HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: DIAGNOSIS OF SLEEP APNEA IN ADULTS

DATE: 5/9/2013

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.

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 Heath 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.* Produced for the Washington HTA Program. Olympia, WA: Center for Evidence-based Policy, Oregon Health and Science University for the Washington Health Technology Assessment Program. Retrieved September 13, 2012, 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.

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]

PROCEDURE

Diagnostic testing for OSA

DIAGNOSES

Obstructive sleep apnea

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
327.20	Organic sleep apnea, unspecified
327.21	Primary central sleep apnea
327.23	Obstructive sleep apnea (adult) (pediatric)
327.27	Central sleep apnea in conditions classified elsewhere
327.29	Other organic sleep apnea

478.29	Nasopharyngeal obstruction
780.5	Sleep disturbance, unspecified
780.51	Insomnia with sleep apnea, unspecified
780.53	Hypersomnia with sleep apnea, unspecified
780.54	Hypersomnia, unspecified
780.57	Unspecified sleep apnea
ICD-9 Volume 3 (Procedure Codes)	
89.17	Polysomnogram
89.1	Other sleep disorder function tests
93.90	Non-invasive mechanical ventilation (CPAP)
CPT Codes	
95800	Sleep study, unattended, simultaneous recording: heart rate, O2 sat, respiratory analysis, sleep time
95801	Sleep study, unattended, simultaneous recording: heart rate, O2 sat, respiratory analysis
95803	Actigraphy
95805	Multiple sleep latency test
95806	Sleep study, unattended, simultaneous recording: heart rate, O2 sat, respiratory airflow and effort
95807	Sleep study,simultaneous recording: ventilation, respiratory effort, ECG or heart rate, O2 sat, attended by technologist
95808	Polysomnography: sleep staging with 1-3 additional parameters, attended by technologist
95810	Polysomnography: sleep staging with 4 or moe additional parameters, attended by technologist
95811	Polysomnography: sleep staging with 4 or more additional parameters, with initiation of CPAP, attended by technologist
HCPCS Codes	
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels

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.

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