

Health Technology Clinical Committee

Findings and Decision

Topic: Sleep Apnea Diagnosis and Treatment

Meeting Date: March 16, 2012

Final Adoption: May 18, 2012

Number and Coverage Topic

20120316A – Sleep Apnea Diagnosis and Treatment

HTCC Coverage Determination

Sleep apnea diagnosis and treatment is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

HTCC Reimbursement Determination

❖ **Limitations of Coverage**

Sleep apnea diagnosis and treatment coverage criteria:

- Adults, age 18 years and older;
- State approved providers;
- Consistent with the Medicare national coverage determination *Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) and Sleep Testing for Obstructive Sleep Apnea* excluding Coverage with Evidence Development (CED); and
- Consistent with the Medicare Local coverage determination (~~L30731~~) [**Refer to L34526 for most current LCD**] for *Surgical Treatment of Obstructive Sleep Apnea*.

❖ **Non-Covered Indicators**

As indicated in referenced Medicare national and local coverage determinations

Agency Contact Information

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC COVERAGE VOTE AND FORMAL ACTION

March 16, 2012 meeting transcript can be found at: www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials .

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on sleep apnea diagnosis and treatment (surgical and non-surgical) is sufficient to cover with conditions. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover diagnostic and treatment services (devices and procedures) for sleep apnea consistent with the coverage determinations outlined in the Medicare national coverage determination, with the exception of coverage with evidence development, and to cover surgical treatments consistent with the Medicare local coverage determination (L30731) for *Surgical Treatment of Obstructive Sleep Apnea*.

Sleep Apnea Diagnosis and Treatment Coverage Vote

HTCC Committee Coverage Determination Vote			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Sleep apnea diagnosis	0	0	7
Sleep apnea treatment- non-surgical	0	0	7
Sleep apnea treatment- surgical	0	0	7

- ✓ *Discussion:* The Chair called for discussion on conditions of coverage for sleep apnea diagnosis and treatment following the majority voting for coverage. The determination is limited to adults age 18 years and older for diagnosis and treatment of obstructive sleep apnea (OSA). The following conditions were discussed and approved by a majority of the clinical committee:
- ✓ *Limitations of Coverage:* Sleep apnea diagnosis and treatment is a covered benefit when the following conditions are met:
 - Adults age 18 years and older;
 - State agency approved providers;
 - Consistent with the Medicare national coverage determination *Continuous positive airway Pressure CPAP Therapy for Obstructive Sleep Apnea (OSA) and Sleep Testing for Obstructive Sleep Apnea* excluding Coverage with Evidence Development (CED); and
 - Consistent with the Medicare Local coverage determination (L30731) for *Surgical Treatment of Obstructive Sleep Apnea*.
- *Action:* The committee chair directed HTA staff to prepare a Findings and Decisions document on Sleep Apnea diagnosis and treatment reflective of the determination.

Complete text of the Medicare national coverage decision and local coverage determination is available in Appendix 2 of the Sleep Apnea report on pages 391 through 399 on the HTA website at:

Final

www.hca.wa.gov/about-hca/health-technology-assessment/sleep-apnea-diagnosis-and-treatment-adults . Excerpts of the text directly applicable to this coverage decision are included below.

Medicare National Coverage Determinations Manual Chapter 1, Part 4

240.4 – Continuous positive Airway Pressure CPAP Therapy for Obstructive Sleep Apnea (OSA) (Various Effective Dates)
(Rev. 96, Issued: 10-15-08, Effective: 03-13-08, Implementation: 08-04-08) <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=226&ncdver=3&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&Keyword=sleep+apnea&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAAACAAAAA&>

Nationally Covered Indications

B. Nationally Covered Indications

Effective for claims with dates of service on and after March 13, 2008, the Centers for Medicare & Medicaid Services (CMS) determines that **CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under the following situations:**

1. The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.
2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.
3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
 - a. attended PSG performed in a sleep laboratory; or
 - b. unattended HST with a Type II home sleep monitoring device; or
 - c. unattended HST with a Type III home sleep monitoring device; or
 - d. unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels.
4. The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision.
5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criterion using the AHI or RDI are met:
 - a. AHI or RDI greater than or equal to 15 events per hour, or
 - b. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.
6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at a minimum the number of events that would have been required in a 2-hour period.
7. Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

C. Nationally Non-covered Indications

Effective for claims with dates of services on and after March 13, 2008, other diagnostic tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP.

240.4.1 – Sleep Testing for Obstructive Sleep Apnea (OSA) (Effective March 3, 2009)

(Rev. 103, Issued: 07-10-09, Effective: 03-03-09, Implementation: 08-10-09) [www.cmms.hhs.gov/medicare-coverage-database/details/ncddetails.aspx?NCDId=330&ncdver=1&NCAId=227&NcaName=Sleep+Testing+for+Obstructive+Sleep+Apnea+\(OSA\)&IsPopUp=y&bc=AAAAAAAAIAAA&](http://www.cmms.hhs.gov/medicare-coverage-database/details/ncddetails.aspx?NCDId=330&ncdver=1&NCAId=227&NcaName=Sleep+Testing+for+Obstructive+Sleep+Apnea+(OSA)&IsPopUp=y&bc=AAAAAAAAIAAA&)

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. 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.
2. 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.
3. 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.

Medicare Local Coverage Determination [L30731](#) (updated 3/24/11) (40 states – includes Washington) [Refer to [L34526](#) for most current LCD]

- A. Uvulopalatopharyngoplasty (UPPP) is covered for those patients who have all of the following:
1. Obstructive sleep apnea diagnosed (prior to any proposed surgery) in a certified sleep disorders laboratory (certification body recognized by the American Academy of Sleep Medicine);
 2. A Respiratory Disturbance Index of 15 or higher
 3. Failed to respond to Continuous Positive Airway Pressure therapy or cannot tolerate CPAP or other appropriate non-invasive treatment;
 4. Documented counseling by a physician, with recognized training in sleep disorders, about the potential benefits and risks of the surgery; and
 5. Evidence of retropalatal or combination retropalatal/retrolingual obstruction as the cause of the obstructive sleep apnea.
- B. Mandibular Maxillary Osteotomy and Advancement and /or genioglossus advancement with or without hyoid suspension is covered for those patients who have all of the following:
1. Obstructive sleep apnea diagnosed (prior to any proposed surgery) in a certified sleep disorders laboratory (certification body recognized by the American Academy of Sleep Medicine);
 2. A Respiratory Disturbance Index of 15 or higher;
 3. Failed to respond to Continuous Positive Airway Pressure therapy or cannot tolerate CPAP or other appropriate non-invasive treatment;
 4. Documented counseling by a physician, with recognized training in sleep disorders, about the potential benefits and risks of the surgery; and
 5. Evidence of retrolingual obstruction as the cause of the obstructive sleep apnea, or previous failure of UPPP to correct the obstructive sleep apnea. Regarding the Mandibular Maxillary Osteotomy and Advancement operation:
 - a. Separate repositioning of teeth would not be necessary except under unusual circumstances; but if necessary the dental work would be covered.
 - b. Application of an interdental fixation device is occasionally necessary, and is a covered service (see Documentation Requirements).
- C. Tracheostomy is covered for obstructive sleep apnea that is in the judgment of the attending physician, unresponsive to other means of treatment or in cases where other means of treatment would be ineffective or not indicated.
- D. When obstructive sleep apnea is caused by discrete anatomic abnormalities of the upper airway (such as, but not limited to, enlarged tonsils or an enlarged tongue), surgery to correct these abnormalities is covered if medically necessary based on adequate documentation in the medical records supporting the significant contribution of these abnormalities to OSA. Submucous radiofrequency reduction of hypertrophied turbinates is covered as an appropriate treatment for nasal obstruction due to turbinate hypertrophy that significantly contributes to OSA or significantly compromises CPAP therapy.
- E. The following procedures are not covered at this time.
1. Laser assisted uvulopalatoplasty (LAUP) is not covered at this time since it is not considered effective for OSA. LAUP must not

be billed as 42145, Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty). This code is not appropriate for this procedure. If LAUP is billed for denial purposes, it should be coded as 42299, (unlisted procedure, palate, uvula) with "LAUP" listed in Item 19 on the CMS-1500 claim form or equivalent field for electronic claims. The claim will then be appropriately denied as not proven effective.

2. Somnoplasty™ is a trade name for palate reduction with the Somnoplasty™ System of Somnus Medical Systems. This is not a term recognized by this Contractor as a covered procedure under Medicare Part B. Therefore Somnoplasty™ must not be billed as 42145.
3. This code is not appropriate for this procedure. If Somnoplasty™ is billed for denial purposes, it should be coded as 42299, (unlisted procedure, palate, uvula) with "Somnoplasty™" listed in Item 19 on the CMS-1500 claim form or equivalent field for electronic claims.
4. This claim will then be appropriately denied as not proven effective.
5. The Pillar Procedure™ is a trade name for palatal implants. Palatal implants have not been shown effective for the treatment of obstructive sleep apnea and are not covered. This procedure should be billed by the physician as 42299 (unlisted procedure, palate, uvula) with "Pillar Procedure™" or "palatal implant" listed in Item 19 on the CMS 1500 claim form or equivalent field for electronic claims. This claim will then be denied as not proven effective. Hospital outpatient would use code C9727.
6. Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session (41530) is not covered

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.