal clinically important difference was defined in only one measure, the HOS-D, and found to be 9 points for the activities of daily living subscale and 6 points for the sports subscale in FAI patients.

Regarding the efficacy of hip surgery for FAI, there are no data available to assess the short- or long-term efficacy of FAI surgery compared with no surgery. There is no evidence that one specific treatment resulted in better outcomes than another (surgery versus no surgery, labral debridement versus refixation, osteoplasty versus no osteoplasty). Several case series report improvement in pain, patient reported and clinician reported hip outcome scores, patient satisfaction and return to normal activities following FAI surgery. However, whether this improvement is a result of the surgery, or the postoperative rehabilitation, or the change in activity subsequent to the surgery or placebo is not known. Approximately 8% of patients diagnosed with FAI who undergo surgery in published series go on to have a total hip arthroplasty within 3 years. There are no data available to assess long-term effectiveness of FAI surgery compared with no surgery. There are no data yet published to test the hypothesis that FAI surgery prevents or delays hip osteoarthritis or the need for total hip arthroplasty.

Regarding the safety of hip surgery for FAI, the risk of reoperation (other than conversion to THA) occurred in 4% (arthroscopy and open dislocation) and 9% of the patients (mini-open). There was only one reported head-neck fracture (0.1%) and no reports of AVN, osteonecrosis or trochanteric nonunion. Heterotopic ossification occurred in 2% to 3% of those receiving arthroscopy or mini-open, and 6% in those receiving open dislocation. Neurological complications (nerve palsy, paresthesia, and neuropraxia) were rare in those receiving arthroscopy or open dislocation; however, they occurred in 22% of 258 hips undergoing a mini-open procedure. Most were transient in nature.

The National Institute for Clinical Excellence issued interventional procedure guidances on arthroscopic and open surgery for FAI in September and July 2011, respectively. Both guidances state that current evidence on the efficacy of arthroscopic or open femoro–acetabular surgery for hip impingement syndrome is adequate in terms of symptom relief in the short and medium term. With regard to safety, there are well recognized complications. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit with local review of outcomes. They have established a registry to track long term outcomes of these procedures.

The literature review conducted to inform the NICE guidance consisted of one non-randomized controlled study and seven case series for the open procedure, and three non-randomized controlled studies, five case series and one case report for the arthroscopic procedure. The reviews report the following regarding the evidence base:

- Little or no controlled data are available comparing the procedure with other interventions or against natural history.
- A range of outcome assessment scales are used; validation of these scales is often not reported.
- The description of hip impingement pathology/lesions is not well defined in all studies.
- The intervention required is usually individualized to each patient, making comparison between studies difficult.
- Study quality is generally poor, with little prospective data collection in case series.

Overall Summary

The most consistent case definition of FAI (cam or mixed) includes hip/groin pain, positive clinical impingement test, and an α -angle >50 - 55° ; the predictive value the impingement test ranges from moderate to 86%, and the α -angle has poor diagnostic value. Seven hip outcome measures are commonly used in the FAI patient population, but only three have undergone psychometric analysis in FAI, and reliability has been inadequately tested for all three. There are no data available to assess the short- or long-term efficacy of FAI surgery compared with no surgery, and no evidence that one specific treatment results in better outcomes than another. Regarding safety, the risk of reoperation (other than conversion to THA) is 4% to 9%, and heterotopic ossification occurs in 2% to 6% of patients, while neurological complications occur in up to 22% of patients. NICE has issued a guidance allowing for use of both arthroscopic and open procedures, despite a poor quality evidence base. They have established a registry to track long term outcomes.

[\[Evidence Source\]](#)

PROCEDURE

Hip surgery (arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach)

DIAGNOSES

Femoroacetabular impingement syndrome

APPLICABLE CODES

Additional codes TBD

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
715-715.9	Osteoarthritis
718.05	Articular cartilage disorder, pelvic region
718.45	Contracture of joint, pelvic region and thigh
718.65	Unspecified intrapelvic protrusion acetabulum, pelvic region and thigh
718.85	Other joint derangement, not elsewhere classified
718.95	Unspecified derangement of joint
719.45	Pain in joint, pelvic region and thigh
719.55	Stiffness of joint, not elsewhere classified, pelvic region and thigh
719.7	Difficulty in walking
719.85	Other specified disorders of join, pelvic region and thigh
719.95	Unspecified disorder of joint, pelvic region and thigh
736.30	Acquired deformities of hip, unspecified deformity
736.39	Acquired deformities of hip, other
ICD-9 Volume 3 (Procedure Codes)	
00.85	Resurfacing Hip, Total, Acetabulum And Femoral Head
00.86	Resurfacing Hip, Partial, Femoral Head
00.87	Resurfacing Hip, Partial, Acetabulum
81.51	Total hip replacement
81.52	Partial hip replacement
CPT Codes	
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles
27299	Unlisted procedure, pelvis or hip joint [when specified as open procedure for femoroacetabular impingement syndrome]
29862	Arthroscopy, hip, with debridement/shaving or articular cartilage (chondroplasty), abrasion athroplasty, and/or resection of labrum.
29863	Arthroscopy, hip, with synovectomy
29914	Arthroscopy, hip, surgical; with femoroplasty (i.e., treatment of cam lesion)
29915	Arthroscopy, hip, surgical; with acetabuloplasty (i.e., treatment of pincer lesion)
29916	Arthroscopy, hip, surgical; with labral repair
29999	Unlisted procedure, arthroscopy
27120	Acetabulum Replacement
27122	Resection femoral head
27125	Partial hip replacement
27130	Total hip replacement
HCPCS Codes	

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by Health Evidence Review Commission (HERC) staff and members of the HERC Evidence-based Guidelines Subcommittee. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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.

DRAFT

HERC Coverage Guidance – Hip Surgery Procedures for Femoroacetabular Impingement (FAI) Syndrome Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
Industry Andover, MA	1	Smith & Nephew, Inc. is a global medical technology business specializing in Endoscopy, Orthopedics and Wound Management. We comment on the no coverage recommendation based on the flawed 2011 Washington State FAI review for hip surgeries for Femoroacetabular Impingement (FAI). Focus on the lack of definitive evidence that FAI surgery alters the course of osteoarthritis is shortsighted.	<i>[For EBGS discussion]</i>
	2	Non-surgical treatment of symptomatic FAI is widely acknowledged ¹⁻¹⁹ to: <ul style="list-style-type: none"> • not provide permanent symptom relief; • require lifestyle modification; • and, fail to allow patients to return to desired activity levels. 	The non-surgical treatment of FAI was included in the scope of this review or addressed in this coverage guidance document.
	3	Failure to cover hip surgery for FAI despite the fact that medically- and cost-effective ²⁰ surgery is available should concern affected constituents who may find permanent activity reduction and possibly sustained hip pain and disability unacceptable.	Ref #20 is a cost-effectiveness analysis that employed a number of assumptions about disease progression and efficacy of hip arthroscopy that are not well-established based on the WA HTA evidence review.
	4	The American Medical Association concluded FAI surgery was clinically effective granting three Category Level 1 CPT codes effective January 2011. Criteria for such includes “that the clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature.”	The existence of a Level 1 CPT code is not sufficient evidence of effectiveness.
	5	All national U.S. commercial insurers cover FAI surgery because their publically available health technology appraisals determined that FAI surgery helps patients with symptoms and documented inability to participate in desired activities.	The EbGS is aware of this, but does not reach its conclusions based on the decisions of other payers.
	6	The United Kingdom’s National Institute for Clinical Excellence released guidance in September 2011 and July 2011, respectively, on arthroscopic and open surgery for FAI stating published evidence is adequate that surgery in symptomatic patients results in short- and medium-term benefits.	<i>[For EBGS to consider, since this trusted source document (NICE) conflicts with the base guidance document (WA HTA)]</i>
	7	Since 2008, six independent systematic reviews of FAI surgery for symptomatic patients each concludes that published evidence support its safety and effectiveness. ²¹⁻²⁶ Additional favorable reports have subsequently been published. ^{7, 19, 27-34} There are no unfavorable reports.	Refs #7, 21-26 were all published before the date of the WA HTA evidence review (last search date June 2011). See comment #2 regarding ref #19. Ref #27 is a case series, N=200, 19 month follow up, arthroscopy. Ref # 28 is an uninterrupted prospective case series, N=120, 1 year follow up, minimally invasive approach. Ref #29 is case series, N=44, athletes, mini-open approach, 1 year

HERC Coverage Guidance – Hip Surgery Procedures for Femoroacetabular Impingement (FAI) Syndrome Disposition of Public Comments

Stakeholder	#	Comment	Disposition
			<p>FU.</p> <p>Ref #30 is retrospective case series, N=184, open approach, follow up 2-10 years.</p> <p>Ref #31 is a review that compared outcomes based on approach. Included 31 studies, concluded that all three approaches are comparable for functional results, biomechanics and return to sport, but that open and mini-open approaches are contraindicated in patients with severe OA.</p> <p>Ref #32 is prospective, consecutive case series, N=60, ages 11-16, arthroscopic approach, FU 2 years.</p> <p>Ref #33 is prospective, consecutive case series, N=153, age >50, arthroscopic approach, FU 1-3 years.</p> <p>Ref #34 compared patients with FAI and labral tears treated with either labral resection or labral repair.</p>
	8	<p>Over 46 peer-reviewed publications for symptomatic FAI using arthroscopic, open or a combination of these surgeries report patients' symptoms are relieved and the majority of patients are capable of returning to their previous level of activity.^{1-3, 5-11, 13, 14, 17-19, 27-60} Arthroscopic surgery for FAI was associated with the lowest overall risk of complications.</p>	<p>Refs #35-58 and 60 were published before the date of the WA HTA evidence review (last search date June 2011). The EbGS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded based on transparent, reproducible criteria, therefore the EbGS does not investigate individual studies published before the date of the review. The EbGS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.</p> <p>Ref #59 is a consecutive prospective case series, N=100, 2 year FU, arthroscopic approach.</p>
	9	<p>Among these publications, 21 reports with collectively over 1300 patients document favorable surgical outcomes in 75 to 100 percent of symptomatic FAI patients who had failed non-surgical management comprised of medication, reduced activity and physical therapy or rehabilitation programs lasting up to and over one-year. Typical patients have been able to return to recreational and work activities within months and professional athletes have had their careers extended.^{1-5, 7-14, 17-19, 27, 29, 32, 51, 59}</p>	<p>There are no RCTS of surgery for FAI compared to conservative care, or comparing different surgical treatments for FAI.</p>

HERC Coverage Guidance – Hip Surgery Procedures for Femoroacetabular Impingement (FAI) Syndrome Disposition of Public Comments

Stakeholder	#	Comment	Disposition
	10	A cost-effectiveness analysis ²⁰ of FAI surgery compared to observation for patients with symptomatic FAI, with an endpoint of delaying total hip replacement surgery, found FAI surgery to be very cost-effective according to the definition of cost-effectiveness used by the World Health Organization.	See comment #3 regarding Ref #20.
	11	Failure to cover hip surgeries for FAI will prevent patients who are suffering from chronic pain and lifestyle altering disability from having access to surgeries found, by near unanimous preponderance of best available peer-reviewed evidence, reasonable, safe, effective and medically necessary. We urge you to act in the best interest of your patients and reverse the no coverage recommendation.	This evidence base includes only one retrospective study comparing surgery vs. conservative care, and 4 retrospective studies comparing various surgical treatments for FAI. Per the authors of the WA HTA, “The results of these studies should be taken with caution. The fact that these studies (1) are retrospective cohorts mostly using historical controls, (2) did not clearly account for all excluded patients, and (3) only included patients who completed follow-up or who had complete clinical and radiographic data creates the potential for selection, performance and attrition bias. Selection bias is an inherent problem with cohort studies since systematic differences arise from self selection or physician-directed selection of treatments. In these cases, selecting patients for inclusion based on the completeness of the data in one’s database is likely to produce a subset of patients that are different than patients not in the database but who received the treatment of interest. Performance bias in these studies is a real possibility due to the use of historical controls. For example, differences in the level and competency of care may exist between historical controls and those treated with more current and improved surgical methods or by surgeons who have acquired more experience over time. Finally, attrition bias can result when those who do not return for final follow-up are systematically different from those who remain in the study, thus changing the overall group characteristic in a way that is unable to be controlled or accounted for.” The remainder of the evidence base consists of case series.
<i>Professional Society</i> Portland, OR	12	Our members are medical and osteopathic physicians specializing in orthopaedics and practicing throughout Oregon. I want to express our objection to the above-referenced Coverage Guidance. We urge the Commission to consider the fact that since 2008, six independent systematic reviews of FAI surgery have concluded that published evidence supports	Thank you for your comment. Please see response to comments #7 and #11.

HERC Coverage Guidance – Hip Surgery Procedures for Femoroacetabular Impingement (FAI) Syndrome Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		<p>its safety and effectiveness. More than forty peer-reviewed publications for symptomatic FAI using arthroscopic, open, or a combination of these surgeries report that patients' symptoms are relieved and they are able to return to work and other activities. We urge the Commission to hold a hearing and review this information. We believe that evidence clearly shows that surgical treatment of FAI can in fact provide long-lasting relief from pain and be cost-effective by reducing or eliminating a patient's need for costly pain relieving medication.</p> <p>We urge the Commission to re-consider the proposed Coverage Guidance on Hip Surgical Procedures for FAI, so that these procedures can remain an option for Oregon patients.</p> <p>Thank you for your consideration of our objections.</p>	
<i>Professional Society</i> Washington, D.C.	13	<p>Thank you for the opportunity to comment on the draft guidance regarding hip surgery procedures for Femoroacetabular Impingement Syndrome (FAI). The American Association of Orthopaedic Surgeons represents 98% of the orthopaedic surgeons practicing in the United States, 368 of whom practice in Oregon. Orthopaedic surgeons are the preeminent physicians providing medical treatment of musculoskeletal conditions and disease. I currently serve as the President of the AAOS and have practiced in Tualatin, Oregon for more than 30 years.</p>	Thank you for this information.
	14	<p>The AAOS firmly supports the incorporation of evidence into clinical practice, and is actively involved in developing and promoting Evidence Based Clinical Practice Guidelines for a number of musculoskeletal conditions. However, the AAOS opposes the proposed “no coverage” determination because we do not believe this decision is consistent with evidence showing that hip arthroscopy is a cost-effective treatment for the management of FAI Syndrome. Surgical treatment of FAI can provide long-lasting symptom relief and allows patients to return to work or other desired activities without lifestyle modification.</p>	Thank you for your comment. Please see response to comment #11.
	15	<p>The American Medical Association concluded that FAI surgery is clinically effective, granting three Category 1 CPT codes effective January 2011. One criterion for granting Category 1 CPT codes is that “the clinical efficacy of the service/procedure is well established and documented in U.S. peer reviewed literature.” The AAOS believes that if a service or procedure has a Category I CPT code, it is not experimental or investigational. Therefore, payers should not deny reimbursement for these services and procedures when they are medically necessary by claiming that they are experimental or investigational. When payers do otherwise, they</p>	Please see response to comment #4.

HERC Coverage Guidance – Hip Surgery Procedures for Femoroacetabular Impingement (FAI) Syndrome Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		threaten the health of the public and unjustifiably interfere with the physician/patient relationship.	
	16	All national U.S. commercial insurers cover FAI surgery because it has been shown to be clinically effective. This includes Aetna, which the Washington Health Technology Assessment claims does not cover FAI surgery. Aetna’s current health technology appraisal not only recommends coverage of FAI procedures, but also cites the Washington HTA as the only study among dozens that recommends against its clinical effectiveness.	The EbGS appreciates you alerting us that the WA HTA report is erroneous in its claims about Aetna coverage policy. Please see response to comment #5.
	17	Since 2008, six independent systematic reviews of FAI surgery have concluded that published evidence supports its safety and effectiveness. More than 40 peer-reviewed publications for symptomatic FAI using arthroscopic, open, or a combination of these surgeries report that patients’ symptoms are relieved and they are able to return to their normal activity levels.	The primary evidence base for this topic consists almost exclusively of case series. Systematic reviews of low quality studies do not provide strong evidence of efficacy or effectiveness. Please see response to comment #11.
	18	The AAOS urges the Committee to revise its coverage guidance on hip surgery procedures for Femoroacetabular Impingement Syndrome to be consistent with the vast majority of other coverage determinations and provide access to this safe, effective, and cost-effective treatment to Oregon’s public employees and Oregon Health Plan participants. Thank you for your consideration of these comments.	

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: ELECTIVE DELIVERY: INDUCTION OF LABOR

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Induction of labor *should be* covered for the following indications:

- Gestational age beyond 41 0/7 weeks
- Prelabor rupture of membranes at term
- [Diabetes, pre-existing and gestational](#)

Induction of labor *should not be* covered for:

- Macrosomia (in the absence of maternal diabetes)
- Elective purposes (without a medical or obstetrical indication)
- [Breech](#)
- [Logistical reasons \(except history of precipitous labor when a woman lives > ___ hours away from nearest maternity care facility\)](#)

For those indications for which there is insufficient evidence, an individualized treatment plan taking into account maternal and infant health should be developed. These indications include:

- Preterm, prelabor rupture of membranes
- Cholestasis of pregnancy
- Mild and severe preeclampsia
- Eclampsia
- Suspected IUGR (preterm and term)
- Gastroschisis
- Twin gestation
- ~~Gestational diabetes treated with insulin~~
- [Placental abruption](#)
- [Chorioamnionitis](#)
- [Maternal medical conditions \(eg. renal disease, chronic pulmonary disease, chronic hypertension, cardiac disease, antiphospholipid syndrome\)](#)
- [Gestational hypertension](#)
- [Fetal compromise \(eg. severe fetal growth restriction, isoimmunization, oligohydramnios\)](#)
- [Fetal demise](#)

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Health Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

King, V., Pilliod, R., & Little, A. (2010). *Rapid review: Elective induction of labor*. Portland: Center for Evidence-based Policy. Available at: <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/index.cfm>

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

The use of induction of labor (IOL) in the U.S. doubled between 1990 and 2006. Rates of labor induction vary substantially from state to state, from a low of 13.2% (California) to a high of 35.2% (Utah). The rate of increase in medically indicated IOL has been slower than the overall increase, suggesting that the increase in elective inductions has been more rapid. The increase in the overall use of induction is likely multifactorial. There appear to have been shifts in the threshold for induction at earlier gestations with both medically indicated and elective IOL. The practices and preferences of individual physicians also have an effect on the use of IOL and the subsequent risk of cesarean delivery. Women's requests may also contribute to increased demand for elective induction of labor (EIOL).

Evidence Review

Systematic reviews of randomized controlled trials find either a slight increase in cesarean delivery or no effect with EIOI, but there is some evidence of increased risk of operative vaginal delivery. Observational studies using spontaneous labor control groups find increased risk of cesarean delivery for nulliparous women with number needed to harm (NNH) of 4 to 10. Multiparous women may also have an increased risk of cesarean delivery with a NNH of 62 based on one study. Cesarean delivery is increased particularly among nulliparous women who have a low Bishop score (a measure of readiness for labor) at the time of EIOI and receive preinduction cervical ripening. Infants face an increased risk of admission to a neonatal intensive care unit (NICU) if their mothers undergo EIOI prior to 39 weeks of gestation. The length of active labor may be shorter with EIOI, although the total time spent on a labor and delivery unit or in the hospital may be greater. Most commonly cited indications for IOI are not well supported by evidence.

Evidence-supported indications and contraindications

Indications with net benefit

The only indications for induction of labor supported by strong evidence of net benefit are gestational age beyond 41 weeks and prelabor rupture of membranes at term.

Indications with net harm

The only indication for which there is evidence of harm is suspected macrosomia, for which there is no evidence of improved fetal outcomes, but an increase in the risk of cesarean section.

Indications with insufficient evidence

The other indications for induction of labor that were considered in the evidence report but have insufficient evidence to make strong recommendations include the following:

- Preterm, prelabor rupture of membranes
- Cholestasis of pregnancy
- Mild and severe preeclampsia
- Eclampsia
- Suspected IUGR (preterm and term)
- Gastroschisis
- Twin gestation
- Oligohydramnios
- Gestational diabetes treated with insulin
- Maternal cardiac disease

Quality improvement programs targeted at eliminating inappropriate EIOL can be effective at reducing cesarean delivery outcomes, particularly for nulliparous women with a low Bishop score.

Recommendations from Others

The *American College of Obstetrics and Gynecology (ACOG)* identifies the specific indications for induction of labor, including but not limited to the conditions listed below:

- Premature rupture of membranes
- Eclampsia, preeclampsia, gestational hypertension
- Fetal compromise (severe IUGR, isoimmunization, oligohydramnios)
- Placental abruption
- Chorioamnionitis
- Maternal medical conditions (eg. diabetes, renal disease, chronic pulmonary disease, chronic hypertension, cardiac disease, antiphospholipid syndrome)
- Fetal compromise (eg, severe fetal growth restriction, isoimmunization, oligohydramnios)
- Post-term pregnancy
- Logistical reasons (risk for rapid labor, distance from hospital)

In addition, for patients with gestational diabetes, they state the following:

No good evidence to support routine delivery before 40 weeks of gestation. There are no data to support a policy of cesarean delivery purely on the basis of GDM. It would appear reasonable to recommend that patients with GDM be counseled regarding possible cesarean delivery without labor when the estimated fetal weight is 4,500 g or greater.

For patients with pregestational diabetes, they state:

Early delivery may be indicated in some patients with vasculopathy, nephropathy, poor glucose control, or a prior stillbirth. In contrast, patients with well-controlled diabetes may be allowed to progress to their expected date of delivery as long as antenatal testing remains reassuring. Expectant management beyond the estimated due date generally is not recommended. Cesarean delivery may be considered if the estimated fetal weight is greater than 4,500 g in women with diabetes. Induction of labor in pregnancies with a fetus with suspected macrosomia has not been found to reduce birth trauma and may increase the cesarean delivery rate.

For suspected fetal macrosomia, they state:

Recent large cohort and case–control studies demonstrate the safety of allowing a trial of labor for estimated birth weights of more than 4,000 g. Despite the poor predictive value of an estimated fetal weight beyond 5,000 g and a lack of

evidence supporting cesarean delivery at any estimated fetal weight, most, but not all, authors agree that consideration should be given to cesarean delivery in this situation.

For breech presentation, they state:

Mode of delivery should depend on the experience of the healthcare provider. Cesarean will be the preferred mode for most physicians. Planned vaginal delivery may be reasonable. (No comment regarding induction)

The *National Institute for Clinical Excellence (NICE)* has the following recommendations regarding induction of labor:

Induction of labor should be offered in the following circumstances:

- Post-term pregnancy
- Preterm, prelabor rupture of membranes after 34 weeks
- Prelabor rupture of membranes at term after 24 hours
- Maternal diabetes, any type (after 38 completed weeks gestation)

Induction of labor should not be routinely offered in the following circumstances:

- Maternal request
- Breech presentation
- Severe IUGR
- History of precipitous labor
- Suspected macrosomia

Induction of labor may be offered depending on the desires of the patient in the following circumstances:

- Fetal demise

Indications for which there are contradictory recommendations between ACOG and NICE are the following:

- Severe IUGR
- History of precipitous labor
- Maternal diabetes (after 38 completed weeks gestation)

Overall Summary

EIOL likely increases the risk of Cesarean section in nulliparous women, and possibly in multiparous women. It also increases the risk of operative delivery. EIOL at less than 39 weeks increases the risk of NICU admission for infants. EIOL has strong evidence of net benefit for gestational age over 41 weeks and prelabor rupture of membranes, while

EIOL for macrosomia is the only indication for which there is evidence of net harm. There are a number of indications for EIOL for which there is insufficient evidence of net benefit or harm. Indications for which there is conflicting recommendations include the severe IUGR, maternal diabetes and history of precipitous labor, although the latter likely reflects differences in the health care delivery system.

[\[Evidence Source\]](#)

PROCEDURE

Elective Induction of Labor

DIAGNOSES

Pregnancy

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
650	Normal delivery
659.0	Failed mechanical induction
659.1	Failed medical or unspecified induction
V22.0	Supervision of normal first pregnancy
V22.1	Supervision of other normal pregnancy
V22.2	Pregnant state, incidental
V30	Single liveborn
V39	Liveborn unspecified whether single twin or multiple
ICD-10 Diagnosis Codes	
O80	Single spontaneous delivery
Z34.0	Supervision of normal first pregnancy
Z34.8	Supervision of other normal pregnancy
Z34.9	Supervision of normal pregnancy, unspecified
ICD-9 Volume 3 (procedure codes)	
Other procedures inducing or assisting delivery	
73.0	Artificial rupture of membranes
73.1	Other surgical induction of labor: Induction by cervical dilation
73.4	Medical induction of labor
Forceps, vacuum, and breech delivery	
72.0 – 72.9	Forceps, vacuum, and breach delivery
Cesarean section and removal of fetus	
74.0 – 74.4, 74.9	Cesarean section and removal of fetus
CPT Codes	
Dilation	
57800	Dilation of cervical canal, instrumental (separate procedure)

CODES	DESCRIPTION
59200	Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure)
Infusions	
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
96366	Intravenous infusion for therapy, prophylaxis, or diagnosis; each additional hour
96367	Each additional sequential infusion up to 1 hour
96368	Concurrent infusion
Care associated with vaginal delivery	
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care
59409	Vaginal delivery only, with or without postpartum care
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
59612, 59614	Vaginal delivery only, after previous cesarean delivery
Care associated with Cesarean	
59510	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care
59514	Cesarean Delivery only
59515	Cesarean Delivery only, including postpartum care 59618: Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
59620	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery.
59622	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery. Including postpartum care
HCPCS Level II Codes	
J2590	Pitocin 10 units. [NOTE: Appears in a listing of "Drugs Administered Other Than Oral Method J0000-J9999."]
S0191	Misoprostol, oral, 200 mcg [NOTE: Appears in a listing of Temporary National Codes (Non-Medicare), S0012-S9999)

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HERC Coverage Guidance – Elective Delivery: Induction of Labor Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
Physician (OB/GYN) FACOG Portland, OR	1	I applaud HERC in reviewing induction of labor as there is a definite rise in inappropriate inductions of labor and increased rates of Cesarean Sections. However, making 41 weeks the absolute minimum for induction of labor discounts multiple levels of healthcare. Having practiced in both large and small hospitals, there are many factors to consider with induction of labor. In smaller hospitals, it is important to manage your labor and delivery units since there are a limited number of beds and nurses. If there is a hard stop of 41 weeks it can make for unsafe situations in which there are not sufficient resources to manage these patients especially 10 months after an ice storm that reeks havoc on the coast (as was seen several years ago with larger than normal amounts of babies due to hospitals not used to those volumes). Also, there are patients who live remotely from the hospital or who have histories of rapid labors (< 2 hours) who are better served by being able to control their labors in the safety of the hospital. In ACOG's bulletin on Induction of labor, August 2009, the following indications were included for induction of labor: <ul style="list-style-type: none"> • Abruptio placentae • Chorioamnionitis • Fetal demise • Gestational hypertension • Preeclampsia, eclampsia • Premature rupture of membranes • Postterm pregnancy • Maternal medical conditions (eg, diabetes mellitus, renal disease, chronic pulmonary disease, chronic hypertension, antiphospholipid syndrome) • Fetal compromise (eg, severe fetal growth restriction, isoimmunization, oligohydramnios) 	The EbGS is unaware of evidence to support the claim that hospitals in Oregon have insufficient resources to manage spontaneous labor. Thank you for providing the subcommittee the ACOG indications for IOL. While not all of these indications are supported by the evidence, the subcommittee has included additional indications and modified the coverage document to reflect individualized treatment of several of them.
	2	Labor also may be induced for logistic reasons, for example, risk of rapid labor, distance from hospital, or psychosocial indications. In such circumstances, at least one of the gestational age criteria in the box should be met, or fetal lung maturity should be established." I think that allowing a patient and her physician to determine what is in the best interests of each particular patient is important. Some women have a history of sexual abuse and the bond they have with their particular provider is critical to a successful vaginal birth. If their provider cannot be there because they are on vacation or not working at 41w0d hard stop then that patient's needs have not be adequately met and we have not served this woman. I understand the need to control costs and improve outcomes, but there is an art to medicine and this is no different in the vastly complex delivery of obstetrical care. It is made even more complicated by the medical legal climate surround Obstetrical care. I urge this committee to take that all into consideration.	The EbGS appreciates "the art of medicine" but finds the need to make policy that is informed by the evidence more compelling.
	3	I think that following the Portland hospitals minimum for elective induction of labor of at least 39 weeks would be a suggested step to help reduce number of elective inductions and improve fetal outcomes. This is recommended by ACOG in December 2011 as well.	The EbGS agrees with this initiative, but believes the evidence supports a more conservative standard.

Comparison of recommendations for Induction, selected conditions

NICE Recommendation	NICE level of evidence ⁱ	ACOG Position
Fetal Demise- In the event of an intrauterine fetal death, if the woman appears to be physically well, her membranes are intact and there is no evidence of infection or bleeding, she should be offered a choice of immediate induction of labour or expectant management.	None identified	Labor induction, if second trimester D&E not available or not desired by patient. C/S should be reserved for unusual circumstances.
Gestational DM- Pregnant women with diabetes who have a normally grown fetus should be offered elective birth through induction of labor, or by elective caesarean section if indicated, after 38 completed weeks.	1+ to 2-	No good evidence to support routine delivery before 40 weeks of gestation. There are no data to support a policy of cesarean delivery purely on the basis of GDM. It would appear reasonable to recommend that patients with GDM be counseled regarding possible cesarean delivery without labor when the estimated fetal weight is 4,500 g or greater.
Pregestational DM Pregnant women with diabetes who have a normally grown fetus should be offered elective birth through induction of labor, or by elective caesarean section if indicated, after 38 completed weeks.	1+ to 2-	Early delivery may be indicated in some patients with vasculopathy, nephropathy, poor glucose control, or a prior stillbirth. In contrast, patients with well-controlled diabetes may be allowed to progress to their expected date of delivery as long as antenatal testing remains reassuring. Expectant management beyond the estimated due date generally is not recommended. Cesarean delivery may be considered if the estimated fetal weight is greater than 4,500 g in women with diabetes. Induction of labor in pregnancies with a fetus with suspected macrosomia has not been found to reduce birth trauma and may increase the cesarean delivery rate.
Chronic Hypertension (no other chronic diseases identified) – No comment		Women with chronic hypertension who are not taking medications, give birth at 38–39 weeks of gestation, women whose hypertension is controlled with medications should give birth at 37–39 weeks of gestation, and women with severe

NICE Recommendation	NICE level of evidence ⁱ	ACOG Position
		hypertension that is difficult to control should give birth at 36–37 weeks of gestation.
Fetal macrosomia- In the absence of any other indications, induction of labour should not be carried out simply because a healthcare professional suspects a baby is large for gestational age	1++ to 2+	Recent large cohort and case–control studies demonstrate the safety of allowing a trial of labor for estimated birth weights of more than 4,000 g. Despite the poor predictive value of an estimated fetal weight beyond 5,000 g and a lack of evidence supporting cesarean delivery at any estimated fetal weight, most, but not all, authors agree that consideration should be given to cesarean delivery in this situation.
Breech -Induction of labour is not generally recommended if a woman’s baby is in the breech presentation.	1+	Mode of delivery should depend on the experience of the healthcare provider. Cesarean will be the preferred mode for most physicians. Planned vaginal delivery may be reasonable.
History of precipitous labor- Induction of labour to avoid a birth unattended by healthcare professionals should not be routinely offered to women with a history of precipitate labour.	None identified	Labor may be induced for logistical reasons, such as risk of rapid labor or distance from hospital
Distance residing from hospital - No comment		Labor may be induced for logistical reasons, such as risk of rapid labor or distance from hospital

ⁱ NICE levels of evidence:

1++ High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1– Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies; high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2– Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies (for example, case reports, case series)

4 Expert opinion, formal consensus

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: ROUTINE ULTRASOUND IN PREGNANCY

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Routine ultrasound for average risk pregnant women should be covered only:

- Once in the first trimester for the purpose of identifying fetal aneuploidy or anomaly (between 11 and 13 weeks of gestation) and/or dating confirmation. [In some instances, if a patient's LMP is truly unknown, a dating ultrasound may be indicated and should be covered prior to an aneuploidy screen.](#)
- Once for the purpose of anatomy screening after 18 weeks gestation

Only one [type](#) of [routine prenatal](#) ultrasound should be covered in a single day (*i.e. transvaginal or abdominal*).

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Health Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2010). Ultrasonography (ultrasound) in pregnancy: Health technology assessment. Retrieved from http://www.hta.hca.wa.gov/documents/final_report_ultrasound.pdf

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Ultrasound (US) is used in prenatal care as a diagnostic tool for monitoring fetal development and maternal health outcomes. During the first trimester (6 days of gestation up to 13 weeks) an US may be performed for a variety of reasons, including estimation of gestational age diagnosis, evaluation of multiple gestations, or measurement of markers for fetal aneuploidy (abnormal chromosome number). In the second trimester (between 16 weeks and 22 weeks), US is performed to assess anatomical fetal growth and development (fetal anatomical survey), screen for markers for fetal aneuploidy, estimate fetal weight, detect and evaluate gynecological abnormalities, and detect fetal anatomical abnormalities. In the United States, routine US is not typically performed in the third trimester unless the pregnancy is considered a high-risk pregnancy or a specific indication has developed.

Although high-risk pregnancies are not precisely defined, they include such conditions as age ≥ 35 years at delivery, diabetes mellitus, asthma, hypertension, previous pregnancy loss, preeclampsia, fetal intrauterine growth restriction (IUGR), premature rupture of membranes, multiple pregnancy, preterm labor, and postterm pregnancy. All of these conditions may require US to monitor either fetal or maternal well-being. In addition, assessment of cervical length by transvaginal ultrasound (TVU) has been tested as a screening method for women at risk of preterm labor. If short cervix is confirmed, the clinician can administer treatment to delay birth and to prevent perinatal respiratory distress.

Evidence Review

Accuracy: The literature suggests that US has variable accuracy, depending on the target condition. As a screening tool, it is often combined with other tests. Sensitivities of 40% to 99% have been reported, but information about specificity, positive predictive value, and negative predictive value is limited. Evidence addressing the differential accuracy of transabdominal vs. transvaginal US was not identified.

Effectiveness in High-Risk Pregnancy: The evidence provides some support for the use of Doppler US to monitor high-risk patients (which conditions are considered high risk are not specified). The use of TVU to identify patients in need of prophylactic treatment because of imminent risk of preterm birth is also supported by the evidence, but the use of TVU surveillance in women with a history of preterm birth is not.

Effectiveness in Low-Risk Pregnancy, Early Screening: Routine US in early pregnancy (< 24 weeks) does not change patient management, substantially alter delivery modes, or improve health outcomes, at least not in high-resource settings. Routine US doubles the rate of abortion for fetal anomaly, but the estimated absolute increase is 0.10 percentage point.

Effectiveness in Low-Risk Pregnancy, Late Screening: Evidence has not shown routine US in late pregnancy (> 24 weeks) to change patient management, affect delivery mode, or improve health outcomes.

Safety: Evidence for major outcomes has shown US to be a reasonably safe procedure with no serious short-term adverse effects. There is no association between US and childhood cancers, and no impact on developmental outcomes after birth with the exception of an increase in the risk of non-right-handedness in boys.

Differential Effectiveness and Safety: Routine US performed between 14 weeks and 24 weeks (second trimester) is most likely to detect multiple births and to reduce the frequency of induction of labor, compared with US at other gestational ages. However, there is no differential effect by gestational age on perinatal mortality.

[\[Evidence Source\]](#)

Overall Summary

The accuracy of ultrasound is variable, and it may be helpful in monitoring some high-risk pregnancies. In the case of identified fetal anomalies, ultrasound can alter pregnancy management. Otherwise, ultrasound does not change treatment plans, alter delivery modes or improve health outcomes in low-risk pregnancies.

PROCEDURE

Obstetrical ultrasound

DIAGNOSES

Pregnancy

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
V22	Normal pregnancy V22.0. Supervision of normal first pregnancy V22.1 Supervision of other normal pregnancy V22.2 Pregnant state, incidental
V23	Supervision of high-risk pregnancy V23.0 Pregnancy with history of V23.1 Pregnancy with history of trophoblastic disease

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
	V23.2 Pregnancy with history of abortion V23.3 Grand multiparity V23.4 Pregnancy with other poor obstetric history V23.41 Pregnancy with history of pre-term labor V23.49 Pregnancy with other poor obstetric history V23.5 Pregnancy with other poor reproductive history V23.7 Insufficient prenatal care V23.8 Other high-risk pregnancy V23.81 Elderly primigravida V23.82 Elderly multigravida V23.83 Young primigravida V23.84 Young multigravida V23.85 Pregnancy resulting from assisted reproductive technology V23.86 Pregnancy with history of in utero procedure during previous pregnancy V23.89 Other high-risk pregnancy V23.9 Unspecified high-risk pregnancy
640	Hemorrhage in early pregnancy 640.0 Threatened abortion 640.8 Other specified hemorrhage in early pregnancy 640.9 Unspecified hemorrhage in early pregnancy
641	Antepartum hemorrhage, abruptio placentae, and placenta previa 641.0 Placenta previa without hemorrhage 641.1 Hemorrhage from placenta previa 641.2 Premature separation of placenta 641.3 Antepartum hemorrhage associated with coagulation defects 641.8 Other antepartum hemorrhage 641.9 Unspecified antepartum hemorrhage
642	Hypertension complicating pregnancy, childbirth, and the puerperium 642.0 Benign essential hypertension complicating pregnancy, childbirth, and the puerperium 642.1 Hypertension secondary to renal disease, complicating pregnancy, childbirth, and the puerperium 642.2 Other pre-existing hypertension complicating pregnancy, childbirth, and the puerperium 642.3 Transient hypertension of pregnancy 642.4 Mild or unspecified pre-eclampsia 642.5 Severe pre-eclampsia 642.6 Eclampsia 642.7 Pre-eclampsia or eclampsia superimposed on pre-existing hypertension 642.9 Unspecified hypertension complicating pregnancy, childbirth, or the puerperium
643	Excessive vomiting in pregnancy 643.0 Mild hyperemesis gravidarum 643.1 Hyperemesis gravidarum with metabolic disturbance 643.2 Late vomiting of pregnancy 643.8 Other vomiting complicating pregnancy 643.9 Unspecified vomiting of pregnancy
644	Early or threatened labor 644.0 Threatened premature labor

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
	644.1 Other threatened labor 644.2 Early onset of delivery
645	Late pregnancy 645.1 Post term pregnancy 645.2 Prolonged pregnancy
646	Other complications of pregnancy, not elsewhere classified 646.0 Papyraceous fetus 646.1 Edema or excessive weight gain in pregnancy, without mention of hypertension 646.2 Unspecified renal disease in pregnancy, without mention of hypertension 646.3 Recurrent pregnancy loss 646.4 Peripheral neuritis in pregnancy 646.5 Asymptomatic bacteriuria in pregnancy 646.6 Infections of genitourinary tract in pregnancy 646.7 Liver disorders in pregnancy 646.8 Other specified complications of pregnancy 646.9 Unspecified complication of pregnancy
647	Infectious and parasitic conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium 647.0 Syphilis 647.1 Gonorrhoea 647.2 Other venereal diseases 647.3 Tuberculosis 647.4 Malaria 647.5 Rubella 647.6 Other viral diseases 647.8 Other specified infectious and parasitic diseases 647.9 Unspecified infection or infestation
648	Other current conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium 648.0 Diabetes mellitus 648.1 Thyroid dysfunction 648.2 Anemia 648.3 Drug dependence 648.4 Mental disorders 648.5 Congenital cardiovascular disorders 648.6 Other cardiovascular diseases 648.7 Bone and joint disorders of back, pelvis, and lower limbs 648.8 Abnormal glucose tolerance 648.9 Other current conditions classifiable elsewhere
649	Other conditions or status of the mother complicating pregnancy, childbirth, or the puerperium 649.0 Tobacco use disorder complicating pregnancy, childbirth, or the puerperium 649.1 Obesity complicating pregnancy, childbirth, or the puerperium 649.2 Bariatric surgery status complicating pregnancy, childbirth, or the puerperium 649.3 Coagulation defects complicating pregnancy, childbirth, or the puerperium 649.4 Epilepsy complicating pregnancy, childbirth, or the puerperium 649.5 Spotting complicating pregnancy 649.6 Uterine size date discrepancy

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
	649.7 Cervical shortening
651	Multiple gestation 651.0 Twin pregnancy 651.1 Triplet pregnancy 651.2 Quadruplet pregnancy 651.3 Twin pregnancy with fetal loss and retention of one fetus 651.4 Triplet pregnancy with fetal loss and retention of one or more fetus(es) 651.5 Quadruplet pregnancy with fetal loss and retention of one or more fetus(es) 651.6 Other multiple pregnancy with fetal loss and retention of one or more fetus(es) 651.7 Multiple gestation following (elective) fetal reduction 651.8 Other specified multiple gestation 651.9 Unspecified multiple gestation
652	Malposition and malpresentation of fetus 652.0 Unstable lie 652.1 Breech or other malpresentation successfully converted to cephalic presentation 652.2 Breech presentation without mention of version 652.3 Transverse or oblique presentation 652.4 Face or brow presentation 652.5 High head at term 652.6 Multiple gestation with malpresentation of one fetus or more 652.7 Prolapsed arm 652.8 Other specified malposition or malpresentation 652.9 Unspecified malposition or malpresentation
653	Disproportion 653.0 Major abnormality of bony pelvis, not further specified 653.1 Generally contracted pelvis 653.2 Inlet contraction of pelvis 653.3 Outlet contraction of pelvis 653.4 Fetopelvic disproportion 653.5 Unusually large fetus causing disproportion 653.6 Hydrocephalic fetus causing disproportion 653.7 Other fetal abnormality causing disproportion 653.8 Disproportion of other origin 653.9 Unspecified disproportion
654	Abnormality of organs and soft tissues of pelvis 654.0 Congenital abnormalities of uterus 654.1 Tumors of body of uterus 654.2 Previous cesarean delivery 654.3 Retroverted and incarcerated gravid uterus 654.4 Other abnormalities in shape or position of gravid uterus and of neighboring structures 654.5 Cervical incompetence 654.6 Other congenital or acquired abnormality of cervix 654.7 Congenital or acquired abnormality of vagina 654.8 Congenital or acquired abnormality of vulva 654.9 Other and unspecified
655	Known or suspected fetal abnormality affecting management of mother

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
	655.0 Central nervous system malformation in fetus 655.1 Chromosomal abnormality in fetus 655.2 Hereditary disease in family possibly affecting fetus 655.3 Suspected damage to fetus from viral disease in the mother 655.4 Suspected damage to fetus from other disease in the mother 655.5 Suspected damage to fetus from drugs 655.6 Suspected damage to fetus from radiation 655.7 Decreased fetal movements 655.8 Other known or suspected fetal abnormality, not elsewhere classified 655.9 Unspecified
656	Other known or suspected fetal and placental problems affecting management of mother 656.0 Fetal-maternal hemorrhage 656.1 Rhesus isoimmunization 656.2 Isoimmunization from other and unspecified blood-group incompatibility 656.3 Fetal distress 656.4 Intrauterine death 656.5 Poor fetal growth 656.6 Excessive fetal growth 656.7 Other placental conditions 656.8 Other specified fetal and placental problems 656.9 Unspecified fetal and placental problem
657	Polyhydramnios
658.0	Oligohydramnios
659.4	Grand multiparity
659.5	Elderly primigravida
659.6	Elderly multigravida
659.7	Abnormality in fetal heart rate or rhythm
678	Other fetal conditions 678.0 Fetal hematologic conditions 678.1 Fetal conjoined twins
679	Complications of in utero procedures 679.0 Maternal complications from in utero procedure 679.1 Fetal complications from in utero procedure
ICD-9 Volume 3 (procedure codes)	
None	

CODES	DESCRIPTION
CPT Codes	
76801	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (< 14 weeks 0 days), transabdominal approach; single or first gestation
76802	each additional gestation (+76801)
76805	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (≥ 14 weeks 0 days), transabdominal approach; single

	or first gestation
76810	each additional gestation (+76805)
76811	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation
76812	each additional gestation (+76811)
76813	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation
76814	each additional gestation (+76813)
76815	Ultrasound, pregnant uterus, real time with image documentation, limited (eg, fetal heart beat, placental location, fetal position and/or qualitative amniotic fluid volume), 1 or more fetuses
76816	Ultrasound, pregnant uterus, real time with image documentation, follow-up (eg, re-evaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, re-evaluation of organ system(s) suspected or confirmed to be abnormal on a previous scan), transabdominal approach, per fetus
76817	Ultrasound, pregnant uterus, real time with image documentation, transvaginal
76818	Fetal biophysical profile; with non-stress testing
76819	without non-stress testing
HCPCS Codes	
None	

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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.

HERC Coverage Guidance – Routine Ultrasound in Pregnancy Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
Physician Family Medicine Portland, OR	1	Upon review of the Routine US in Pregnancy guideline, I only have the comment that for women who truly have unknown dating, and US may need to be performed twice in the first trimester - once to establish dating, and once to then do the genetic testing. You can only do the genetic testing once you know the dating, and if you choose to do the US too early or too late, you have precluded the patient's ability to get genetic testing covered by her insurance.	The EbGS understands the need for accurate dating and has modified the guidance document to reflect this.
Physician (OB/GYN) FACOG Portland, OR	2	In reviewing the HERC policy on routine ultrasound in pregnancy I have concerns about limiting to only one ultrasound before 14 weeks. The dating ultrasound which many of us perform around 6-8 weeks is critical to determine viability and more important dating. On a routine basis, I change someone's due date to that of the ultrasound. If their dating is incorrect it makes the timing of the 1st trimester screen for genetics impossible because they are too early or too late to receive this test thereby removing the diagnostic efficacy. Also, if someone's dating is incorrect, it can increase costs down the line in pregnancy with additional treatments. For instance, in my practice in residency we often had people who were unsure of their dates and had a late ultrasound that we were using for dating. Since the later one gets an ultrasound the more inaccurate it is, it led us to treat possibly non-preterm patients as preterm since we did not have better dating. The ability to perform an early ultrasound on a patient allows for the most accurate dating and overall decreased health costs.	The EbGS understands the need for accurate dating and has modified the guidance document to reflect this.
	3	Also, limiting an ultrasound to one per day concerns me as well. In some cases I have a patient who presents for pain and pregnancy and I am unable to visualize a gestational sac. I would then refer that patient onto radiology in the same day to rule out an ectopic pregnancy. An undiagnosed ectopic pregnancy is definitely more costly than having a second ultrasound.	<i>[For EbGS discussion]</i>
	4	I understand the need to limit ultrasounds, especially in practices where an ultrasound is being performed at each visit for no indication. However, those of us who practice evidence based medicine and are working to provide the best care for our patients are really limited by these guidelines.	Thank you for your comment.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: INDICATIONS FOR PLANNED CESAREAN SECTION

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Planned cesarean section (CS) should be covered for:

- Breech presentation (if external cephalic version unsuccessful or contraindicated; and vaginal breech delivery is unavailable, undesired, or contraindicated)
- Partial or complete placenta previa
- Morbidly adherent placenta
- Human immunodeficiency virus (HIV) positive mothers who are not receiving anti-retroviral therapy, are receiving anti-retroviral therapy and have a viral load of 400 copies per ml or more, or who are co-infected with Hepatitis C
- Primary herpes simplex virus infection in the third trimester
- [Twin pregnancy \(if the presenting twin is not vertex\)](#)

Planned CS should not be covered for:

- Preterm birth
- Small for gestational age
- Suspected cephalopelvic disproportion
- Maternal Hepatitis B infection
- Maternal Hepatitis C infection
- Elective (without obstetrical or medical indication)

For the following conditions, an individualized treatment plan taking into account maternal and infant health should be developed to determine if planned CS versus planned vaginal delivery are the appropriate route of delivery.

- [Twin pregnancy \(if the presenting twin is vertex\)](#)
- Herpes simplex virus recurrence at birth
- Body mass index over 50
- Prior CS delivery
- HIV positive mothers on highly active anti-retroviral therapy with a viral load less than 400 copies/ml, or on any anti-retroviral therapy with a viral load of less than 50 copies/ml
- [Macrosomia \(estimated fetal weight >4500g if diabetic, or >5000g if obese\)](#)

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
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Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Health Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCES

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SUMMARY OF EVIDENCE

Clinical Background

According to the National Center for Health Statistics, the national rate of CS reached 32.8 percent of all live births in 2010. The largest contributions to this rising rate are an increase in primary cesareans to a rate of 20.6 percent in 2004 and a steep decline in the rate of vaginal birth after cesarean (VBAC) from 28.3% in 1996 to 9.2% in 2004. Over ninety percent of women who have had a CS will deliver by repeat cesarean. This increase is not well explained by changes in the population risk profile. There is interest in understanding the factors underlying this increase and to understand to what extent primary planned CS done without an identifiable medical risk (elective CS) and CS by maternal request contribute to this rate. The best estimate is that between 4% and 18% of primary CS in the United States are elective.

Evidence Review

Elective Cesarean Delivery

The literature pertaining to the benefits and harms of cesarean delivery is limited by the lack of randomized trials that compare mode of *intended* delivery. Nearly all of the evidence compares outcomes based on actual delivery mode rather than intended mode of delivery, limiting the conclusions that can be drawn.

The MED report concluded that although much of the evidence is of low quality, the following outcomes are likely associated with elective CS:

- longer hospital stays;
- increased Neonatal Intensive Care Unit (NICU) admissions;
- increased neonatal respiratory problems; and
- maternal urinary or fecal incontinence is less likely in the short term, with no difference in longer term follow up.

The differences between an intended vaginal delivery group and an intended cesarean group are less marked for these outcomes at 39 or more weeks of gestation. Elective cesarean delivery likely has no benefit for urinary or fecal continence in the longer term, although immediate postpartum outcomes may favor elective CS. There are important downstream effects to consider in the performance of elective CS, most notably in maternal morbidity due to abnormal placentation. There are some important issues around quality of life such as post partum pain, recovery time, and postpartum mood which are important, but which have not been well studied as they apply to elective CS.

The 2010 MED report draws heavily from the AHRQ systematic review that was commissioned to inform the 2006 National Institute of Health (NIH) State of the Science Consensus Statement on Cesarean Delivery on Maternal Request, as well as the AHRQ review commissioned to inform the 2010 NIH Consensus Development Conference on Vaginal Birth after Cesarean: New Insights. The 2006 NIH consensus statement draws the following conclusions:

- There is insufficient evidence to evaluate fully the benefits and risks of cesarean delivery on maternal request as compared to planned vaginal delivery, and more research is needed.
- Until quality evidence becomes available, any decision to perform a cesarean delivery on maternal request should be carefully individualized and consistent with ethical principles.
- Given that the risks of placenta previa and accreta rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children.
- Cesarean delivery on maternal request should not be performed prior to 39 weeks of gestation because of the significant danger of neonatal respiratory complications.
- Maternal request for cesarean delivery should not be motivated by unavailability of effective pain management. Efforts must be made to assure availability of pain management services for all women.

The majority of planned CS in the United States are performed for women who have a prior history of cesarean birth. The 2010 AHRQ systematic review Vaginal Birth after Cesarean: New Insights concluded the following:

“Each year 1.5 million childbearing women have cesarean deliveries, and this population continues to increase. This report adds stronger evidence that VBAC is a reasonable and safe choice for the majority of women with prior cesarean. Moreover, there is emerging evidence of serious harms relating to multiple cesareans. Relatively unexamined contextual factors such as medical liability, economics, hospital structure, and staffing may need to be addressed to prioritize VBAC services. There is still no evidence to inform patients, clinicians, or policy-makers about the outcomes of *intended* route of delivery because the evidence is based largely on the actual route of delivery.

This inception cohort is the equivalent of intention to treat for randomized controlled trials and this gap in information is critical.”

This AHRQ systematic review contributed to the evidence presented to a NIH Consensus Conference. The 2010 NIH Consensus Development Conference on Vaginal Birth after Cesarean: New Insights found the following:

Maternal Benefits of a trial of labor

- Women who have a trial of labor, regardless of ultimate mode of delivery, are at decreased risk of maternal mortality compared to elective repeat cesarean delivery. (Evidence grade: high)
- There is an association between cesarean delivery and abnormal placental position and growth in subsequent pregnancies and the risk of having abnormal placental position and growth increases with increasing number of cesarean deliveries. Overall, the major benefit of trial of labor is the 74 percent likelihood of VBAC and avoidance of multiple cesarean deliveries. The following health outcomes occur less frequently in women who have a VBAC (i.e. a successful trial of labor) (Evidence grade: moderate):
 - The incidence of placenta previa (placenta covering the cervix) significantly increases in women with each additional cesarean delivery
 - The incidence of placenta accreta, increta, and percreta (growth of the placenta into or through the uterine muscle) increases with the number of cesarean deliveries.
 - There does not appear to be an increased incidence of placental abruption (i.e., premature separation of the normally implanted placenta from the uterus) with increasing number of cesarean deliveries, although the risk is increased when women who have one prior cesarean delivery are compared to women who have not had a cesarean delivery.
- The overall risk of hysterectomy is statistically similar for trial of labor compared with elective repeat cesarean delivery (157 versus 280 per 100,000 respectively) and may be less in women at term. Limited evidence suggests that the risk of hysterectomy increases with induction of labor, high-risk pregnancy, and increasing number of cesarean deliveries (Evidence grade: moderate)
- The risk of blood transfusion is not significantly different for trial of labor or elective repeat cesarean delivery (900 versus 1,200 per 100,000). Factors that increase this risk include induction of labor with no prior vaginal delivery, high-risk pregnancy, and an increased number of prior cesarean deliveries.(Evidence grade: moderate)

- There is shorter hospitalization overall for trial of labor compared to elective repeat cesarean delivery. This benefit does not pertain to morbidly obese women. A single study suggests lower rates of deep venous thrombosis (DVT) in women undergoing trial of labor compared with elective repeat cesarean delivery (Evidence grade: low)

Maternal Harms of a trial of labor

- There is a clear increased risk of uterine rupture in women who have a trial of labor compared to elective repeat cesarean delivery. (Evidence grade: Moderate). Low grade evidence finds the following:
 - Women with classical and low vertical uterine scars have an increased risk of rupture when compared to women who had a low transverse uterine incision
 - Induction of labor has been associated with uterine rupture.
 - Increasing number of prior cesarean deliveries may increase risks of uterine rupture
 - A prior vaginal birth (before or after the previous cesarean delivery) decreases the risk of uterine rupture to approximately
- The evidence is insufficient to address a woman's perceptions of her birth experience, initial parent-infant interactions, ability to perform activities of daily living or initiate breastfeeding, association with other conditions such as chronic pain, ectopic pregnancy, stillbirth, infertility, complications related to subsequent surgery, pelvic floor function, rates of infection or surgical injury.

Neonatal effects of a trial of labor

- Studies of perinatal mortality (death between 20 weeks of gestation and 28 days of life) are of moderate quality and show that the perinatal mortality rate is increased for trial of labor (Evidence grade: moderate)
- Studies of fetal mortality (deaths in utero at 20 weeks of gestation or greater) suggest a higher death rate in trial of labor (Evidence grade: low)
- The evidence on hypoxic ischemic encephalopathy is unclear. The NIH Consensus Conference, noting a recent large observational study that found a significantly higher incidence of hypoxic ischemic encephalopathy in trial of labor compared with elective repeat cesarean delivery, rated the evidence grade on this finding as low, while the AHRQ SR rated it as insufficient.
- The evidence is insufficient to address respiratory sequelae, sepsis, birth trauma, breastfeeding and mother-infant bonding.

Indications for Cesarean Section

The 2010 MED report relied on the guideline and systematic review conducted by the National Institute for Clinical Excellence (NICE) published in 2004 to determine the indications for planned cesarean section, but noted that this guideline would be updated in 2011. The updated guideline was published in November 2011

(<http://www.nice.org.uk/nicemedia/live/13620/57162/57162.pdf>). The 2011 NICE guideline identified one small study (N= 357), published after the 2004 guideline, that compared primiparous women planning a CS in the absence of medical indication to those planning a vaginal birth. That study found the following outcomes in the planned CS group:

- Longer maternal hospital stays
- Better “birth experience” at 2 days and 3 months
- Worse “uncomplicated breast feeding” at 3 months
- Lower likelihood of plans for another child at 3 months

There were no statistically significant differences between groups in the following outcomes:

- Resumption of coitus at 3 months
- Depression
- NICU care

The quality of the evidence was rated very low, however, the guideline authors recommend that “For women requesting a CS, if after discussion and offer of support (including perinatal mental health support for women with anxiety about childbirth), a vaginal birth is still not an acceptable option, offer a planned CS. “

Indications for Cesarean Delivery

The 2011 NICE guideline recommends planned CS for the following indications:

- Breech presentation (if external cephalic version unsuccessful or contraindicated)
- Twin pregnancy, if the presenting twin is not cephalic
- Partial or complete placenta previa
- Morbidly adherent placenta
- HIV positive mothers who are not receiving anti-retroviral therapy, are receiving anti-retroviral therapy and have a viral load of 400 copies per ml or more, or who are co-infected with Hepatitis C
- Primary herpes simplex virus infection in the third trimester

The 2011 NICE guideline does not recommend planned cesarean, either because of insufficient evidence, or because there is a balance of trade offs between clinical benefits and harms or net health benefits and resource use, for the following indications:

- Twin pregnancy, if the presenting twin is cephalic
- Preterm birth
- Small for gestational age
- Suspected cephalopelvic disproportion
- HIV positive mothers on highly active anti-retroviral therapy with a viral load less than 400 copies/ml, or on any anti-retroviral therapy with a viral load of less than 50 copies/ml
- Maternal Hepatitis B infection
- Maternal Hepatitis C infection
- HSV recurrence at birth
- Body mass index over 50
- Prior CS delivery

In addition, the NICE guidance on Diabetes in Pregnancy (2008) recommends that pregnant women with diabetes who have a normally grown fetus should be offered elective birth through induction of labor, or by elective caesarean section if indicated, after 38 completed weeks.

Recommendations from Others

The American College of Obstetrics and Gynecology (ACOG) does not list specific indications for cesarean section, but some of their documents suggest when it is appropriate. When a guideline or bulletin exists, their recommendations do not contradict the NICE recommendations presented above, with two exceptions. For women with herpes simplex virus who have active genital lesions or prodromal symptoms, ACOG recommends CS. In addition, they state that CS should be considered for obese women with an estimated fetal weight of more than 5000 grams, or more than 4500 grams for patients with diabetes (whether obese or not). For patients with gestational diabetes, they state that there is “no good evidence to support routine delivery before 40 weeks of gestation. There are no data to support a policy of cesarean delivery purely on the basis of GDM. It would appear reasonable to recommend that patients with GDM be counseled regarding possible cesarean delivery without labor when the estimated fetal weight is 4,500 g or greater”. For pregestational diabetics, they state that “early delivery may be indicated in some patients with vasculopathy, nephropathy, poor glucose control, or a prior stillbirth. In contrast, patients with well-controlled diabetes may be allowed to progress to their expected date of delivery as long as antenatal testing remains reassuring. Expectant management beyond the

estimated due date generally is not recommended. Cesarean delivery may be considered if the estimated fetal weight is greater than 4,500 g in women with diabetes.”

Overall Summary

Elective CS is likely associated with longer hospital stays, increased NICU admissions and increased neonatal respiratory problems. While maternal urinary or fecal incontinence is less likely in the short term, there is no difference in longer term follow up. A 2006 NIH consensus statement concludes that there is insufficient evidence to fully evaluate the benefits and risks of cesarean delivery on maternal request, and given that the risks of placenta previa and accreta rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children. The majority of planned CS in the US are performed for women who have a prior history of Cesarean birth. A 2010 AHRQ systematic review reports stronger evidence that VBAC is a reasonable and safe choice for the majority of women with prior cesarean, and that there is emerging evidence of serious harms relating to multiple cesareans. The 2011 NICE guideline recommends planned CS only for breech presentation, twin pregnancy (if the presenting twin is not cephalic), placenta previa and accreta, HIV positive mothers in some circumstances and primary herpes simplex virus infection in the third trimester. These indications are supported by ACOG, and in addition, ACOG considers obesity with high estimated fetal weight and HSV recurrence at birth additional indications for planned CS. For all other indications, the evidence is insufficient to recommend cesarean section. Planned cesareans without an evidence-based indication may increase neonatal and maternal harms, increase costs, and result in unnecessary procedures.

PROCEDURE

Cesarean Section

DIAGNOSES

Pregnancy

APPLICABLE CODES

CODES	DESCRIPTION
ICD 9 Codes	
V22.0	Supervision of normal first pregnancy
V22.1	Supervision of other normal pregnancy
V22.2	Pregnant state, incidental
V30	Single liveborn
V39	Liveborn unspecified whether single twin or multiple
ICD 9 Volume 3 (procedure codes)	

74.0	Classical cesarean section
74.1	Low cervical caesarean section
74.4	Cesarean section of other specified type
ICD 10 Codes	
O82	Single delivery by caesarean section
O82.0	Delivery by elective caesarean section
O82.2	Delivery by caesarean hysterectomy
O82.8	Other single delivery by caesarean section
O82.9	Delivery by caesarean section, unspecified
CPT Codes	
Elective Cesarean	
59510	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care
59514	Cesarean Delivery only
59515	Cesarean Delivery only, including postpartum care
Nonelective Cesarean	
59618	Routine Obstetric care including antepartum care, Cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
59620	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery.
59622	Cesarean Delivery only, following attempted vaginal delivery after previous Cesarean delivery. Including postpartum care
Vaginal Delivery	
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care
59409, 59410	Vaginal delivery only, with and without postpartum care
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
59612, 59614	Vaginal delivery only, after previous cesarean delivery; with or without postpartum care
HCPCS Codes	
None	

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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.

HERC Coverage Guidance – Indications for Planned Cesarean Section Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
Physician (OB/GYN) Portland, OR	1	<p>I would like to comment on the proposed HERC indications. I am an OB GYN in the community of Portland, Oregon, and have been in practice for >20 years. My comments appear in bold font.</p> <p>Your recommendations area as follows: Planned CS should not be covered for:</p> <ul style="list-style-type: none"> • Twin pregnancy, if the presenting twin is cephalic <p>Regardless of presentation and regardless of successful vaginal delivery of the first twin, the risk of requiring a cesarean in a second twin exceeds 50%. The patient should be given the option of having a primary cesarean in the face of such daunting odds. In addition, second twins may still be at higher risk of perinatal mortality when delivered vaginally. The relative risk of anoxic death of the second twin is increased after vaginal birth of the first twin and appears to be most significant when the infants are greater than 36 weeks gestation. It is irresponsible and discriminatory to use financial pressure to force a patient to make a decision she would not otherwise make.</p> <ul style="list-style-type: none"> • Preterm birth • Small for gestational age 	The EbGS agrees that perinatal morbidity and mortality for the second twin is increased, and although there is no evidence to support the contention that C/S improves those outcomes, the subcommittee agrees that the treatment plan should be individualized. The coverage guidance document has been updated to reflect this.
	2	<ul style="list-style-type: none"> • Suspected cephalopelvic disproportion <p>Maternal diabetes mellitus increases the likelihood of shoulder dystocia two to sixfold over the nondiabetic population. The correlation between shoulder dystocia and birth weight in diabetic and nondiabetic gravidas is well known. The increased risk of shoulder dystocia occurs even among infants less than 4000 g because of body habitus changes in diabetics. The American College of Obstetricians and Gynecologists advises that prophylactic cesarean delivery to prevent shoulder dystocia may be considered for an estimated fetal weight greater than 5000 g in nondiabetic women and greater than 4500 g in women with diabetes. It is inexcusable and ill-advised to withhold cesarean delivery as an option when the risk of dystocia and associated brachial plexus injury is high.</p> <ul style="list-style-type: none"> • Maternal Hepatitis B infection • Maternal Hepatitis C infection 	Coverage guidance modified to include individualized treatment plans for patients with suspected macrosomia, with or without diabetes.
	3	<p>Elective (without obstetrical or medical indication)</p> <p>"At this time, the best delivery mode for any woman is best decided by her and her physician, considering her individual circumstances. A woman must be thoroughly and accurately informed about the risks and benefits of each option for her as she participates in the decision," ACOG guidelines, 2006. This is currently and has been widely interpreted to indicate that a woman has the right to choose primary cesarean without obstetrical or medical indications; it is our job to inform her of the risks of making that choice, it is not consistent with the best patient care to present insurmountable obstacles like failure of her insurance plan to pay for the procedure.</p> <p>Vaginal delivery has risks similar to cesarean delivery (eg, deep vein thrombosis and pulmonary emboli). ACOG 2000. Most of the comments regarding risk of cesarean section are centered not on the original procedure but on future pregnancy and repeat procedures, which may be discussed at the PAR conference, but should not be</p>	<p>The EbGS does not agree that it is the obligation of the payer to pay for health care without proven benefit and known harms. The individual and their physician are free to make those choices.</p> <p>While the evidence is clear that there are risks to both vaginal delivery and C/S, the EbGS believes the risks of C/S (without indication) outweigh those of vaginal delivery.</p>

HERC Coverage Guidance – Indications for Planned Cesarean Section Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		<p>considered relevant or overwhelming at the time of the original decision for cesarean.</p> <p>I hope that you will consider these statements.</p>	<p>Commenter did not provide a citation to support the statement concerning vaginal delivery risks being similar to Cesarean. The EbGS also does not agree that the risks to future pregnancies should not be considered relevant.</p>
<p><i>Physician (OB/GYN) FACOG Portland, OR</i></p>	4	<p>I am pleased to see that the Oregon Health Policy and Research is looking at evidence based medicine to help decrease the financial burden of unnecessary procedures and combat rapidly rising health costs. I am concerned regarding restricting the use of C-Sections for two of the proposed criteria:</p> <p>Twin Pregnancy if presenting twin is vertex:</p> <p>According to ACOG, "The route of delivery for twins should be determined by the position of the fetuses, the ease of fetal heart rate monitoring, and maternal and fetal status. Data are insufficient to determine the best route of delivery for high-order multiple gestations. There are retrospective case series that validate vaginal delivery as a potential mode of delivery, especially for triplet gestations. However, most such pregnancies are delivered by cesarean delivery." I am a strong believer in vaginal delivery of twins and have had success with that in my own practice. However, I use my clinical judgement, in consultation with the patient, to determine rate of delivery. With second coming twins, there is literature showing as high as a 50% C-section rate after the successful delivery of the first twin vaginally. Not all patients are willing to accept the risks of both a vaginal and Cesarean delivery for their twins. With twin deliveries, it is not just the position of the first infant that is critical importance, it is the size and position of the second infant. Not all practitioners are comfortable doing a cephalic version if the second twin is breech or a breech extraction. If the second infant is breech and larger than the first infant there is a risk that there will be a head entrapment since the pelvis is only proven for the size of the first infant. Also, not all practitioners have access to a second trained person that really needs to be present to help ensure the safe delivery of the second infant (utilizing a second set of hands and U/S to visualize the position of the second twin). It concerns me greatly about declining to cover a C-section for a vertex first twin. I think the medical legal implications on a practitioner and the increased risk to the infant does not warrant this being a criteria.</p>	<p>See response to comment #1; guidance concerning twins changed to address these concerns.</p>
	5	<p>Elective (without medical or obstetrical indication)</p> <p>With regard to an elective (non medical indication), the latest update on ACOG in their bulletin Patient Requested Cesarean Update in May 2006, "Patient-requested cesarean is but one of the many factors that have converged over the years to produce the current cesarean rate," says Fredric D. Frigoletto Jr, MD, associate chief of staff and vice chair at Massachusetts General Hospital in Boston, and an ACOG past president. "At this time, the best delivery mode for any woman is best decided by her and her physician, considering her individual circumstances. A woman must be thoroughly and accurately informed about the risks and benefits of each option for her as she participates in the decision," Dr. Frigoletto added. In this age, a woman has the right to choose her route of delivery. Pelvic floor injuries are a real entity and have significant impact on a woman's quality of life and ability to</p>	<p>While the EbGS acknowledges the ability of a woman and her physician to choose mode of delivery, they are compelled to adopt policies that adhere to the evidence. The evidence reviewed shows that elective cesarean delivery likely has no benefit for urinary or fecal continence in the longer term,</p>

HERC Coverage Guidance – Indications for Planned Cesarean Section Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		<p>perform activities of daily living. Some women are so concerned about pelvic floor injuries that they elect for a C-section. It is up to their providers to counsel regarding risks and benefits and determine the best route of delivery for each individual woman. I would hope we would continue to allow woman to have a voice with regards to their own bodies.</p>	<p>although immediate postpartum outcomes may favor elective CS. While there are risks to both vaginal delivery and C/S, the EbGS believes the risks of C/S (without indication) outweigh those of vaginal delivery. Commenter did not provide a citation for the claim regarding pelvic floor injuries.</p>
	6	<p>I would propose another criteria for planned C-section. The Portland Hospitals have moved to a 39 week minimum criteria for all elective C-sections and inductions and would urge this body to consider this as well. I think that a planned C-section below 39 weeks is not indicated (unless twins and current criteria there is 38 weeks) and does reflect a growing number of admissions to the NICU for babies with respiratory problems due to being born via C-section below 39 weeks. I think moving this statewide would help decrease the financial burden and improve overall health of babies born in Oregon.</p>	<p>The EbGS agrees that C/S without indication should not be performed before 39 weeks. They also believe, based on the evidence, that it should not be performed at any gestational age without indication.</p>

DRAFT

Conditions for which Cesarean section is not routinely indicated based on NICE report

Condition	NICE Grade of Recommendation (based on level of evidence)	ACOG Position
Twin pregnancy, with cephalic first twin	C	Should be determined by fetal positions, ease of FHT monitoring and maternal/fetal status. For high-order (more than 2) multiple gestations, they state: "There are retrospective case series that validate vaginal delivery as a potential mode of delivery".
Prematurity	C	No recommendation
Small for gestational age	C	No recommendation
Suspected CPD	A for pelvimetry/ B for shoe size, maternal height, estimation of fetal size	Unable to find
HIV + mothers receiving anti-retroviral (ARV) therapy who have viral load < 400 copies/ml	Not graded	HIV+ women with < 1000 copies/ml have 2% risk of transmission, regardless of C/S (does not disagree with NICE)
Hepatitis B	B	No recommendation
Hepatitis C (unless co-infected with HIV)	C	Agrees with NICE
Herpes simplex virus (HSV) recurrence at birth	C	C/S is indicated in women with active genital lesions or prodromal symptoms
BMI > 50	Not graded	C/S should be considered for obese women with estimated fetal weight > 5000 gms without diabetes, or > 4500 gms with diabetes
Prior Cesarean delivery <ul style="list-style-type: none"> "Inform women who have had up to and including four CS that the risk of fever, bladder injuries and surgical injuries does not vary with planned mode of birth and that the risk of uterine rupture, although higher for planned vaginal birth, is rare." 	Not graded	"Most women with one previous cesarean delivery with a low transverse incision are candidates for and should be counseled about VBAC and offered TOLAC"

Condition	NICE Grade of Recommendation (based on level of evidence)	ACOG Position
<ul style="list-style-type: none"> Offer women planning a vaginal birth who have had a previous CS: electronic fetal monitoring during labour care during labour in a unit where there is immediate access to CS and onsite blood transfusion services. 	Good Practice Point (GPP)	
<ul style="list-style-type: none"> During induction of labour, women who have had a previous CS should be monitored closely, with access to electronic fetal monitoring and with immediate access to CS, because they are at increased risk of uterine rupture. 	GPP	
<ul style="list-style-type: none"> Pregnant women with both previous CS and a previous vaginal birth should be informed that they have an increased likelihood of achieving a vaginal birth than women who have had a previous CS but no previous vaginal birth. 	B	

NICE Grade of recommendation

A - Based directly based on level 1 evidence

B - Based directly on level 2 evidence or extrapolated from level 1 evidence

C - Based directly on level 3 evidence or extrapolated from level 1 or level 2 evidence

D - Based directly on level 4 evidence or extrapolated from level 1, level 2 or level 3 evidence

GPP - Good practice point based on the view of the guideline development group

NICE Level of Evidence

1a - Systematic review or meta-analysis of randomised controlled trials

1b - At least one randomised controlled trial

2a - At least one well-designed controlled study without randomisation

2b - At least one well-designed quasi-experimental study, such as a cohort study

3 - Well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, case-control studies, and case series

4 - Expert committee reports, or opinions and/or clinical experience of respected authorities

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: LOW BACK PAIN: PHARMACOLOGIC INTERVENTIONS*

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Pharmacologic therapy

- Initial pharmacologic therapy should be acetaminophen or non-steroidal anti-inflammatory medications and/or skeletal muscle relaxants.
- Second line agents include benzodiazepines, and opioids due to associated risks.
- Systemic steroids should NOT be covered for this diagnosis.
- For chronic low back pain, tricyclic antidepressants should be covered.

*Coverage guidance for imaging, percutaneous interventions and surgery for low back pain will be addressed in subsequent documents.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Health Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCES

Livingston, C., King, V., Little, A., Pettinari, C., Thielke, A., & Gordon, C. (2011). *State of Oregon Evidence-based Clinical Guidelines Project. Evaluation and management of low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain)*. Salem: Office for Oregon Health Policy and Research. Available at: <http://www.oregon.gov/OHA/OHPR/HERC/Evidence-Based-Guidelines.shtml>

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The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Low back pain is the fifth most common reason for all physician visits in the United States. Approximately one quarter of U.S. adults reported having low back pain lasting at least 1 whole day in the past 3 months, and 7.6% reported at least 1 episode of severe acute low back pain within a 1-year period. Low back pain is also very costly: Total incremental direct health care costs attributable to low back pain in the U.S. were estimated at \$26.3 billion in 1998. In addition, indirect costs related to days lost from work are substantial, with approximately 2% of the U.S. work force compensated for back injuries each year.

Many patients have self-limited episodes of acute low back pain and do not seek medical care. Among those who do seek medical care, pain, disability, and return to work typically improve rapidly in the first month. However, up to one third of patients report persistent back pain of at least moderate intensity 1 year after an acute episode,

and 1 in 5 report substantial limitations in activity. Approximately 5% of the people with back pain disability account for 75% of the costs associated with low back pain.

Many options are available for evaluation and management of low back pain. However, there has been little consensus, either within or between specialties, on appropriate clinical evaluation and management of low back pain. Numerous studies show unexplained, large variations in use of diagnostic tests and treatments. Despite wide variations in practice, patients seem to experience broadly similar outcomes, although costs of care can differ substantially among and within specialties.

Evidence Review

Recommendation 1: *For patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data before initiating therapy (strong recommendation, moderate-quality evidence). For most patients, first-line medication options are acetaminophen or nonsteroidal anti-inflammatory drugs.*

Medications in several classes have been shown to have moderate, primarily short-term benefits for patients with low back pain. Each class of medication is associated with unique trade-offs involving benefits, risks, and costs. For example, acetaminophen is a slightly weaker analgesic than NSAIDs but is a reasonable first-line option for treatment of acute or chronic low back pain because of a more favorable safety profile and low cost. Nonselective NSAIDs are associated with well-known gastrointestinal and renovascular risks, and there is an association between exposure to cyclooxygenase-2–selective or most nonselective NSAIDs and increased risk for myocardial infarction. Opioid analgesics or tramadol are an option when used judiciously in patients with acute or chronic low back pain who have severe, disabling pain that is not controlled (or is unlikely to be controlled) with acetaminophen and NSAIDs. Because of substantial risks, including aberrant drug-related behaviors with long-term use in patients vulnerable or potentially vulnerable to abuse or addiction, potential benefits and harms of opioid analgesics should be carefully weighed before starting therapy.

For skeletal muscle relaxants, although the antispasticity drug tizanidine has been well studied for low back pain, there is little evidence for the efficacy of baclofen or dantrolene, the other FDA-approved drugs for the treatment of spasticity. Other medications in the skeletal muscle relaxant class are an option for short-term relief of acute low back pain, but all are associated with central nervous system adverse effects (primarily sedation). Tricyclic antidepressants are an option for pain relief in patients with chronic low back pain and no contraindications to this class of medications. Antidepressants in the selective serotonin reuptake inhibitor class and trazodone have not been shown to be effective for low back pain, and serotonin–norepinephrine

reuptake inhibitors (duloxetine and venlafaxine) have not yet been evaluated for low back pain.

Gabapentin is associated with small, short-term benefits in patients with radiculopathy and has not been directly compared with other medications or treatments. There is insufficient evidence to recommend for or against other antiepileptic drugs for back pain with or without radiculopathy. For acute or chronic low back pain, benzodiazepines seem similarly effective to skeletal muscle relaxants for short-term pain relief but are also associated with risks for abuse, addiction, and tolerance. Herbal therapies, such as devil's claw, willow bark, and capsicum, seem to be safe options for acute exacerbations of chronic low back pain, but benefits range from small to moderate. Systemic corticosteroids are not recommended for treatment of low back pain with or without sciatica, because they have not been shown to be more effective than placebo.

[\[Evidence source\]](#)

Overall Summary

Medications in several classes, including NSAIDs, opioids, tramadol, skeletal muscle relaxants, antidepressants and antiepileptics, have been shown to have moderate, primarily short-term benefits for patients with low back pain. Each class of medication is associated with unique trade-offs involving benefits, risks, and costs. For most patients, first-line medications are acetaminophen or NSAIDs.

PROCEDURES

Pharmacologic therapy

DIAGNOSES

Low back pain

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
170.2	Tumor lumbosacral region primary
198.5	Tumor lumbosacral region secondary
344.60	Cauda equine syndrome
720.1	Spinal enthesopathy
720.2	Sacroiliitis, not elsewhere classified
721.3	Lumbosacral spondylosis without myelopathy
721.42	Spondylosis with myelopathy, lumbar region
721.5	Kissing spine
721.6	Ankylosing vertebral hyperostosis
721.7	Traumatic spondylopathy

CODES	DESCRIPTION
721.8	Other allied disorders of spine
721.9	Spondylosis of unspecified site
722.1	Displacement of thoracic or lumbar intervertebral disc without myelopathy
722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.32	Schmorl's nodes, lumbar region
722.39	Schmorl's nodes, other region
722.5	Degeneration of thoracic or lumbar intervertebral disc
722.6	Degeneration of intervertebral disc, site unspecified
722.70	Intervertebral disc disorder with myelopathy, unspecified region
722.72	Intervertebral disc disorder with myelopathy, thoracic region
722.73	Intervertebral disc disorder with myelopathy, lumbar region
722.80	Postlaminectomy syndrome, unspecified region
722.82	Postlaminectomy syndrome, thoracic region
722.83	Postlaminectomy syndrome, lumbar region
722.90	Other and unspecified disc disorder, unspecified region
722.92	Other and unspecified disc disorder, thoracic region
722.93	Other and unspecified disc disorder, lumbar region
724	Other and unspecified disorders of back
724.0	Spinal stenosis other than cervical
724.00	Spinal stenosis, unspecified region
724.01	Spinal stenosis, thoracic region
724.02	Spinal stenosis, lumbar region, without neurogenic claudication
724.03	Spinal stenosis, lumbar region, with neurogenic claudication
724.09	Spinal stenosis, other region
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.6	Disorders of sacrum
724.7	Disorders of coccyx
724.70	Unspecified disorder of coccyx
724.71	Hypermobility of coccyx
724.79	Other disorders of coccyx
724.8	Other symptoms referable to back
724.9	Other unspecified back disorders
730.2	Unspecified osteomyelitis
732.0	Juvenile osteochondrosis of spine
733.0	Osteoporosis
737.2	Lordosis (acquired)
737.30	Scoliosis [and kyphoscoliosis], idiopathic
737.39	Other kyphoscoliosis and scoliosis
737.4	Curvature of spine associated with other conditions
737.8	Other curvatures of spine

CODES	DESCRIPTION
737.9	Unspecified curvature of spine
738.4	Acquired spondylolisthesis
738.5	Other acquired deformity of back or spine
739.2	Nonallopathic lesions, thoracic region
739.3	Nonallopathic lesions, lumbar region
739.4	Nonallopathic lesions, sacral region
754.2	Congenital musculoskeletal deformities of spine
756.1	Congenital anomalies of spine
846	Sprains and strains of sacroiliac region
847.1	Sprain of thoracic
847.2	Sprain of lumbar
847.3	Sprain of sacrum
847.4	Sprain of coccyx
847.9	Sprain of unspecified site of back
ICD-9 Volume 3 (procedure codes)	
None	
CPT Codes	
None	
HCPCS Level II Codes	
J7506	Prednisone, oral, per 5 mg
J7509	Methylprednisolone, oral, per 4 mg
J7510	Prednisolone, oral, per 5 mg

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: NON-PHARMACOLOGIC INTERVENTIONS FOR TREATMENT RESISTANT DEPRESSION

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

In patients with major depressive disorder who have failed an initial trial of antidepressants, psychotherapy and additional antidepressants should be covered.

In treatment-resistant depression (defined as having two or more prior treatment failures), the following treatments should be covered:

- 1) Repetitive transcranial magnetic stimulation
- 2) Electroconvulsive therapy

Vagus nerve stimulation should not be covered.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCE

Gaynes, B.N., Lux, L., Lloyd, S., Hansen, R.A., Gartlehne, G., Thieda, P., et al. (2011). *Nonpharmacologic interventions for treatment-resistant depression in adults. Comparative effectiveness review no. 33.* (Prepared by RTI International-University of North Carolina [RTI-UNC] Evidence-Based Practice Center under Contract No. 290-02-00161.) AHRQ Publication No. 11-EHC056-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from www.effectivehealthcare.ahrq.gov/reports/final.cfm

Trivedi, R.B., Nieuwsma, J.A., Williams, J.W., & Baker, D. (2009). *Evidence synthesis for determining the efficacy of psychotherapy for treatment resistant depression.* Washington, DC: Department of Veterans Affairs Veterans Health Administration Health Services Research & Development Service. Retrieved from <http://www.hsrd.research.va.gov/publications/esp/Depression-Q3.pdf>

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Major depressive disorder is common and costly. Over the course of a year, between 13.1 million and 14.2 million people will experience major depressive disorder. Approximately half of these people seek help for this condition, and only 20% of those receive adequate treatment. For those who do initiate treatment for their depression, approximately 50% will not adequately respond following acute phase treatment. Patients with two or more prior treatment failures are considered to have treatment-resistant depression. Patients with treatment-resistant depression incur the highest direct and indirect medical costs among those with major depressive disorder. These costs increase with the severity of treatment-resistant depression. Treatment-resistant patients are twice as likely to be hospitalized, and their cost of hospitalization is more than six times the mean total costs of depressed patients who are not treatment resistant.

Given the burden of treatment-resistant depression generally, the uncertain prognosis of the disorder, and the high costs of therapy, clinicians and patients alike need clear evidence to guide their treatment decisions. Somatic treatments, which may involve use of a pharmacologic intervention or a device, are commonly considered for patients with treatment-resistant depression. Antidepressant medications, which are the most commonly used intervention, have decreasing efficacy for producing remission after patients have experienced two treatment failures. Such drugs also often have side effects, sometimes minor but sometimes quite serious. For these reasons, clinicians often look for alternative strategies for their treatment-resistant depression patients.

Evidence Review

The Gaynes 2011 review provides a comprehensive summary of the available data addressing the comparative effectiveness of four nonpharmacologic treatments as therapies for patients with treatment-resistant depression: electroconvulsive therapy, repetitive transcranial magnetic stimulation, vagus nerve stimulation, and cognitive behavioral therapy or interpersonal psychotherapy. While the definition of treatment resistant depression remains controversial, it is defined in this report as *an episode of MDD that has not recovered following two or more adequate antidepressant medication treatments, regardless of the class of antidepressant used or whether the treatment failures were required to be in the current episode*. In addition, studies using alternate or unclear definitions are also included, although they are identified as a lower source of evidence. Results are presented as direct or indirect evidence, with direct evidence being a direct comparison between two of the four included interventions. In contrast, indirect evidence compares two or more interventions by comparing differences in effectiveness or safety of each intervention compared to placebo.

Because the Gaynes review identified no eligible trials of cognitive behavioral or interpersonal psychotherapy for their definition of treatment resistant depression, the Trivedi 2009 review was included to provide evidence about psychotherapy in patients who have failed at least one course of antidepressant therapy.

Gaynes 2011

Efficacy of Nonpharmacologic Interventions Against Other Nonpharmacologic Interventions

Direct evidence. The available head-to-head literature concerning the efficacy of the nonpharmacologic interventions for treatment-resistant depression is limited to two fair trials (both in major depressive disorder-only populations). One compared electroconvulsive therapy and repetitive transcranial magnetic stimulation, and the other compared electroconvulsive therapy and electroconvulsive therapy plus transcranial magnetic stimulation. They showed, with low strength of evidence, no differences between treatment options for depressive severity, response rates, and remission rates. No trial involved a direct comparison of cognitive behavioral therapy, interpersonal psychotherapy or vagus nerve stimulation with another nonpharmacologic intervention.

Indirect evidence. We identified trials that compared a nonpharmacologic intervention, generally repetitive transcranial magnetic stimulation or vagus nerve stimulation, with a control or sham procedure. We identified no eligible electroconvulsive therapy or cognitive behavior/ interpersonal psychotherapy versus control studies that used the stricter definition of treatment resistant depression. Repetitive transcranial magnetic stimulation was beneficial relative to controls receiving a sham procedure for all three outcomes (severity of depressive symptoms, response rate, remission rate). Specifically, repetitive transcranial magnetic stimulation produced a greater decrease in depressive severity (high strength of evidence), averaging a decrease in depressive severity measured by the Hamilton Rating Scale for Depression of more than 5 points

relative to sham control, and this change meets the minimum threshold of the 3-point rating scale difference that is considered clinically meaningful. Response rates were greater with repetitive transcranial magnetic stimulation than sham (also high strength of evidence); those receiving repetitive transcranial magnetic stimulation were more than three times as likely to achieve a depressive response as patients receiving a sham procedure. Finally, repetitive transcranial magnetic stimulation was also more likely to produce remission than the control procedure (moderate strength of evidence); patients receiving repetitive transcranial magnetic stimulation were more than six times as likely to achieve remission as those receiving the sham. One good-quality vagus nerve stimulation versus sham control trial (a mixed major depressive disorder/bipolar population) reported no differences between the groups as measured by a change in depressive severity or response rates (low strength of evidence).

Efficacy of Nonpharmacologic Interventions Compared With Antidepressant Pharmacotherapies

Direct evidence. The available head-to-head literature concerning the efficacy of the nonpharmacologic interventions compared with pharmacologic treatment (in this case, paroxetine) is limited to one fair-quality trial (a mixed major depressive disorder/bipolar population). Electroconvulsive therapy produced a significantly greater decrease in depressive severity (9 points by Hamilton Rating Scale for Depression) and significantly better response rates (71% vs. 28%) than medications (low strength of evidence).

Indirect evidence. In order to allow for comparison to non-pharmacologic therapy, mean average outcomes for pharmacologic treatments were calculated, and are presented below:

- For switching strategies¹, mean pharmacologic response rates averaged 39.8% and mean remission rates averaged 22.3%.
- For augmentation², mean response rates averaged 38.1% and mean remission rates averaged 27.2%.
- For maintenance strategies, mean response rates averaged 27.3% and mean remission rates averaged 16.8%.

Although these results provide an idea of the general degree of response seen with next-step pharmacologic treatment in treatment-resistant depression, they serve as an uncontrolled case series and should be compared to nonpharmacologic outcomes only with caution.

Maintenance of Remission or Prevention of Relapse

Direct evidence. With respect to maintaining remission (or preventing relapse), there were no direct comparisons involving electroconvulsive therapy, repetitive transcranial magnetic stimulation, vagus nerve stimulation, or cognitive behavioral/ interpersonal psychotherapy.

¹ Changing from one antidepressant to another

² Adding a second antidepressant

Indirect evidence. Three fair trials compared repetitive transcranial magnetic stimulation with a sham procedure and found no significant differences. However, too few patients were followed during the relapse prevention phases in two of the three studies, and patients in the third received a cointervention providing insufficient evidence for a conclusion. There were no eligible studies for electroconvulsive therapy, vagus nerve stimulation, or psychotherapy.

Efficacy of Nonpharmacologic Interventions for Patients With Different Symptomatology

Direct evidence. There were no trials that addressed whether procedure-based treatments differed as a function of symptom subtypes. Also, no comparative evidence was available about psychotherapy in subgroups defined by symptom clusters.

Indirect evidence. No studies were identified that tested either procedure-based or psychotherapeutic interventions against sham procedures or other controls.

Safety, Adverse Events, and Adherence

Direct evidence. In examining safety, adverse events, and adherence, there were some differences across the interventions in the harms and negative side effects to patients. However, the data were insufficient to reach a conclusive result. For this analysis only, both clinical trials and cohort studies were included, with specific focus on cognitive functioning, occurrence of specific adverse events, and withdrawals.

Cognitive functioning. For studies on cognitive functioning, some evidence suggests no differences in changes in cognitive functioning between groups, while some evidence suggests electroconvulsive therapy may have a deleterious impact on cognitive functioning compared to repetitive transcranial magnetic stimulation (insufficient strength of evidence). No differences between groups on a single-item measure of cognitive functioning were found in a study comparing electroconvulsive therapy with electroconvulsive therapy and repetitive transcranial magnetic stimulation (insufficient strength of evidence).

Specific adverse events. One study comparing electroconvulsive therapy with a combination of electroconvulsive therapy and repetitive transcranial magnetic stimulation found no differences in specific adverse events (low strength of evidence).

Withdrawals. A single study with a small sample size indicated no difference in withdrawals due to adverse events for the electroconvulsive therapy group when compared to repetitive transcranial magnetic stimulation but did not report on the significance of this result (low strength of evidence). Evidence for electroconvulsive therapy compared with repetitive transcranial magnetic stimulation indicated higher rates of overall withdrawals in the electroconvulsive therapy compared to the repetitive transcranial magnetic stimulation group (low strength of evidence).

Indirect evidence.

Cognitive functioning. Mixed evidence on cognitive functioning in repetitive transcranial magnetic stimulation versus sham was insufficient evidence to draw a conclusion (insufficient strength of evidence).

Specific adverse events. Repetitive transcranial magnetic stimulation groups reported significantly more scalp pain at the stimulation site (low strength of evidence). Some differences in the frequency of specific adverse events were seen when comparing vagus nerve stimulation and sham groups, but the significance of the findings was not reported (low strength of evidence).

Withdrawals. Findings were mixed as to whether repetitive transcranial magnetic stimulation groups had greater rates of withdrawals (overall and due to adverse events) than groups receiving sham procedures (insufficient evidence for both). Withdrawals attributable to adverse events were higher in the vagus nerve stimulation group compared with sham (low strength of evidence). No studies reported on withdrawals for cognitive behavioral / interpersonal psychotherapy groups versus those receiving some form of usual care.

Efficacy or Harms of Nonpharmacologic Treatments for Selected Patient Subgroups

Direct evidence. No studies were identified that directly compared nonpharmacologic interventions in selected populations, such as the elderly, those with stroke, or those with other medical comorbidities.

Indirect evidence. Two trials compared repetitive transcranial magnetic stimulation with sham. All findings provided low strength of evidence. For young adults (ages 18–37), one trial found that repetitive transcranial magnetic stimulation produced a greater decrease in depressive severity and a greater response rate than sham. A second trial, conducted in older adults with post-stroke depression, found that repetitive transcranial magnetic stimulation produced a greater decrease in depressive severity and a greater response rate but no difference in remission rates compared with a sham control.

Health-Related Outcomes of Nonpharmacologic Treatments

Direct evidence. The focus of patient-reported health-related outcomes in this report was quality of life (various measures) and ability to function in daily life. One study compared electroconvulsive therapy with a combination of electroconvulsive therapy and repetitive transcranial magnetic stimulation and found no differences between groups in improvement on the Global Assessment of Functioning scale (low strength of evidence).

Indirect evidence. Two trials (both in mixed major depressive disorder/bipolar populations) assessed general health status and mental and physical functioning (all health domains related to quality of life). In one fair trial, low repetitive transcranial magnetic stimulation had significantly greater improvement in health status and daily functioning than sham, while this relationship approached statistical significance when comparing high repetitive transcranial magnetic stimulation to sham (as measured by the Global Assessment of Functioning scale; low strength of evidence). In the other fair trial, vagus nerve stimulation and sham groups did not differ significantly in daily functioning (as measured by the 36-item Medical Outcomes Study Short Form [MOS SF-36]; low strength of evidence). No studies of psychotherapy were identified.

Trivedi 2009

This systematic review included five unique RCTs comparing medications to psychotherapy in patients with major depressive disorder who have not responded to initial treatment with antidepressants. One trial had both “substitution with psychotherapy” and “augmentation with psychotherapy” arms, therefore it was treated as two different studies, resulting in a total of six studies evaluating 567 patients. Psychotherapy was examined as an augmentation to antidepressant medication in four studies and as a substitution treatment to replace medication in two studies.

Two good quality, moderate-sized trials showed equal benefit from augmenting antidepressant medication with cognitive therapy and from active medication management, one fair quality small study showed lithium augmentation to be more beneficial than cognitive therapy, and one fair quality trial showed short-term benefit from augmentation through 16 sessions of dialectic behavior therapy. A moderate-sized, good quality study and a small, poor quality study found equal benefit from substituting cognitive therapy for antidepressant treatment and from continuing management of depression with medication. In conclusion, current trials do not support favoring psychotherapy over antidepressant medication for mid-life adults with treatment resistant MDD; however, psychotherapy appears to be an equally effective treatment compared to antidepressant medication and is therefore a reasonable treatment option for this demographic.

[\[Evidence Source\]](#)

Overall Summary

Repetitive transcranial magnetic stimulation is beneficial for all three depression outcomes (severity of depressive symptoms, response rate, remission rate) compared to placebo, but vagus nerve stimulation is not. While there are no placebo controlled trials of electroconvulsive therapy, it produces a significantly greater decrease in depression severity and better response rates than medications. When comparing electroconvulsive therapy to repetitive transcranial magnetic stimulation, there are no differences in terms of depression severity, response rates, and remission rates. There is little difference between interventions in safety profiles, with the exception of electroconvulsive therapy compared with repetitive transcranial magnetic stimulation, for which there are higher rates of overall withdrawals in the electroconvulsive therapy compared to the repetitive transcranial magnetic stimulation group. When compared to placebo, repetitive transcranial magnetic stimulation had significantly more scalp pain at the stimulation site, and the vagus nerve stimulation group had more withdrawals attributable to adverse events compared with sham. There were no eligible studies identified that evaluated psychotherapy for patients who had failed two different trials of antidepressants. For patients who have not responded to initial treatment with antidepressants, psychotherapy appears to be an equally effective treatment compared to antidepressant medication and is therefore a reasonable treatment option.

PROCEDURES

Electroconvulsive therapy

Repetitive transcranial magnetic stimulation
 Vagus nerve stimulation
 Cognitive behavioral therapy or interpersonal psychotherapy

DIAGNOSES

Major depressive disorder

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
296.2	Major depressive disorder single episode
296.20	Major depressive affective disorder, single episode, unspecified
296.21	Major depressive affective disorder, single episode, mild
296.22	Major depressive affective disorder, single episode, moderate
296.23	Major depressive affective disorder, single episode, severe, without mention of psychotic behavior
296.24	Major depressive affective disorder, single episode, severe, specified as with psychotic behavior
296.25	Major depressive affective disorder, single episode, in partial or unspecified remission
296.26	Major depressive affective disorder, single episode, in full remission
296.3	Major depressive disorder recurrent episode
296.30	Major depressive affective disorder, recurrent episode, unspecified
296.31	Major depressive affective disorder, recurrent episode, mild
296.32	Major depressive affective disorder, recurrent episode, moderate
296.33	Major depressive affective disorder, recurrent episode, severe, without mention of psychotic behavior
296.34	Major depressive affective disorder, recurrent episode, severe, specified as with psychotic behavior
296.35	Major depressive affective disorder, recurrent episode, in partial or unspecified remission
296.36	Major depressive affective disorder, recurrent episode, in full remission
296.82	Atypical depressive disorder
ICD-9 Volume 3 (Procedure Codes)	
94.27	Other Electroshock Therapy
CPT Codes	
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
90804	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient

CODES	DESCRIPTION
90805	with medical evaluation and management services
90806	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient
90807	with medical evaluation and management services
90808	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face the patient
90809	with medical evaluation and management services
90816	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient
90817	with medical evaluation and management services
90818	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient
90819	with medical evaluation and management services
90821	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient
90822	with medical evaluation and management services
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Subsequent delivery and management, per session
90870	Electroconvulsive therapy (includes necessary monitoring)
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/ transmitter, without reprogramming
95974	Complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
95975	Complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour
HCPCS Codes	
None	

Note: Inclusion on this list does not guarantee coverage

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DRAFT

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: NEUROIMAGING FOR HEADACHE

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

The following represent red flag conditions for underlying abnormality with headache, and imaging (CT or MRI) should be covered:

- new onset or change in headache in patients who are aged over 50
- thunderclap headache: rapid time to peak headache intensity (seconds to 5 min)
- focal neurologic symptoms (e.g. limb weakness, aura <5 min or >1 hour)
- non-focal neurological symptoms (e.g. cognitive disturbance)
- change in headache frequency, characteristics or associated symptoms
- abnormal neurological examination
- headache that changes with posture
- headache wakening the patient up
- headache precipitated by physical exertion or valsalva manoeuvre (e.g. coughing, laughing, straining)
- patients with risk factors for cerebral venous sinus thrombosis
- jaw claudication or visual disturbance
- neck stiffness
- fever
- new onset headache in a patient with a history of human immunodeficiency virus (HIV) infection
- new onset headache in a patient with a history of cancer
- headache with a history of dizziness, lack of coordination, numbness or tingling
- cluster headache, paroxysmal hemicrania or Short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing) (SUNCT).

In patients who present with a variation of their usual headache (e.g. more severe, longer in duration, or not responding to drugs), CT or MRI should not be covered.

Neuroimaging should not be covered for those with a clear history of migraine, without red flag features.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCE

Clark, E.E., Little, A., & King, V. (2010). *Red flags and imaging in headache*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

McCormack RF, Hutson A. Can Computed Tomography Angiography of the Brain Replace Lumbar Puncture in the Evaluation of Acute-onset Headache After a Negative Noncontrast Cranial Computed Tomography Scan? 2010. *Acad. Emerg. Med.*; 17:444

Frishberg BM, Rosenberg JH, Matchar DB, McCrory DC, Pietrzak MP, Rozen TD, Silberstein Sd. Evidence-based Guidelines in the Primary Care Setting: Neuroimaging in Patients with Nonacute Headache. 2000. US Headache Consortium. American Academy of Neurology. Accessed at:

<http://www.aan.com/professionals/practice/pdfs/gl0088.pdf>

Detsky ME, McDonald DR, Baerlocher MO, Tomlinson GA, McCrory DC, Booth CM. Does this Patient With Headache Have a Migraine or Need Neuroimaging? 2006. *JAMA*; 206:1274.

Scottish Intercollegiate Guidelines Network. (2008). *Diagnosis and Management of Headaches in Adults*. A National Clinical Guideline. Edinburg: Scottish Intercollegiate Guidelines Network. Retrieved from <http://www.sign.ac.uk/pdf/grg107.pdf>

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Headache is a common condition. Lifetime prevalence of headache is estimated at more than 90% and annual prevalence is estimated at 20% to 40%. Most headaches are classified as primary, meaning that they are not associated with organic disease. Secondary headaches are caused by underlying organic disease. The prevalence of organic disease or significant intracranial abnormality causing headache is low. Since headaches are common and there are many causes, clinical evaluation may be difficult. Red flags have been proposed to help identify patients with significant intracranial abnormality. MRI and CT are often used to identify significant intracranial abnormalities. MRI and CT of the brain are commonly performed, high cost imaging procedures. The combination of high prevalence of headaches, low prevalence of significant intracranial abnormalities and frequent use of MRI and CT may lead to unnecessary harms through radiation and false positives (incidental findings).

Statistical Background for Interpreting the Evidence

The statistic used to quantify the usefulness of a feature in predicting a finding is the likelihood ratio (LR). A likelihood ratio incorporates both the sensitivity and the specificity of the test and provides a direct estimate of how much a test result will change the odds of having a disease. Sensitivity is the ability of a test to correctly identify people with a condition. A test with high sensitivity will nearly always be positive for people who have the condition. Specificity is the ability of a test to identify correctly people without a condition. A test with high specificity will rarely be wrong about who does NOT have the condition. The LR for a positive result (LR+) tells you how much the odds of the disease increase when a test is positive. The LR for a negative result (LR-) tells you how much the odds of the disease decrease when a test is negative. Likelihood positive ratios that are > 1.0 increase the probability of disease and likelihood negative ratios less than 1.0 (e.g., 0.2, 0.05) decrease the probability of disease. Likelihood ratios have a large and more significant impact on the probability of disease when they are > 10 or < 0.1 .

Evidence Review

Headache Prevalence

There are a number of epidemiologic surveys of different populations from the US and elsewhere, which give widely varying prevalence rates. Migraine headache in adults in the US is reported at 6% to 18% per year, while tension headaches have been reported as 38% of adults per year. Frequent or severe headaches have been reported in 10% to 28% of children per year. Headaches were the presenting complaint for 2% of all

emergency room visits in a sample of emergency room visits in one sample, while sudden severe headache was the presenting complaint in 0.7%.

Prevalence of Significant Intracranial Abnormality

Of the two systematic reviews identified, McCormack (2010) reports that patients presenting to the emergency room with sudden severe headache have a prevalence of subarachnoid hemorrhage of 3% to 16%. Another study reported subarachnoid hemorrhage in 25% of 148 patients who presented to general practitioners with thunderclap headache in the Netherlands over 5 years. Frishberg (2000) reports average prevalence of significant intracranial abnormality in migraine patients of 0.18% and average prevalence of significant intracranial abnormality in tension headache of 0%. Individual studies report prevalence of significant intracranial abnormalities in adults with chronic headache of 0.7%, in adults with headache of 1.2%, and in adults with a normal neurological examination of 0.9%.

For children, individual studies have reported the prevalence of significant intracranial abnormalities in children with chronic headache to be 2%, and in children with headache presenting to a specialty clinic to be 10%, although in the latter study, positive findings included Chiari malformation, sinusitis, dilated Virchow Robin spaces, gliosis, arachnoid cysts, leukomalacia. Most of these would not be considered significant intracranial abnormalities or responsible for headaches by most authors, and their inclusion in the significant intracranial abnormality category overstates the prevalence of significant intracranial abnormality in these patients.

Red Flags (Clinical Features that Distinguish Between Patients with and without Significant Intracranial Abnormality)

There are two systematic reviews that examine clinical features (red flags) as predictors for the presence of significant intracranial abnormalities on neuroimaging (Detsky 2006; Frishberg 2000). Several additional retrospective and prospective case series address the value of red flags in the prediction of significant intracranial abnormalities in patients with headaches.

Detsky (2006) performed a systematic review of 11 case series assessing performance characteristics of screening questions and clinical examination in predicting the presence of underlying intracranial pathology on neuroimaging. Clinical features with a high positive likelihood ratio include cluster headache (LR + = 11), abnormal neurological examination (LR + = 5.3), “undefined headache” (LR + = 3.8), headache with aura (LR + = 3.2) and headache with focal symptoms (LR + = 3.1). Clinical features with low negative likelihood ratios included absence of an abnormal neurological examination (LR - = 0.71), headache not aggravated by Valsalva maneuver (LR - = 0.70), absence of vomiting (LR - = 0.47) and defined type (migraine and tension) headache (LR - = 0.66).

Frishberg (2000) performed a systematic review of 28 case series. Clinical features with a high positive likelihood ratio included abnormal neurological exam (LR + = 1.7-5.4), rapidly increasing headache frequency (LR + = 12), headache awakening from sleep (LR+ = 1.7 - 98), history of dizziness, lack of coordination, numbness or tingling (LR+ = 49), headache with Valsalva maneuver (LR+ = 2.3). Clinical features with a low negative likelihood ratio included absence of abnormal neurological exam (LR - = 0.7), absence of rapidly increasing headache frequency (LR - = 0.73), headache not awakening from sleep (LR - = 0.72), absence of headache with Valsalva maneuver (LR - = 0.67).

In one case series adult patients with non-acute headache referred to a neurology clinic, neuroimaging studies identified significant intracranial abnormalities in 1.2% of patients. The only red flag that had a significant positive likelihood ratio for significant intracranial abnormality was abnormal neurological examination (LR + = 42). Gender of patient, intensity of headache, duration of headache, worsening of headache all had LR that were close to 1.0.

Two studies from emergency rooms in Italy evaluated a clinical pathway (guideline) for the emergency room evaluation of non-traumatic headaches. One study grouped patients into three clinical scenarios and the other grouped patients into four clinical scenarios. The three common scenarios were Group 1: sudden, severe headache, “worst headache ever”, abnormal neurological signs, associated syncope, nausea or vomiting or headache after exertion. Group 2: recent onset of headache, worsening headache or first headache in patient age > 40 yrs. Group 3: usual headache but more severe, longer in duration or not responding to drugs. The additional Group 4 was severe headache with fever or neck stiffness. Groups 1, 2 and 4 received a CT scan in the emergency room. Group 3 did not receive CT. Computed tomography (CT) and 6 month clinical follow-up were used to make the final diagnosis. The first study reported only one missed diagnosis of 247 patients using the clinical pathway and noted a reduction in neurological consultations and shorter hospital stays compared to a similar group of patients from the year prior to the initiation of the clinical pathway. The second study reported that sensitivity of the clinical pathway was 100% and specificity was 64%, while positive likelihood ratio was 2.67 and negative likelihood ratio was 0.04.

Diagnostic Parameters for Neuroimaging in Patients with Headache

There is no comparative evidence demonstrating superior diagnostic performance in detecting significant intracranial abnormalities for either CT or MRI.

Effect of Neuroimaging on Patient Management or Outcomes

There is no evidence that suggests that MRI or CT use results in altered management or improved outcomes for patients with headache, whether the neurologic exam is normal or not.

Four good quality guidelines were identified in this report, one of which was from the Scottish Intercollegiate Guidelines Network (SIGN), published in 2008. They identify the following red flags which should prompt referral for further investigation:

- new onset or change in headache in patients who are aged over 50
- thunderclap headache: rapid time to peak headache intensity (seconds to 5 min)
- focal neurologic symptoms (e.g., limb weakness, aura <5 min or >1 hour)
- non-focal neurological symptoms (e.g., cognitive disturbance)
- change in headache frequency, characteristics or associated symptoms
- abnormal neurological examination
- headache that changes with posture
- headache wakening the patient up
- headache precipitated by physical exertion or valsalva manouver (e.g., coughing, laughing, straining)
- patients with risk factors for cerebral venous sinus thrombosis
- jaw claudication or visual disturbance
- neck stiffness
- fever
- new onset headache in a patient with a history of human immunodeficiency virus (HIV) infection
- new onset headache in a patient with a history of cancer

In addition, the guideline recommends the following:

- Brain MRI should be considered in patients with cluster headache, paroxysmal hemicrania or SUNCT.

Overall Summary

The prevalence of headache is high in adults, children and emergency room patients. The prevalence of significant intracranial abnormalities in headache patients is low, occurring 1% to 2% of children and adults, with the exception of subarachnoid hemorrhage in patients presenting to the emergency room with sudden, severe (thunderclap) headache, which has a prevalence between 3% and 25%. The red flags that have likelihood ratios sufficiently high to be helpful in predicting the presence of significant intracranial abnormalities are cluster headaches, rapidly increasing headache frequency, headache awakening from sleep, headache with a history of dizziness, lack of coordination, numbness or tingling and an abnormal neurologic examination. There are no individual red flags that have likelihood ratios sufficiently low to be helpful in predicting the absence of significant intracranial abnormalities, although some clinical pathways may reach this goal. There is no evidence that suggests that MRI or CT use results in altered management or improved outcomes for patients with headache and a normal neurologic exam.

PROCEDURE

Computed Tomography of the head
Magnetic Resonance Imaging of the head

DIAGNOSES

Headache

APPLICABLE CODES

Additional codes TBD

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
784	Headache
339.00	Cluster Headache
339.1	Tension headache
339.12	Chronic tension type headache
339.20	Post-traumatic headache, unspecified
339.21	Acute post-traumatic headache
339.22	Chronic post-traumatic headache
339.4	Complicated headache syndromes
339.43	Primary thunderclap headache
339.82	Headache associated with sexual activity
339.84	Primary exertional headache
339.89	Other specified headache syndromes
346.0-9	Migraine and variants
430	Subarachnoid hemorrhage
432.1	Subdural hematoma
784.2	Mass head
331.0-9	Hydrocephalus
320,321,322	Meningitis
323	Encephalitis
324	Intracranial abscess
ICD-9 Volume 3 (Procedure Codes)	
CPT Codes	
70450	CT Head without contrast material
70460	CT head with contrast material
70470	CT head without followed by with contrast material
70496	CT angiography with contrast material, including post processing
70544	MRI brain without contrast material

70545	MRI brain with contrast material
70546	MRI brain without followed by with contrast material
70551	MRI brain including brainstem without contrast material
70552	MRI brain including brainstem with contrast material
70553	MRI brain including brainstem without followed by with contrast material
HCPCS Codes	

Note: Inclusion on this list does not guarantee coverage

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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.

DRAFT

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: IMAGING IN DEMENTIA

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Screening of asymptomatic patients for dementia with neuroimaging should not be covered.

Reversible causes of dementia should be ruled out with a clinical evaluation and neuroimaging (CT or MRI).

In patients with mild cognitive impairment, imaging should not be used to predict progression of the risk of developing dementia.

In patients who have recently diagnosed dementia who meet the diagnostic criteria for both Alzheimer's disease and frontotemporal dementia and for whom the cause of the clinical symptoms remains in doubt, PET or SPECT should be covered.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCE

Clark, E.E., & Little, A., (2010). *Imaging in dementia*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

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Yuan, Y., Gu, Z.X., & Wei, W.S. (2009). FDG-positron emission tomography, single-photon emission tomography and structural imaging for prediction of rapid conversion to Alzheimer disease in patients with mild cognitive impairment: A meta-analysis. *Am J Neuroradiology*, 30, 404-410.

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Dementia is a common and growing problem affecting primarily the elderly. An estimated 4.5 million people in the US had Alzheimer's disease in 2000 and the forecasted burden of Alzheimer's disease is 13 million people by 2050. Although Alzheimer's disease makes up 60-70% of dementia cases, there are other subtypes of dementia with different clinical courses and there are a small number of patients with reversible dementia.

In addition to screening laboratory tests, CT and MRI are recommended and widely used to detect intracranial abnormalities which might cause dementia. Structural (CT and MRI) and functional (PET, SPECT and fMRI) neuroimaging are currently being used to aid in the differential diagnosis of dementia subtype and to help predict those patients with milder forms of cognitive decline (mild cognitive impairment) who will progress to frank dementia.

Prior to the year 2000, most guidelines recommended MRI or CT only on a select group of patients who met clinical prediction rules. After published studies suggested that the clinical prediction rules would result in missing a few cases of reversible dementia, guidelines changed to recommend structural neuroimaging on each dementia patient at the time of initial diagnosis. Additionally, PET and SPECT began to be investigated and advocated to confirm the diagnosis of Alzheimer's dementia, distinguish between subtypes of dementia and predict the progression of dementia in patients with memory loss. The Center for Medicare and Medicaid Services (CMS) first considered coverage of PET for dementia in 2000, at which time they commissioned an AHRQ technology assessment. The conclusions of that report were that "For patients with dementia who have had a recommended clinical evaluation, treatment without further testing is superior to treatment based on an additional test using PET." In response to a request to broaden coverage of PET in dementia in 2004, CMS commissioned an update of the earlier technology assessment, which concluded that there was no additional evidence on the value of PET in differential diagnosis beyond the evidence in the 2001 technology assessment. However, an expert panel recommended limited coverage, and CMS changed its coverage policy to cover PET for patients with recently diagnosed dementia who meet the diagnostic criteria for both Alzheimer's disease and frontotemporal dementia and for whom the cause of the clinical symptoms remains in doubt in 2004.

Statistical Background for Interpreting the Evidence

The statistic used to quantify the usefulness of a feature in prediction of a finding is the likelihood ratio (LR). A likelihood ratio incorporates both the sensitivity and the specificity of the test and provides a direct estimate of how much a test result will change the odds of having a disease. Sensitivity is the ability of a test to identify correctly people with a condition. A test with high sensitivity will nearly always be positive for people who have the condition. Specificity is the ability of a test to identify correctly people without a condition. A test with high specificity will rarely be wrong about who does NOT have the condition. The LR for a positive result (LR+) tells you how much the odds of the disease increase when a test is positive. The LR for a negative result (LR-) tells you how much the odds of the disease decrease when a test is negative. Likelihood positive ratios that are > 1.0 increase the probability of disease and likelihood negative ratios less than 1.0 (e.g., 0.2, 0.05) decrease the probability of disease. Likelihood ratios have a very large and ~~more~~ significant impact on the probability of disease when they are > 10 or < 0.1 . The odds ratio is the chance of an event occurring in one group compared to the chance of it occurring in another group. It is a measure of effect size and is commonly used to compare results in clinical trials.

Evidence Review

Prevalence of Reversible Dementia

There are a number of medical conditions that may present as dementia including depression, vitamin B12 (cyanocobalamin) deficiency, hypothyroidism, tertiary syphilis and some medications. These conditions can be diagnosed without the use of neuroimaging. Although causes of reversible dementia, these conditions are not considered in this report since they do not relate to neuroimaging. Causes of potentially reversible dementia that can be detected by neuroimaging include tumors, normal pressure hydrocephalus and chronic subdural hematoma but do not include cerebral ischemia or infarcts, although these latter findings may have importance in the differential diagnosis of the subtypes of dementia.

Foster (1999), a systematic review including six case series, found that potentially reversible dementia occurs in 20.7% of young (< 55 years) patients and in 5.4% of patients over 65 years. In their review, brain tumors occurred in 1% to 4% of dementia cases. Normal pressure hydrocephalus occurred in less than 2% of dementia patients and chronic subdural hematoma occurred in less than 1%. Another systematic review (Gifford 2000) also included six studies and reported prevalence rates of potentially reversible dementia that ranged from 1% to 10%.

Role of Neuroimaging in Differential Diagnosis of Dementia

Identifying the specific sub-type of dementia may provide the treating physician and family with information about the actual diagnosis and its expected clinical course, as well as identifying whether treatment directed at preventing further cognitive decline is indicated. Although most sub-types are diagnosed based on clinical findings, there is considerable clinical overlap of symptoms and clinical course in the dementia subtypes so that proper categorization of subtype might potentially be aided by neuroimaging findings. Neuroimaging diagnosis of dementia subtypes is based on both structural and functional changes in different regions of the brain; hence both structural MRI studies and functional SPECT, PET and fMRI studies have been advocated for differential diagnosis. The sub-types of dementia include Alzheimer's disease, vascular dementia, dementia with lewy bodies and frontotemporal dementia. The sensitivity of PET for making these diagnoses is 86-96%, while the sensitivity of SPECT is 71-77% and clinical evaluation alone is 43-93%. With regard to specificity, PET is 16-87% specific, SPECT is 76-89% specific and clinical evaluation alone is 48-100% specific.

Effect of Neuroimaging on Patient Management or Outcomes

Gifford (2000) reviewed the value of clinical prediction rules for the performance of neuroimaging in patients with dementia. Seven different clinical prediction rules were evaluated, each one including a different set of clinical findings such as presence of focal signs, headaches, rapidity of onset of symptoms, gait disorder, etc. The authors

found that the sensitivity of clinical prediction rules ranged from 25-100% and specificity ranged from 37-85%. Based on these findings the authors concluded that there is considerable uncertainty in the evidence underlying clinical prediction rules and that application of these rules may result in missed cases of potentially reversible dementia. A case series of 119 consecutive patients (Chui 1997) found that clinical prediction rules were 82% sensitive and 50% specific in predicting that neuroimaging studies would change the diagnosis. Clinical prediction rules had 5% false negatives and 36% false positives. The failure to diagnose those 5% of patients using clinical prediction rules resulted in the author's assumption that routine CT and MRI alter management by detecting cases of potentially reversible dementia. Based on the evidence addressing differential diagnosis reviewed above, any additional benefit of adding neuroimaging to clinical diagnosis on the ability to identify the correct dementia subtype appears to be small. In general, there is no evidence of improved outcomes from any neuroimaging intervention other than detecting causes of reversible dementia.

Role of Neuroimaging in Predicting Progression of Dementia

The prevalence data suggests that 10-15% of mild cognitive impairment patients will progress to dementia annually. Prediction of which individuals will progress using MRI, SPECT and PET is addressed by one meta-analysis (Yuan 2009) and six case series. However, without treatments that are effective at halting or reversing the progression of dementia, the ability to predict progression or prognosis may not have clinical value at this time.

Yuan (2009) evaluates PET, SPECT and MRI, and reports that pooled sensitivities for predicting progression of dementia ranged from 72-89% while specificities ranged from 70-85%. Positive likelihood ratios ranged from 2.56-4.61 and negative likelihood ratios range from 0.15-0.37. These likelihood ratios suggest small to moderate changes in probabilities. Odds ratios¹ ranged from 9.2-40.1. The authors concluded that PET performs slightly better than SPECT and MRI in predicting conversion of mild cognitive impairment to Alzheimer's dementia but no statistical tests were performed comparing MRI, PET and SPECT diagnostic efficacy. The individual case series had generally similar findings.

¹The odds ration in this case it represents the odds of a patient with MRI, PET or SPECT findings predictive of progression of dementia converting from mild cognitive impairment to Alzheimer's dementia compared to the odds of a patient with MRI, PET or SPECT findings predictive of non-progression. Thus a patient with a "progression" MRI has a 10.6 fold greater chance of conversion than a patient with a "non-progression" MRI (for PET the odds are 40.1 fold greater chance and for SPECT the odds are 9.3 fold greater chance of conversion).

Guidelines

National Institute for Health and Clinical Excellence (NICE 2006) recommends the use of SPECT or PET when the differential diagnosis of Alzheimer's dementia, vascular dementia and frontotemporal dementia is in doubt. Scottish Intercollegiate Network of Guidelines (SIGN 2006) also recommends the use of SPECT when the differential diagnosis of dementia is in doubt.

The US Preventive Services Task Force (USPSTF 2003) recommends against screening of normal patients for dementia with any form of testing including neuroimaging.

All of the guidelines recommend the use of structural neuroimaging (CT or MRI) in the initial evaluation of patients presenting with dementia in order to rule out reversible dementia.

Overall Summary

Potentially reversible dementia occurs in 20.7% of young (< 55 years) patients and in 5.4% of patients over 65 years. Clinical prediction rules aimed at identifying patients for whom neuroimaging would result in a changed diagnosis had a 5% false negative rate and 36% false positive rate. The failure to diagnose those 5% of patients using clinical prediction rules suggests that structural imaging with CT and MRI may alter management by detecting cases of potentially reversible dementia. The sensitivity of PET for diagnosing the various sub-types of dementia (86-96%) is higher than SPECT (71-77%) and potentially similar to clinical evaluation alone (43-93%). With regard to specificity, PET is 16-87% specific, SPECT is 76-89% specific and clinical evaluation alone is 48-100% specific. In general, there is no evidence of improved outcomes from any neuroimaging intervention other than detecting causes of reversible dementia. With regard to predicting progression of dementia using PET, SPECT or MRI, positive likelihood ratios ranged from 2.56-4.61 and negative likelihood ratios range from 0.15-0.37, suggesting small to moderate changes in probabilities.

PROCEDURE

Positron Emission Tomography (PET) of the brain
Magnetic Resonance Imaging (MRI) of the brain
Functional Magnetic Resonance Imaging (fMRI) of the brain
Single Photon Emission Computed Tomography (SPECT)

DIAGNOSES

Dementia (including Alzheimer's, vascular, Lewy body and frontotemporal types)
Mild Cognitive Impairment

APPLICABLE CODES

Additional codes TBD

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
293.0-293.1	Delirium
290.0	Senile dementia
290.1	Pre-senile dementia
290.4	Vascular dementia
331.0	Alzheimer's disease
331.1	Frontotemporal dementia
331.82	Dementia with Lewy bodies
331.83	Mild cognitive impairment
292.82	Dementia due to drugs
ICD-9 Volume 3 (Procedure Codes)	
CPT Codes	
70450	CT Head or brain without contrast material
70460	CT Head or brain with contrast material
70470	CT Head or brain without and with contrast material
70551	MRI Brain without contrast material
70552	MRI Brain with contrast material
70553	MRI Brain without and with contrast material
70554-70555	Functional MRI of Brain
78607	SPECT imaging of brain
78608	PET imaging of the brain
HCPCS Codes	

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