



**Health Evidence Review
Commission's
Health Technology Assessment
Subcommittee**

May 21, 2012

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

AGENDA

HEALTH TECHNOLOGY ASSESSMENT SUBCOMMITTEE (HTAS)

Meridian Park Hospital Health
Education Center, Room 117B
Tualatin, Oregon
May 21, 2012 from 1:00pm - 4:00pm

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

#	Time	Item	Presenter	Action Item
1	1:00 PM	Call to Order	Alissa Craft	
2	1:05 PM	Review of April minutes	Alissa Craft	X
3	1:10 PM	Review Public Comment on MRI for Breast Cancer Screening guidance	Allison Little	X
4	1:20 PM	Review Draft Coverage Guidances 1) Viscosupplementation for osteoarthritis of the knee 2) MRI in breast cancer diagnosis 3) Diagnosis of sleep apnea in adults 4) Treatment of sleep apnea in adults	Wally Shaffer	X
5	3:30 PM	Next month's topics Review Public Comment 1) Vertebroplasty, sacroplasty, and kyphoplasty 2) Lumbar discography 3) Artificial disc replacement 4) Hip resurfacing New coverage guidances 1) Continuous monitoring of blood glucose in Type 1 diabetes 2) Self monitoring of blood glucose	Alissa Craft	
6	3:45 PM	Confirm next meeting June 25 th	Alissa Craft	
7	3:50 PM	Public Comment		
8	4:00 PM	Adjournment	Alissa Craft	

HERC Coverage Guidance – MRI for Breast Cancer Screening Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
Stakeholder Location Unknown	1	MRI screening for breast cancer is non-carcinogenic diagnostic tool that would promote well-being and insure women's health. Current imaging using mammography radiates the woman's breast placing her at risk of developing a metastasy.	Thank you for your comment.
Industry Arlington, Virginia	2	The Medical Imaging and Technology Alliance (MITA) appreciates this opportunity to comment on the Health Evidence Review Commission's (HERC) draft coverage guidance for the use of MRI for breast cancer screening. As the leading trade association representing medical imaging and radiotherapy technology manufacturers, we have an in-depth understanding of the significant benefits to the health of women that breast MRI provides, particularly those at high risk for breast cancer. MITA looks forward to working with you to continue exploring the effectiveness of this technology as this area continues to be evaluated and researched as a means to better diagnose and treat Oregonians.	Thank you for outlining your interest in this topic.
	3	Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, related image acquisitions, diagnostic ultrasound, and nuclear medical imaging (including positron emission tomography (PET)), and magnetic resonance imaging (MRI). Medical imaging is used to diagnose patients with disease, often reducing the need for costly medical services and invasive surgical procedures.	The HTAS agrees with this statement, with the exception of radiation therapy, which is treatment, not imaging.
	4	MITA appreciates the work that the HERC has put into studying the importance of MRI for evaluation of the breast. In your draft guidance you state, “While screening for breast cancer with MRI has been shown to increase the detection of breast cancer when compared to screening with mammography alone, there is no evidence of a benefit on morbidity or mortality, and there is the possibility of over diagnosis associated with harm.” Your report also references the research conducted by the Washington State Health Technology Assessment (HTA) Program conducted on the use of MRI for the breast. In their final report, the Committee found that: “Based on these findings, the committee voted 7 to 2 to cover with conditions Breast MRI. Breast MRI is a covered benefit for screening for breast cancer with a minimum of 11 months between screenings in women at high risk of breast cancer. Women at high risk are defined as: 1. A personal history or strong family history of breast cancer; 2. A genetic mutation of BRCA 1, BRCA2, TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and	The HTAS is aware of the decision reached by the Washington HTA committee, but has made a different decision, based on the lack of demonstrated effect of MRI screening on patient important outcomes.

HERC Coverage Guidance – MRI for Breast Cancer Screening Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		<p>Bannayan-Riley-Ruvalcaba syndromes); 3. GAIL model lifetime cancer risk of 20% or higher; or 4. History of radiation treatment to the chest between ages 10 and 30, such as for Hodgkin’s disease.”</p>	
	5	<p>MITA strongly supports the findings of the Washington State HTA Program as a responsible and reasonable approach to the current state of the science with regard to this particular application of MRI technology. MITA agrees that the use of MRI for breast cancer screening is an important tool for physicians and the subset of patients outlined in their decision. We appreciate the work that the Oregon HERC has applied to this evaluation and the analysis done by your staff. We would encourage further consideration of an application of the technology in this case for the above outlined subset of women posing a higher risk for developing breast cancer. We look forward to continuing to work with you and your staff as additional evidence presents itself with regards to this important technology application.</p>	Please see comment above.

MINUTES

Health Technology Assessment Subcommittee
Meridian Park Community Health Education Center
19300 SW 65th Avenue, Tualatin, OR
April 23, 2012, 1:00-4:00pm

Members Present: Alissa Craft, DO, MBA; James MacKay, MD; Gerald Ahmann, MD (via phone); George Waldmann, MD, Ed Toggert, MD (via phone).

Members Absent: none

Staff Present: Darren Coffman; Wally Shaffer, MD, MPH; Dave Lenar.

Also Attending: Alison Little, MD (CEBP); Shannon Vandergriff (CEBP); Anna Thompson (Medtronic); Dena Searce (Medtronic); Joanie Cosgrove (Medtronic); Mike Bolen (Medtronic); Jeff Christensen (Jazz Pharmaceuticals); Chris Arapiff (Medtronic); Laura Modjeski (Pac/West Communications); Richard Kosasad.

I. CALL TO ORDER

Alissa Craft called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:05 pm.

2. REVIEW OF MARCH MINUTES

No changes were made to the March minutes.
Minutes approved 5-0.

3. REVIEW OF THE COVERAGE GUIDANCE AND PUBLIC INPUT PROCESS

Darren Coffman presented a review of the coverage guidance process including timelines for public input and posting of notices. He noted the discrepancy between a 30-day public comment period and fewer than 30 days between subcommittee meetings would mean an elongated process for completing coverage guidances.

4. REVIEW DRAFT COVERAGE GUIDANCE

A. LUMBAR DISCOGRAPHY

Wally Shaffer presented the evidence summary for lumbar discography and the draft coverage guidance was discussed. Expert written testimony, at the request of the subcommittee, was accepted from Dr. Don Ross, a neurosurgeon at OHSU. Dr. Ross outlined his reasons and supporting evidence for not recommending the use of discography, including the possibility of accelerated degenerative changes due to the

procedure. There was discussion about the meaning of “uncomplicated lumbar degenerative disc disease” and how that is differentiated from “complicated lumbar degenerative disc disease.” It was decided to leave out any mention of “uncomplicated” in the coverage guidance.

Action

- 1) Adopt revised draft coverage guidance:
Lumbar discography should not be a covered service for patients with low back pain.

A motion was made to approve and seconded. **Motion approved 5-0.**

B. VERTEBROPLASTY, SACROPLASTY, AND KYPHOPLASTY

Wally Shaffer presented the evidence summary for vertebroplasty, sacroplasty, and kyphoplasty and the draft coverage guidance was discussed. There was discussion about the immediate versus long term benefits of kyphoplasty. Some members felt that even though there may not be long term benefits, the immediate pain relief could justify covering the procedure. Members discussed the fact that there have been over 100 studies published regarding these procedures since the publication of the Washington HTA. The members felt there was sufficient evidence about the use of these procedures in treating osteoporotic compression fractures, but did not have enough evidence to make a conclusion about their use in malignancy related fractures or if there was any benefit for certain subpopulations.

Action

- 1) Adopt revised draft coverage guidance:
Vertebroplasty, sacroplasty, and kyphoplasty should not be covered for routine osteoporotic compression fractures.

A motion was made to approve and seconded. **Motion approved 5-0.**

C. ARTIFICIAL DISCS

Wally Shaffer presented the evidence summary on artificial discs (ADs) and the draft coverage guidance was discussed. Members discussed whether there were age limitations for cervical ADs and how much of the FDA approved indications to include in this and subsequent coverage guidances. Dr. MacKay raised concerns about durability, especially for load bearing lumbar ADs, and noted that there was not clear evidence.

Action

- 1) Adopt draft coverage guidance with the following revision:
“...Reconstruction of a single disc following single level discectomy...”

A motion was made to approve and seconded. **Motion approved 4-1.**

D. HIP RESURFACING

Wally Shaffer presented the evidence summary for hip resurfacing and the draft coverage guidance was discussed. Members were mainly concerned with the age of the Washington HTA and more recent evidence concerning the safety of metal-on-metal joint replacements. Wally Shaffer noted that the FDA was concerned enough with metal-on-metal safety that they added contraindications to the use of hip resurfacing specifically aimed at reducing complications from metal-on-metal. Members discussed if they would be able to rescind a coverage approval recommendation if a review of the metal-on-metal hip resurfacing evidence showed safety risks.

Action

- 1) Adopt draft coverage guidance as written.
- 2) Request the Center for Evidence-based Practice to evaluate any new evidence on the safety of metal-on-metal hip resurfacing.

A motion was made to approve and seconded. **Motion approved 5-0.**

5. PUBLIC COMMENT

Prior to a vote on the coverage guidance for vertebroplasty, sacroplasty, and kyphoplasty, public comment was received from Dena Scarce, a representative of Medtronic. She commented that the Washington HTA report which the subcommittee was basing their decision on was out of date given the numerous studies published since the HTA's release. She also raised concerns about the studies used in the HTA, noting that some of the studies used a mix of procedures to draw conclusions instead of using a single type of procedure. It was also commented that the Washington coverage decision was positive and all commercial payers in Oregon currently cover these procedures.

6. ADJOURNMENT

The meeting was adjourned at 3:10pm. The next meeting is scheduled for May 21, 2012 from 1:00-4:00 pm in Room 117B of the Meridian Park Hospital Community Health Education Center in Tualatin.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)
DRAFT COVERAGE GUIDANCE: VISCOSUPPLEMENTATION FOR
OSTEOARTHRITIS OF THE KNEE
DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Viscosupplementation is a covered benefit for the treatment of pain associated with Osteoarthritis (OA) of the knee when all of the following conditions are met:

- In patients who have not had an adequate response to nonpharmacological conservative treatment and simple analgesics;
- Is limited to two courses per year with at least four months between courses; and
- Documented evidence of clinical benefit from the prior course of treatment is required for subsequent treatment courses.

Hyaluronic Acid / Viscosupplementation is not covered for any other joint besides the knee.

RATIONALE FOR GUIDANCE DEVELOPMENT

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- 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

Hayes, Inc. (2010). *Hyaluronic Acid/Viscosupplementation*. Produced for the Medicaid Evidence-based Decisions Project and the Washington Health Technology Assessment Program. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University. Retrieved from http://www.hta.hca.wa.gov/documents/ha_final_report_042610.pdf

Hayes, Inc. (2010). *Viscosupplementation for osteoarthritis of the knee*. Produced for the Medicaid Evidence-based Decisions Project. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University. Retrieved from <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/index.cfm>

Samson, D. J., Grant, M. D., Ratko, T. A., Bonnell, C. J., Ziegler, K. M., & Aronson, N. (2007). *Treatment of primary and secondary osteoarthritis of the knee*. AHRQ Evidence Report/Technology Assessment No. 157. AHRQ Publication No. 107-E012. Evidence Report/Technology Assessment, (157), 1-157.

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 the most common form of chronic articular disease, affecting approximately 27 million adults in the United States. The most commonly affected joint is the knee, with prevalence estimates ranging from 12% to 16%. To date, there is no known cure for OA nor is there a disease-modifying agent. Optimal management generally requires a combination of both nonpharmacological and pharmacological therapies, and joint replacement surgery or a joint salvage procedure may be considered for selected patients with severe symptomatic OA who have not obtained adequate pain relief and functional improvement from medical therapy. Pharmacological therapy generally begins with acetaminophen, followed by nonsteroidal anti-inflammatory drugs (NSAIDs) if sufficient pain relief is not obtained. There is a small risk of systemic adverse effects with NSAIDs. Aspiration of fluid followed by intraarticular injection of a corticosteroid ameliorates pain in some patients, but duration of relief is usually limited to one to three weeks. Additionally, repeated intraarticular injections of corticosteroids have the potential to cause postinjection flare, infection, and progressive, long-term cartilage damage.

Recently, viscosupplementation with hyaluronan has been introduced as an alternative intraarticular injection therapy for OA. Hyaluronans are also known as sodium hyaluronate or hyaluronic acid (HA). HA is a normal component of synovial fluid and cartilage. The viscous nature of the compound allows it to act as a joint lubricant, whereas its elasticity allows it to act as a shock absorber. Hyaluronic products are characterized by their molecular weight, which varies according to the source of the compound and method of preparation. Five HA products are currently marketed in the United States: Euflexxa® (Ferring), Hyalgan® (Sanofi-Aventis), Orthovisc® (Anika Therapeutics), Supartz® (Seikagaku Corporation), and Synvisc® (Genzyme). Synvisc is a derivative of HA that consists of cross-linked polymers; the compound is referred to as Hylan G-F 20. Hyaluronate preparations have been approved by the Food and Drug Administration (FDA) for treatment of pain associated with OA of the knee in patients who have not had an adequate response to nonpharmacological, conservative treatment and simple analgesics. Recent systematic reviews have come to contradictory conclusions regarding the effectiveness of viscosupplementation, and national guidelines vary in their recommendations.

Evidence Review

There is consistent evidence demonstrating that viscosupplementation results in lower mean pain scores and improves mean function scores a few weeks after treatment. However, the magnitude of benefit may be too small to be clinically important. This evidence is derived from a quantitative synthesis of six meta-analyses performed by the Agency for Healthcare Research and Quality in 2007 which included 42 randomized placebo controlled trials and over 5000 patients. The authors found that the average change in pain score, although consistent and statistically significant, was small, with weighted mean differences in the range of 1.0 to 22.5 on a 100 point visual acuity scale. While there is no definitive definition of clinical significance, several authors, including Sampson, consider a 20 to 40 point improvement on 100 point pain scales to be clinically significant. There is a much greater volume of evidence regarding impact on pain than on function, and many studies did not follow patients beyond three months. Therefore, the impact of viscosupplementation on eventual recovery of function is uncertain. Compared with intraarticular corticosteroid injection, viscosupplementation appears to confer longer-lasting benefit, but the evidence was considered low quality. For comparisons with other treatments, there was insufficient evidence to allow any conclusion. Adverse events occur at a frequency of approximately 2% in single courses of treatment and are primarily transient local reactions, although rare, serious reactions are possible. The rate of adverse events per patient has been shown to increase with repeat courses of treatment, but the only available data were for hylan (high-molecular weight HA).

Evidence pertaining to issues other than efficacy and safety is of low quality:

- Available evidence suggests that viscosupplementation may be as effective as NSAIDs (four RCTs) and results in fewer systemic adverse events (two RCTs); in comparison with intraarticular corticosteroids, it has a delayed onset and longer lasting benefit (nine RCTs plus meta-analysis).
- Hylan may have a superior benefit compared with that of non-cross-linked HA, but the magnitude of difference is very uncertain and hylan poses a small increase in the risk of adverse events.
- To date, there is no evidence of a difference in benefit between low and medium molecular weight HA.
- Younger age may be associated with greater efficacy; evidence pertaining to effectiveness by other patient characteristics and history is lacking.

LIMITATIONS OF COVERAGE

The WA HTA Clinical Committee recommended the following limitations based on their evidence review:

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, Hyaluronic Acid / Viscosupplementation is a covered benefit for the treatment of pain associated with Osteoarthritis (OA) of the knee when all of the following conditions are met:

- In patients who have not had an adequate response to nonpharmacological conservative treatment and simple analgesics;
- Is limited to two courses per year with at least four months between courses; and
- Documented evidence of clinical benefit from the prior course of treatment is required for subsequent treatment courses.

Hyaluronic Acid / Viscosupplementation is not covered for any other joint besides the knee.

PROCEDURE

Viscosupplementation

DIAGNOSES

Osteoarthritis of the knee

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
715	Osteoarthritis and allied disorders Note: Localized, in the subcategories below, includes bilateral involvement of the same site. Includes: arthritis or polyarthritis: degenerative hypertrophic degenerative joint disease osteoarthritis
715.16	Osteoarthritis localized primary involving lower leg
715.26	Osteoarthritis localized secondary involving lower leg
715.36	Osteoarthritis localized not specified whether primary or secondary involving lower leg
715.96	Osteoarthritis unspecified whether generalized or localized involving lower leg
717	Internal derangement of knee Includes: degeneration of articular cartilage or meniscus of knee; rupture, old of articular cartilage or meniscus of knee; tear, old of articular cartilage or meniscus of knee
ICD-9 Volume 3 (procedure codes)	
81.92	Injection of therapeutic substance into joint or ligament as an ICD-9 procedure
ICD-10 Diagnosis Codes	
M15	Polyarthrosis Includes: arthrosis with mention of more than one site Excludes: bilateral involvement of single joint (M16-M19)
M15.0	Primary generalized (osteo)arthrosis
M15.3	Secondary multiple arthrosis
M15.4	Erosive (osteo)arthrosis
M15.8	Other polyarthrosis
M15.9	Polyarthrosis, unspecified
M17	Gonarthrosis (arthrosis of knee)
M17.0	Primary gonarthrosis, bilateral
M17.1	Other primary gonarthrosis
M17.2	Post-traumatic gonarthrosis, bilateral
M17.3	Other post-traumatic gonarthrosis
M17.4	Other secondary gonarthrosis, bilateral
M17.5	Other secondary gonarthrosis
M17.9	Gonarthrosis, unspecified
M19	Other arthrosis
CPT Codes applicable to viscosupplementation	
20610	Arthrocentesis, aspiration, and/or injection; major joint or bursa (e.g. shoulder, hip, knee joint)
CPT Codes applicable to total knee replacement (TKR)	

CODES	DESCRIPTION
27440	Arthroplasty, knee tibial plateau
27441	Arthroplasty, knee tibial plateau; with debridement and partial synovectomy
27442	Arthroplasty, femoral condyles, or tibial plateau(s) knee
27443	Arthroplasty, femoral condyles, or tibial plateau(s) knee; with debridement and partial synovectomy
27445	Arthroplasty, knee, hinge prosthesis (e.g., Walldius type)
27446	Arthroplasty, knee condyle and plateau; medial or lateral compartment
27437	Arthroplasty, patella; without prosthesis
27438	Arthroplasty, patella; with prosthesis
27447	Arthroplasty, knee condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)
HCPCS Level II Codes for viscosupplementation	
J7321	Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose
J7323	Hyaluronan or derivative, Euflexxa, for intraarticular injection, per dose
J7324	Hyaluronan or derivative, Orthovisc, for intraarticular injection
J7325	Hyaluronan or derivative, Synvisc or Synvisc-One, for intraarticular injection, 1 mg
HCPCS Level II Codes for intraarticular cortisone injection	
J0702	Injection betamethasone acetate 3 mg and betamethasone sodium phosphate, 3 mg
J0704	Injection, betamethasone sodium phosphate per 4 mg
J1020	Injection, methylprednisone acetate, 20 mg
J1030	Injection, methylprednisone acetate, 40 mg
J1040	Injection, methylprednisone acetate, 80 mg
J1094	Injection, dexamethasone acetate, 1 mg
J1100	Injection, dexamethasone sodium phosphate, 1 mg
J1700	Injection, hydrocortisone acetate, up to 25 mg
J1710	Injection, hydrocortisone sodium phosphate, up to 50 mg
J1720	Injection, hydrocortisone sodium succinate, up to 100 mg
J2650	Injection, prednisolone acetate, up to 1 mL
J2920	Injection methylprednisone sodium succinate up to 40 mg
J2930	Injection methylprednisone sodium succinate up to 125 mg
J3302	Injection triamcinolone diacetate, per 5 mg
J3303	Injection triamcinolone hexacetonide, per 5 mg

Note: Inclusion on this list does not guarantee coverage

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HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: MRI FOR BREAST CANCER DIAGNOSIS

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

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

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). *HTA Report: Breast MRI in diagnosis and treatment of cancer in women at high risk*. Olympia, WA: Health Technology Assessment Program. Retrieved from http://www.hta.hca.wa.gov/documents/breast_mri_072310_final.pdf

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SUMMARY OF EVIDENCE

Clinical Background

In 2009, an estimated 192,370 cases and 40,170 deaths occurred in women with breast cancer. In 2002, the United States Preventive Services Task Force found adequate evidence of film mammography's sensitivity and specificity and evidence of mammography's effectiveness in decreasing breast cancer mortality in women at average risk and concluded that film mammography was the standard for detecting breast cancer in women at average risk of developing breast cancer. In women recently diagnosed with breast cancer, MRI has been used to evaluate the contralateral breast, and has also been used to assist with treatment planning prior to definitive treatment. Whether these uses of breast MRI improve patient outcomes is not clear, and is the focus of this report.

Evidence Review

Detecting Contralateral Breast Cancer in Women Recently Diagnosed

MRI detects contralateral breast lesions in a substantial proportion of women with breast cancer, but does not reliably distinguish benign from malignant findings. This evidence review identified the following results:

- Detection of suspicious findings (true positives plus false positives): 9.3% (95% CI, 5.8% to 14.7%)
- Incremental cancer detection rate (ICDR): 4.1% (95% CI, 2.7% to 6.0%)
- PPV, 47.9% (95% CI, 31.8% to 64.6%)
- True positive: false positive ratio, 0.92 (95% CI, 0.47 to 1.82).

Some women will undergo treatment changes based on false positive tests, with one study reporting that 6.9% of women with changes in treatment based on MRI were found to have benign lesions. There were no RCTs which assessed the effect of adding MRI to conventional breast cancer screening on mortality rates.

Changes in Treatment in Women with Recently Diagnosed Breast Cancer

Preoperative MRI testing in women with recently diagnosed breast cancer will change treatment plans for some women (15.7%). Conversion of wide local excision to more extensive surgery will occur in up to 11.3% of women, and conversion from wide excision to mastectomy will occur in up to 8.1% of women. In women with breast cancer with dense breast tissue, microcalcifications suspicious for carcinoma in situ or discordance between mammography and ultrasound, MRI may add clinical information which may alter treatment plans (44.3% of the time in one retrospective observational study).

Changes in Treatment – Incomplete Excision

Adding MRI will change treatment plans and result in more extensive surgery for some women, but may not change incomplete excision rates or breast cancer recurrence

rates. The evidence is insufficient to determine whether MRI affects the rate of incomplete cancer excision because it is conflicting. One study found no difference between groups while another found an 18% decrease in re-excision rates in women who underwent MRI preoperatively. The study reporting of no difference between groups may have been underpowered to find a difference if one existed. The evidence is insufficient to determine whether changes in treatment plans based on the results of preoperative MRI testing are beneficial.

Changes in Treatment – Recurrence Rates

The evidence regarding the effect of preoperative MRI testing in women with early invasive breast cancer on recurrence rates is inconclusive. One retrospective observational study reported a 5.6% reduction in recurrence rates in patients receiving preoperative MRI before breast conservation surgery. Another larger observational study found that MRI was not associated with a lower recurrence rate or 8-year rate of local failure.

Safety

Gadolinium-based MRI contrast agents appear to be safe. There is no evidence of adverse events associated with MRI radiation exposure. We found no evidence that breast implants increase the risk of developing breast cancer. The evidence is insufficient to conclude that false-positive breast cancer screening or testing results lead to clinically meaningful negative psychological outcomes.

Technical and Provider Issues in MRI Testing

The evidence is insufficient to establish technical MRI specifications or provider qualifications.

[\[Evidence Source\]](#)

Overall Summary

MRI of the breast identifies contralateral breast lesions in women who have been recently diagnosed with breast cancer and may result in a change in treatment plans, but some women will undergo those changes based on false positive tests, and whether those changes are beneficial is unknown. Preoperative MRI testing in women with recently diagnosed breast cancer may change treatment plans, but there is no clear evidence that it changes incomplete excision rates or breast cancer recurrence rates. There is no evidence of a benefit on mortality with contralateral or preoperative MRI of the breast.

PROCEDURE

MRI of the Breast

DIAGNOSES

Breast cancer

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Codes	
V10.3	Personal history of malignant neoplasm, breast
V16.3	Family history of malignant neoplasm, breast
V76.10	Special screening for malignant neoplasms, breast, unspecified
V76.19	Special screening for malignant neoplasms, breast, other screening breast examination
V84.01	Genetic susceptibility to malignant neoplasm of breast
ICD-9 Volume 3 (procedure codes)	
None	
CPT Codes	
77058	MRI breast, with or without contrast, unilateral
77059	MRI breast, with or without contrast, bilateral
HCPCS Codes	
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8904	Magnetic resonance imaging without contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8907	Magnetic resonance imaging without contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

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HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: DIAGNOSIS OF SLEEP APNEA IN ADULTS

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

The following diagnostic tests for Obstructive Sleep Apnea (OSA) should be covered for adults:

1. Type I PSG is covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
3. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
4. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

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EVIDENCE SOURCE

Gleitsmann, K., Kriz, H., Thielke, A., Bunker, K., Ryan, K., Lorish, K., & King, V. (2012). *Sleep apnea diagnosis and treatment in adults*. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University. Retrieved from http://www.hta.hca.wa.gov/documents/sleep_apnea_final_report.pdf

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SUMMARY OF EVIDENCE

Clinical Background

Obstructive sleep apnea (OSA) refers to sleep-disordered breathing due to the recurrent collapse of pharyngeal tissues resulting in snoring, fitful sleep, and daytime somnolence. These episodes are characterized by either reduced airflow (hypopnea), or a complete obstruction (apnea), with a subsequent drop in oxygen saturation, interfering with gas exchange. Obstructive sleep apnea is a cause of significant morbidity and mortality and is associated with hypertension, neuropsychological impairment, motor vehicle accidents, stroke, cardiovascular disease, diabetes, and decreased quality of life. The prevalence of OSA is 2% to 7% in the general adult population. Prevalence increases steadily with age, to approximately 20% among people older than age 60.

Risk factors for OSA include male gender, age, obesity, airway characteristics, familial/genetic predisposition, smoking, and alcohol consumption. The majority of patients with OSA are asymptomatic, unaware of their sleep disordered breathing and associated health risks.

The diagnosis as well as the treatment of OSA is complicated by the difficulty in defining the syndrome. There is controversy surrounding the parameters to be used in a clinical definition as well as which diagnostic method is most appropriate to detect OSA. The current standard for diagnosing OSA is polysomnography (PSG) administered in a sleep study facility. The frequency of obstructed breathing events (i.e., the apnea-hypopnea index (AHI)), combined with multiple other clinical features of obstruction (e.g., oxygen desaturation, air flow, choking episodes) are recorded during sleep. A diagnosis of OSA is generally made when AHI is greater than or equal to 15 or greater than 5 with noticeable daytime symptoms. Considerable costs and patient inconvenience are involved in a PSG study. Portable PSG monitors, various

questionnaires, and predictive models using anatomic and demographic variables have been developed to aid in screening candidates for referral for further diagnostic testing (e.g., sleep lab PSG).

Evidence Review

Diagnosing OSA: The “Gold Standard”

Most experts consider laboratory-based PSG to be the reference standard for measuring Apnea-Hypopnea Index (AHI) in order to diagnose OSA. However, there are significant challenges that can be raised in considering PSG to be the “gold standard”. This would imply that this test is essentially error-free and therefore has the ability to prognosticate patients diagnosed with OSA from those without OSA. No current established threshold level for AHI exists that indicates the need for treatment. Furthermore, several facets raise uncertainty regarding PSG’s place as the diagnostic “gold standard”:

- There are variations across laboratories in the definitions of OSA (using different thresholds of AHI, from 5 to 15 events/hr) and in the way that the PSG results are read and interpreted.
- Apnea-Hypopnea Index, which is used as the single metric to define OSA, can vary from night to night and does not take into account symptoms, comorbidities, or response to treatment.
- Apnea-Hypopnea Index has variable value as a predictor of clinical outcomes:
 - The strength of evidence is high (based on four trials) that high baseline (AHI>30 events/hr or range) AHI is a strong and independent predictor of all-cause mortality over several years of follow-up (2-14 years).
 - The association between baseline AHI and the other long-term clinical outcomes is less robust, having been analyzed by only one or two studies:
 - Cardiovascular (CV) disease (studies reported mixed results regarding CV death, but AHI >30 was an independent predictor of nonfatal CV disease).
 - Stroke (one study suggested that the association between AHI and stroke may be confounded by obesity).
 - Hypertension (studies had uncertain conclusions regarding the possible association between AHI and incident hypertension)
 - Non-insulin-dependent diabetes and other metabolic abnormalities (studies reported mixed results that suggested an association between AHI and incident type 2 diabetes which, in one study, was confounded by obesity)
 - Decreased quality of life (a single study found no significant association between AHI and future quality of life [SF-36 after 5 years]).
- No current established threshold level for AHI exists that indicates the need for treatment.

In addition to the uncertainty surrounding the clinical utility of the AHI, the measurement of this index is also subject to several sources of variability. Airflow measurements are assessed by different instruments between laboratories and are subject to variation depending on the extent of mouth breathing in the subject. Oxygen saturation sampling is also measured by different types of oximeters using different methods of sampling, and other probes which measure respiratory movements and EEGs may differ between labs.

Interpretation of the PSG results is another area of potential uncertainty. Manual versus automated PSG scoring in the same lab may yield different results. Intra- and inter-rater variability may be problematic, and the definition of hypopnea varies, which results in different AHI measurements.

Repeatability and reproducibility of PSG measurements are also a concern. Serial studies with the same patient in the same lab may result in differential classifications, especially in patients whose AHI scores are close to the OSA diagnostic cut-off point.

Polysomnograms on the same patient in different labs would be expected to have even more variation due to differing measurement apparatus.

Based on the limitations of the test as described, it is clear that while lab-based PSG indices provide the current reference standard, they alone are not a “gold standard” for diagnosing OSA. Even so, clinicians agree that from a pragmatic point of view, the PSG information is important in the management of patients with disturbed sleep. Interestingly, no “strength of evidence” was assessed for this test, although it is the reference standard used throughout this report.

Methods of Measurement

Diagnosing OSA by detailing obstructive episodes is done using a variety of types of monitors in either the laboratory or home setting, and are categorized as follows:

- Type I: PSG in sleep facility
- Type II: Portable recording; same information as Type I (3 sleep arousal channels and minimum of 2 respiratory information channels)
- Type III: Portable recording; minimum of 2 respiratory channels (with no channels which differentiate waking and sleeping)
- Type IV: Portable monitors that fail Type III criteria

Compared to the current diagnostic standard (PSG), the strength of evidence is low that that Type II monitors can accurately diagnosis OSA, although there is wide variation in estimating the actual AHI, with discrepancies between the monitors and PSG as wide as negative 36 to positive 36 events/hr. In one study, the difference between the two measurements was dependent on their average value, with the portable monitor over estimating laboratory-based measurements for AHI<20 events/hr, but under estimating it in more severe cases. For Type III and IV monitors, the strength of the evidence is moderate that they can accurately predict an elevated AHI (as determined by full PSG). Type III monitors perform better than type IV monitors at AHI cut offs of 5, 10 and 15 events/hour.

Several questionnaire designs and clinical prediction models have been used to assess sleep disordered breathing. The conclusion of study authors is that there is a low strength of evidence supporting the use of the Berlin questionnaire to screen for OSA, while other questionnaires could not be evaluated due to insufficient strength of evidence (only one study evaluating each). There is a low strength of evidence supporting the usefulness of some clinical prediction modeling in OSA diagnosis.

There was insufficient evidence for the utility of phased testing (i.e., using a screening test result to determine the next test to be performed in a series), as compared to PSG.

Predictive Utility of OSA Diagnostic Tests

There was insufficient evidence to assess the utility of preoperative screening for OSA.

With regard to the relationship between AHI and long term outcomes, using AHI greater than 30 events per hour was found to be an independent predictor of all cause mortality with a high strength of evidence. A higher AHI was also associated with incident diabetes based on a low strength of evidence. The association of diabetes and OSA may be confounded by obesity which may contribute to both conditions. There was insufficient evidence to determine an association of AHI with other clinical outcomes (e.g., cardiovascular mortality and hypertension).

Overall Summary

Although PSG (type I monitor) is considered the gold standard for diagnosing sleep apnea, the strength of evidence that AHI is a strong and independent predictor of all-cause mortality is limited to AHI > 30. The association between baseline AHI and the other long-term clinical outcomes is less robust, no current established threshold level for AHI exists that indicates the need for treatment. Type II, III and IV monitors can all accurately diagnosis OSA, although there is wide variation in estimating the actual AHI for type II monitors, and type III monitors perform better than type IV monitors. Some clinical prediction models and the Berlin questionnaire have evidence of efficacy as screening tools for OSA.

[\[Evidence Source\]](#)

LIMITATIONS OF COVERAGE

Washington HTA Program

The WA HTA Clinical Committee reviewed the evidence and ultimately recommended that testing for OSA be covered using the same criteria as the Medicare national coverage determination. The Washington criteria are presented below, followed by the exact text of the Medicare policy:

Washington Coverage of testing for OSA is limited to:

- Adults age 18 years and older

- Testing must be performed by state approved providers
- Covered types of testing include:
 - Type I PSG in an attended sleep lab facility,
 - Type II or Type III sleep testing devices performed unattended in or out of a facility, or attended in a facility;
 - Type IV sleep testing devices measuring three or more channels, one of which is airflow, performed unattended in or out of a facility, or attended in a facility;
 - Sleep testing devices measuring three or more channels including actigraphy, oximetry, and peripheral arterial tone, performed unattended in or out of a facility, or attended in a facility.

Medicare National Covered Indications

Item/Service Description

A. General

Obstructive sleep apnea (OSA) is the collapse of the oropharyngeal walls and the obstruction of airflow occurring during sleep. Diagnostic tests for OSA have historically been classified into four types. The most comprehensive is designated Type I attended facility based polysomnography (PSG), which is considered the reference standard for diagnosing OSA. Attended facility based polysomnogram is a comprehensive diagnostic sleep test including at least electroencephalography (EEG), electro-oculography (EOG), electromyography (EMG), heart rate or electrocardiography (ECG), airflow, breathing/respiratory effort, and arterial oxygen saturation (SaO₂) furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed. Overnight PSG is the conventional diagnostic test for OSA. The American Thoracic Society and the American Academy of Sleep Medicine have recommended supervised PSG in the sleep laboratory over 2 nights for the diagnosis of OSA and the initiation of continuous positive airway pressure (CPAP).

Three categories of portable monitors (used both in attended and unattended settings) have been developed for the diagnosis of OSA. Type II monitors have a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, breathing/respiratory effort, SaO₂)-this type of device monitors sleep staging, so AHI can be calculated). Type III monitors have a minimum of 4 monitored channels including ventilation or airflow (at least two channels of respiratory movement or respiratory movement and airflow), heart rate or ECG, and oxygen saturation. Type IV devices may measure one, two, three or more parameters but do not meet all the criteria of a higher category device. Some monitors use an actigraphy algorithm to identify periods of sleep and wakefulness.

Indications and Limitations of Coverage

B. Nationally Covered Indications

Effective for claims with dates of service on and after March 3, 2009, the Centers for Medicare & Medicaid Services finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and

receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.

2. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

3. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

4. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

C. Nationally Non-Covered Indications

Effective for claims with dates of services on and after March 3, 2009, other diagnostic sleep tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP and are not covered.

PROCEDURE

Diagnostic testing for OSA

DIAGNOSES

Obstructive sleep apnea

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	

ICD-9 Volume 3 (Procedure Codes)	
CPT Codes	
HCPCS Codes	

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: TREATMENT OF SLEEP APNEA IN ADULTS

DATE: XX/XX/XXXX

HERC COVERAGE GUIDANCE

Coverage of treatment for Obstructive Sleep Apnea (OSA) in adults should be limited, as follows:

- CPAP should be covered initially when all of the following conditions are met:
 - 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour or if between 5 and 14 events with additional symptoms including excessive daytime sleepiness or impaired cognition, or documented hypertension, ischemic heart disease, or history of stroke;
 - Providers must provide education with patient prior to use of CPAP machine to ensure proper use. Caregivers may be educated instead if they will be consistently operating the device; and
 - Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).
- CPAP coverage subsequent to the initial 12 weeks should be based on documented patient tolerance, compliance, and clinical benefit.
- Laser-assisted uvulopalatoplasty (LAUP), somnoplasty, palatal implants, and submucosal ablation of the tongue base 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

Gleitsmann, K., Kriz, H., Thielke, A., Bunker, K., Ryan, K., Lorish, K., & King, V. (2012). *Sleep apnea diagnosis and treatment in adults*. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University. Retrieved from http://www.hta.hca.wa.gov/documents/sleep_apnea_final_report.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

Obstructive sleep apnea (OSA) refers to sleep-disordered breathing due to the recurrent collapse of pharyngeal tissues resulting in snoring, fitful sleep, and daytime somnolence. These episodes are characterized by either reduced airflow (hypopnea), or a complete obstruction (apnea), with a subsequent drop in oxygen saturation, interfering with gas exchange. Obstructive sleep apnea is a cause of significant morbidity and mortality and is associated with hypertension, neuropsychological impairment, motor vehicle accidents, stroke, cardiovascular disease, diabetes, and decreased quality of life. The prevalence of OSA is 2 to 7% in the general adult population. Prevalence increases steadily with age, to approximately 20% among people older than age 60. Risk factors for OSA include male gender, age, obesity, airway characteristics, familial/genetic predisposition, smoking, and alcohol consumption. The majority of patients with OSA are asymptomatic, unaware of their sleep disordered breathing and associated health risks.

There have been various modalities developed to treat OSA, most attempting to reduce the airway obstructive component. Continuous positive airway pressure (CPAP) is the first-line therapy for OSA and opens the airway with compressed air. However, the CPAP machinery required is poorly tolerated and compliance is a major concern. Various oral appliances, which attempt to splint open the airway, have been used as an alternative to CPAP. Surgical procedures, including various surgeries on the oropharyngeal anatomy to alter airway mechanics, are performed to treat OSA. Bariatric surgery may be performed to reduce the volume of obstructive tissues. Other interventions that have been used to treat OSA include: weight loss regimens; smoking cessation; caffeine and alcohol avoidance; positional therapy; oropharyngeal physical

therapy to strengthen the musculature and reduce obstruction; arrhythmia treatment for nocturnal bradycardia; complementary and alternative medicine (e.g., acupuncture), and a variety of pharmacologic agents.

Evidence Review

Continuous Positive Airway Pressure

A moderate strength of evidence was found for the effectiveness of treatment of OSA with CPAP. However, there was insufficient evidence to determine which patients CPAP might benefit the most. The reviewed studies report sufficient evidence supporting large improvements in sleep measures with CPAP compared with control (e.g., reducing AHI, improving symptoms as measured by the Epworth Sleepiness Scale (ESS), reducing arousal index, and raising the minimum oxygen saturation). Weak evidence demonstrated no consistent benefit in improving quality of life, neurocognitive measures or other intermediate outcomes. Despite no or weak evidence for an effect of CPAP on clinical outcomes, given the large magnitude of effect on the intermediate outcomes of AHI and ESS, the strength of evidence that CPAP is an effective treatment to alleviate sleep apnea signs and symptoms was rated moderate. However, the link between AHI reduction and long term clinical outcomes is not directly proven. There was insufficient evidence regarding most comparisons of various different CPAP devices, including nasal vs. oral, bilevel vs. fixed, flexible bilevel vs. fixed and humidified vs. non-humidified. However, there was a low strength of evidence that C-Flex (a proprietary CPAP technology that reduces the pressure slightly at the beginning of exhalation) is not significantly different than fixed CPAP in compliance or other outcomes, and a moderate strength of evidence that autoCPAP and fixed CPAP result in similar compliance and treatment effects.

Other Treatments for Obstructive Sleep Apnea

Mandibular advancement devices (MAD) had moderate strength of evidence supporting their use as an effective treatment for OSA. However, as with CPAP, there was insufficient evidence to indicate which patients might benefit from their use. There was moderate evidence that the use of CPAP is superior to MAD with regard to improved sleep study measures, but weak evidence that there is minimal difference between the two for improving compliance, treatment response, quality of life or neurocognitive measures. There was insufficient evidence to compare the different oral devices, other than MAD.

Six surgical interventions for the treatment of OSA were reviewed (uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatoplasty (LAUP), radiofrequency ablation (RFA), and combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty, radiofrequency ablation of the inferior nasal turbinates, or combination nasal surgery) compared to sham, conservative therapy or no treatment. No surgical interventions were compared to each other. Overall there was insufficient evidence with which to evaluate their efficacy. When each modality was compared to CPAP, the evidence was insufficient to determine their

relative merits. No evidence that met inclusion criteria was identified for any other surgical procedures.

Of the other treatments for OSA that were considered, only intensive weight loss programs were an effective treatment in obese patients with OSA with a low strength of evidence. The remainder of the other management modalities (e.g., atrial overdrive pacing, medications, palatal implants, oropharyngeal exercises, tongue-retaining devices with positional alarms either in isolation or in combination, bariatric surgery, acupuncture, and auricular plaster) had insufficient evidence to determine the effects of using them for treatment of OSA.

Compliance with Treatment

Compliance in OSA patients prescribed nonsurgical treatments had moderate strength of evidence that compliance was greater with CPAP use with more severe OSA and insufficient evidence regarding potential predictors of MAD compliance.

The strength of evidence is low for identifying any specific intervention which may improve CPAP compliance. No intervention type (e.g., education, telemonitoring) was more promising than others.

Overall Summary

CPAP is effective for improving sleep measures (e.g., reducing AHI, improving symptoms as measured by the ESS, reducing arousal index, and raising the minimum oxygen saturation), but there is no evidence of consistent benefit in improving quality of life, neurocognitive measures or other intermediate outcomes. AutoCPAP and fixed CPAP result in similar compliance and treatment effects. Mandibular advancement devices are effective treatment for OSA, although CPAP is superior to MAD with regard to improved sleep study measures. The evidence is insufficient to evaluate the efficacy of all surgical procedures and other treatments except intensive weight loss for obese patients with OSA.

LIMITATIONS OF COVERAGE

The WA HTA Clinical Committee reviewed the evidence, and ultimately recommended that treatments for OSA be covered using the same criteria as the Medicare local coverage determination (L30731), as outlined below:

Coverage of treatment for OSA is limited to:

- Adults age 18 years and older
- Treatment must be performed by state approved providers.
- CPAP is covered when all of the following conditions are met:
 - 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (API) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour or if between 5 and 14 events

- with additional symptoms including excessive daytime sleepiness or impaired cognition, or documented hypertension, ischemic heart disease, or history of stroke;
 - Providers must provide education with patient prior to use of CPAP machine to ensure proper use. Caregivers may be educated instead if they will be consistently operating the device; and
 - Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).
- Surgical options are covered for treatment of OSA when a diagnosis has been made, CPAP or other non-invasive treatments are not tolerated, and patients have been informed of the benefits and risks of surgery. Additional criteria are necessary for coverage of these procedures:
 - Uvulopalatopharyngoplasty (UPPP) - evidence of retropalatal and/or retrolingual obstruction as the cause of OSA;
 - Mandibular maxillary osteotomy - Evidence of retrolingual obstruction or previous failure of UPPP; and
 - Tracheostomy - when other treatments have failed or would not be effective
 - Correction of discrete anatomic abnormalities of the upper airway when contributing to OSA.

Laser-assisted uvulopalatoplasty (LAUP), Somnoplasty, palatal implants, and submucosal ablation of the tongue base are not covered.

PROCEDURE

Continuous positive airway pressure
 Uvulopalatopharyngoplasty
 Mandibular maxillary osteotomy
 Tracheostomy

DIAGNOSES

Obstructive sleep apnea

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
ICD-9 Volume 3 (Procedure Codes)	

CPT Codes	
HCPCS Codes	

Note: Inclusion on this list does not guarantee coverage

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Topics for Development by Health Technology Assessment Subcommittee

COVERAGE GUIDANCES COMPLETED

TOPIC	STATUS	REPORTS AVAILABLE	HERC APPROVAL	PRIORITY
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COVERAGE GUIDANCES CURRENTLY UNDER DEVELOPMENT BY HEALTH TECHNOLOGY ASSESSMENT SUBCOMMITTEE

TOPIC	STATUS	REPORTS AVAILABLE	For HERC Review	PRIORITY
MRIs for Breast Cancer Screening	30 Public Comment period April 3 - May 2, 2012	WA HTA	For HERC Review on Jun 14, 2012	<i>High</i>
Discography	30 Public Comment period May 1-May 30, 2012	WA HTA	For HERC Review on August 9, 2012	<i>High</i>
Hip Resurfacing	30 Public Comment period May 1-May 30, 2012	WA HTA	For HERC Review on August 9, 2012	<i>High</i>
Vertebroplasty, Kyphoplasty and Sacroplasty	30 Public Comment period May 1-May 30, 2012	WA HTA	For HERC Review on August 9, 2012	<i>High</i>
Artificial Disc Replacement	30 Public Comment period May 1-May 30, 2012	WA HTA	For HERC Review on August 9, 2012	<i>Medium</i>
Self Monitoring of Blood Glucose Type 1	Review at HTAS June 25, 2012 meeting	MED Report (Summary needed) WA HTA	For HERC Review on October 11, 2012	<i>High</i>
Self Monitoring of Blood Glucose Type 2	Review at HTAS June 25, 2012 meeting	MED Report (Summary needed) WA HTA (children only)	For HERC Review on August 9, 2012	<i>Medium</i>
Real Time Continuous Glucose Monitoring	Review at HTAS June 25, 2012 meeting	MED Report (Summary needed)	For HERC Review on August 9, 2012	<i>Medium</i>
Diagnosis of sleep apnea in adults	Review at HTAS May 21, 2012 meeting	AHRQ report WA HTA	For HERC Review on August 9, 2012	<i>Medium</i>
Treatment of sleep apnea in adults	Review at HTAS May 21, 2012 meeting	AHRQ report WA HTA	For HERC Review on August 9, 2012	<i>Medium</i>
Viscosupplementation for osteoarthritis of the knee	Review at HTAS May 21, 2012 meeting	Public MED Report (needs updating) WA HTA	For HERC Review on August 9, 2012	<i>Medium</i>
Vagus nerve stimulators for epilepsy	Review at HTAS June 25, 2012 meeting	Public MED Report WA HTA	For HERC Review on August 9, 2012	<i>Medium</i>
Bone growth stimulators	Review at HTAS June 25, 2012 meeting	Public MED Report WA HTA	For HERC Review on August 9, 2012	<i>Low</i>
Implantable infusion pumps	Review at HTAS September 24, 2012 meeting		For HERC Review on August 9, 2012	
PET Scan for Cancer	Review at HTAS on May 21, 2012 meeting	MED Report (Summary needed)	For HERC Review on August 9, 2012	<i>Medium</i>

FUTURE POTENTIAL TOPICS IDENTIFIED FOR Health Technology Assessment Subcommittee

TOPIC	STATUS	REPORTS AVAILABLE	For HERC Review	PRIORITY
Upper endoscopy (indications:GERD and Dyspepsia)		AHRO		<i>High (waiting for WA HTA report)</i>
Functional electrical stimulators for spinal cord and head injury, CP and upper motor neuron diseases		MED Report (Summary needed)		
Insulin pumps vs multiple daily injections for Type 1 and Type 2 diabetes		MED Report (Summary needed)		
Left ventricular assist devices (LVAD)		MED Report (Summary needed)		
New radiation therapies for non-intercranial malignancies		MED Report (Summary needed)		
Spinal cord stimulators for chronic pain		MED Report (Summary needed)		
Vacuum wound closure (negative pressure wound therapy)		MED Report (Summary needed)		
		HRC Report		