CLINICAL MEDICAL POLICY	
Policy Name:	Surgical Treatment of Obstructive Sleep Apnea
Policy Number:	MP-098-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	10/01/2023; 10/01/2022; 10/15/2021; 08/20/2020; 11/18/2019
Effective Date:	11/01/2023; 11/01/2022; 11/15/2021; 11/16/2020; 11/18/2019
Next Annual Review:	08/2024
Revision Date:	08/16/2023; 08/17/2022; 08/18/2021; 08/19/2020
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

Policy History

Date	Activity
11/01/2023	Provider Effective date
09/13/2023	PARP Approval
08/16/2023	QI/UM Committee review
08/16/2023	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
11/01/2022	Provider Effective date
09/19/2022	PARP Approval
08/17/2022	QI/UM Committee review
08/17/2022	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
11/15/2021	Provider effective date
09/20/2021	PARP Approval
08/18/2021	QI/UM Committee review
08/18/2021	Annual Review: Changed policy title to "Surgical Treatment for Obstructive Sleep Apnea". Added 'Program Exception' statement and TAG determination information. Updated Summary of Literature and Reference Sources sections. Updated the following CPT code descriptions: 41512 (removed 'Repose') & 42299 (removed 'Coblation').
11/16/2020	Provider effective date
9/10/2020	PARP Approval

08/19/2020	Annual Review: No change in noncoverage position. Updated Summary of Literature and Reference sections.
08/19/2020	QI/UM Committee review
11/18/2019	Provider effective date
09/06/2019	PARP approval
08/21/2019	QI/UM Committee approval
08/09/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ does not provide coverage for the Company's Medicaid products for radiofrequency ablation of the tongue base, uvula or soft palate or the nasal passages and soft palate, hyoid and tongue base suspension.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Obstructive Sleep Apnea (OSA) - A form of sleep disturbance in which the upper airway becomes occluded during sleep causing periods of apnea and hypopnea due to repetitive collapse of the upper airway during sleep.

Radiofrequency Ablation of the Soft Palate and/or Tongue - A lower-power, low-temperature radiofrequency energy device to shrink the size of the uvula, soft palate and/or tongue in the treatment of nasal airway obstruction, obstructive sleep apnea or snoring. There are two trade names for this technology: the Somnoplasty™ and the Coblation® (ENT Coblator Surgery System). The procedure is also known as radiofrequency tissue reduction.

Tongue Base Suspension (previously branded as the Repose System®) - Minimally invasive procedure used for anterior tongue-base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a screw with pre-threaded suture to treat obstructive sleep apnea.

Procedures

1. Radiofrequency ablation (e.g., Somnoplasty) used to reduce excess tissue in patients with obstructive sleep apnea (OSA) is considered experimental and investigational and therefore, not medically necessary.

   The coblation procedure (e.g., ENT Coblator System) used to reduce excess tissue in patients with snoring is considered experimental and investigational and therefore, not medically necessary

   Tongue base suspension (e.g., AIRvance [formerly the Repose system]) used to treat OSA is considered experimental and investigational and therefore not medically necessary.

   Hyoid suspension systems (e.g., AIRvance and Encore system) used to treat OSA is considered experimental and investigational and therefore, not medically necessary.

   Any surgical procedure for simple snoring in the absence of OSA is considered not medically necessary.

   Note: This policy does not address uvulopalatopharyngoplasty.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

3. Place of Service
   The proper place of service for radiofrequency ablation procedures is outpatient.

4. Related Policies
   - MP-079-MD-PA Hypoglossal Nerve Stimulation Implantation in the Treatment of Obstructive Sleep Apnea

Governing Bodies Approval

The ENT Coblator Surgery System (ArthroCare Corp.; Austin, TX) is a device that has FDA approval for otorhinolaryngology (ear, nose, and throat [ENT]) procedures such as throat surgery to reduce excess tissue in the uvula/soft palate for the treatment of snoring. It is also approved for traditional uvulopalatoplasty and tonsillectomy. Tissue is vaporized, one cell layer at a time, without using heat energy.

The Somnoplasty System (Olympus, formally Gyrus ACMI and Somnus Medical Technologies; Center Valley, PA) is a device with an FDA 510(k) approval for reducing the incidence of airway obstruction in individuals suffering from upper airway resistance syndrome or OSA.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

In August 2009, the TAG workgroup assigned submucosal ablation of tongue base, radiofrequency (Entac Reflex Wand) and tongue base suspension, permanent suture technique (Repose System) an Option #4, specifically for CPT code 41530.

Summary of Literature

Obstructive sleep apnea (OSA) is a common condition in which the airway becomes obstructed during sleep which causes periods of apnea and hypopnea due to repetitive collapse of the upper airway during sleep. Recent studies have indicated that 1 in 4 adults in the United States (31% of all men and 21% of all women over age 18) are at high risk for developing OSA, and it is estimated that 25 million U.S. adults have OSA (American Sleep Association). Individuals at higher risk of developing sleep apnea include individuals diagnosed with hypertension, males, obese (BMI >30), use of alcohol or sedatives excessively, smoking, family history of OSA, have a large neck circumference (>17" in men and >16"in women), suffer from endocrine and metabolic disorders, or have upper airway or facial abnormalities. Complications from OSA include excessive daytime sleepiness, mental impairment, metabolic dysfunction, cardiovascular problems, heart attack, stroke, diabetes, impotence, acid reflux, and even death if untreated (Sesso, 2016).

OSA occurs at one or more levels of the nasopharyngo-tracheal airway. Type I disease involves narrowing or collapse of the retropalatal region. Type II disease involves collapse in the retrolingual area (tongue base). Type III disease involves narrowing or collapse of both the retropalatal and retrolingual areas. Major OSA is usually a multi-level disorder, with tissues of the soft palate, lateral pharyngeal walls, and tongue base all contributing to airway impingement. Intra-nasal tissue, adenoids, and tonsils may also play a role Management of OSA is based on symptomatology, the severity of the disease, and patient education regarding the risk factors and associated outcomes of OSA. Management begins with appropriate diagnostic testing to confirm OSA diagnosis (AASM, 2008).

Treatment options for OSA can include making lifestyle changes—losing weight, exercising regularly, limiting use of alcohol and sedatives, avoiding cigarette smoking, and adjusting sleeping position. A core component of treatment for OSA is the use of a positive airway pressure (PAP) device. PAP machines work by pumping pressurized air through a hose and into the airway. Treatment with a PAP device is considered to be the current gold standard in sleep apnea treatment and is offered as initial therapy to the majority of patients. Oral appliances or mouthpieces are another treatment option for mild or moderate OSA, especially if a person is unable to adjust to using a PAP device. Several types of surgery can be employed as a treatment for OSA. In adults, surgery is rarely a first-line treatment for OSA. It is most often

considered when a patient does not improve with other types of therapy, such as using a CPAP or oral appliances. Though these surgeries are normally well-tolerated, there are risks of complications such as infection, bleeding, pain, or other problems near the surgical site (Sleep Foundation, 2020).

Complications
Complications that may arise with OSA surgery may include extended pain, bleeding, impaired healing, failure to cure sleep apnea, thermal or electrical injury to mucus membranes of the soft palate, uvula or mouth, and the need of repeat procedures to fully resolve symptoms.

Surgical candidates include children with OSA, adults intolerant to CPAP or an oral appliance, adults with anatomical narrowing of the pharynx (e.g., tonsillar hypertrophy, macroglossia, retrognathia), adults with anatomical features that impair proper CPAP mask fit, adults who refuse to wear a CPAP device, and those with no contraindications to anesthesia or surgery. Surgery is generally reserved for patients with severe OSA because the risk-benefit ratio increases with the severity of the underlying disease. Patients considering surgery must be given information regarding surgical success rates and potential complications of the procedure. The procedure(s) chosen must be individualized based on the patient's unique anatomy and the root cause of upper-airway collapse. Surgical options may focus on correcting the anatomy of the nasal cavity, nasopharynx, oropharynx, and/or hypopharynx, as well as completely bypassing the normal airway (Chan, Kim, Avena-Woods, Pisano, 2019).

There is insufficient evidence in the published medical literature to demonstrate the safety and long-term outcomes of radiofrequency tissue reduction of the soft palate, uvula or tongue base in the treatment of obstructive sleep apnea. Optimal patient selection criteria have not been established and comparative effectiveness trials with long-term follow up are necessary.

The surgical intervention for OSA compared to other surgical or nonsurgical interventions or no intervention was reported by Cochran in 2008. A limited number of trials were identified that assessed diverse surgical techniques that included uvulopalatopharyngoplasty (UPPP), laser-assisted UPPP, palatal implants, radiofrequency volumetric tissue reduction UPPP versus oral appliances, expansion sphincter pharyngoplasty, mandibular osteotomy, multilevel temperature controlled radiofrequency tissue ablation compare dot CPAP and radiofrequency assisted UPPP versus channeling. The report indicated that there were inconsistent effects reported across all trials. Therefore, the evidence from all the small studies identified does not support the widespread use of surgery in people with mild to moderate daytime sleepiness associated with sleep apnea.

A 2015 systematic review of tongue base suspension techniques noted that data interpretation of the studies included in the review is somewhat difficult with some differences in the criteria of surgical success between studies, small numbers of patients, variable study designs, and insufficient follow-up (ranging 2–36 months) for adequate analysis. The authors also noted that none of the results are convincing enough to provide an answer to the question of which TBS technique is most effective and safe for patients with hypopharyngeal obstruction especially in the tongue base (Bostanci, 2015).

In regards to the use of hyoid suspension systems, a systematic review stated that the current literature lacks high-quality evidence with regard to hyoid surgery, and additional studies are needed to further elucidate the effect of hyoid surgery in OSA (Song, 2016).

A 2016 paper reviewed a variety of surgical techniques for the treatment of OSA. The authors stated that while some studies showed RFA seemed to improve the apnea-hypopnea index (AHI), but some studies

showed no change in the AHI at all. The authors concluded that all surgical techniques require that the benefits and risks need to be weighed for each patient. More importantly, more large randomized controlled studies on treatments or combination of treatments for OSA are needed using parameters such as treatment adherence, AHI, oxygen desaturation, subjective sleepiness, quality of life, and adverse events (both minor and major) to gauge treatment success in the short-term and long-term. Only then can OSA patients in partnership with their health care provider choose the best treatment option (Calik, 2016).

Two main clinical guidelines for the management of OSA have been developed by the American College of Physicians (ACP) and the American Academy of Sleep Medicine (AASM). The AASM published updated guidelines on specific OSA-management considerations in positive airway pressure (PAP) in 2019 and on oral-appliance therapy in 2015. The ACP guideline describes outcomes of studies that examined the efficacy and limitations of treatment options. Both guidelines agree that for all levels of severity in OSA, PAP is first-line therapy. Surgery, which is invasive, is the last resort. Patients considering surgery should be assessed for eligibility based on specific anatomical features, psychological and social factors, and degree of willingness.8 Transient pain, difficulty swallowing, globus sensation, and voice change can occur (Chan, Kim, Avena-Woods, Pisano, 2019).

Coding Requirements

Noncovered Procedure Codes

CPT Code	Description
41530	Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session
41512	Tongue base suspension, permanent suture technique
42299	Unlisted procedure, palate, uvula

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

Pennsylvania Department of Human Services. Technology Assessment Group (TAG) Coverage Decisions. Managed Care Operations Memorandum: #08-2009-017. Submucosal ablation of tongue base (Entac Reflex Wand). Option #4. Accessed on August 7, 2023.

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Bostanci A, Turhan M. A systematic review of tongue base suspension techniques as an isolated procedure or combined with uvulopalatopharyngoplasty in obstructive sleep apnea. Eur Arch Otorhinolaryngol 273, 2895–2901 (2015). Accessed July 1, 2020.

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