Clinical Policy Title: Uvulopalatopharyngoplasty

Clinical Policy Number: 10.03.05

Effective Date: October 1, 2015
Initial Review Date: June 17, 2015
Most Recent Review Date: July 3, 2018
Next Review Date: July 2019

Policy contains:
- Obstructive sleep apnea.
- Soft palate surgery.
- Uvulopalatopharyngoplasty.

Related policies:

- CP# 07.01.01 Treatment for obstructive sleep apnea in adults
- CP# 07.01.05 Diagnosing obstructive sleep apnea in adults
- CP# 07.03.02 Supraglottoplasty and laryngoplasty
- CP# 08.03.02 Bariatric surgery for adults
- CP# 11.03.04 Tonsillectomy and (or) adenoidectomy in children up to 12 years old

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers uvulopalatopharyngoplasty as a single or in-phased surgery to be clinically proven and, therefore, medically necessary in adults diagnosed with obstructive sleep apnea and any of the following criteria (Medicare Local Coverage Determination L34526, 2018; American Academy of Otolaryngology — Head and Neck Surgery, 2014; Qaseem, 2013; Aurora, 2010; Epstein, 2009):

- Failure to tolerate positive airway pressure therapy or mandibular advancement devices.
- Failure of positive airway pressure therapy or mandibular advancement devices to eliminate obstructive sleep apnea after a six-month trial.
- Evidence of surgically correctable retropalatal or combination retropalatal/retrolingual obstruction as the cause of obstructive sleep apnea.

Limitations:
All other uses of uvulopalatopharyngoplasty are not medically necessary, including, but not limited to:

- Treating snoring without significant obstructive sleep apnea.
- Improving adherence to obstructive sleep apnea treatment with positive airway pressure.

Uvulopalatopharyngoplasty is not medically necessary in pediatric populations, as surgery with tonsillectomy and adenoidectomy is considered the primary treatment for obstructive sleep apnea (Roland, 2011).

**Alternative covered services:**

See Clinical Policy # 07.01.01: Treatment for obstructive sleep apnea in adults.

- Positive airway pressure therapy.
- Mandibular advancement device devices (oral appliances).
- Palatal implants.
- Weight management programs.

**Background**

Obstructive sleep apnea is an important public health issue, with associated morbidity and mortality risks. Untreated obstructive sleep apnea is associated with symptoms of sleep deprivation and excessive sleepiness, cognitive dysfunction, diminished quality of life and productivity, sexual dysfunction, mood changes, increased accident risk, hypertension, non-insulin-dependent diabetes and other metabolic abnormalities, cardiac disease, and stroke. It affects all age groups, especially middle-aged and elderly people, and its frequency is increasing, most likely associated with escalating obesity rates (Balk, 2011).

The standard diagnostic test for obstructive sleep apnea is polysomnography performed at a sleep laboratory. The American Academy of Sleep Medicine classifies obstructive sleep apnea severity according to apnea-hypopnea index as mild (5 – 14 events per hour), moderate (15 – 30 events per hour), and severe (>30 events per hour) (Qaseem, 2013). There is no current established threshold level for the apnea-hypopnea index that indicates the need for treatment.

The goal of obstructive sleep apnea treatment is to alleviate airway obstruction during sleep. Tonsillectomy and adenoidectomy are the first-line treatments for obstructive sleep apnea in children. In adults, treatment of obstructive sleep apnea includes behavioral therapy (e.g., weight loss), drug therapy, continuous positive airway pressure (continuous positive airway pressure), dental or mandibular advancement devices, palatal implants, and surgery (upper airway or bariatric) (Qaseem, 2013; Randerath, 2011; Aurora, 2010). Some adults whose obstructive sleep apnea has been treated inadequately may benefit from surgical procedures that remodel the upper airway to repair upper airway obstruction causing airway collapse and obstructive sleep apnea.

Uvulopalatopharyngoplasty is a surgical procedure that increases the oropharyngeal airspace by removing tissue of the uvula, soft palate, tonsils, adenoids, and/or pharynx (Adil, 2015). In the United States, it is the most common surgery for adults with obstructive sleep apnea. Uvulopalatopharyngoplasty can be
performed as a stand-alone procedure, combined with other pharyngeal procedures during the same surgical session (non-phased), or as part of a step-wise (multi-phased) surgical protocol (Adil, 2015).

**Searches**

Select Health of South Carolina searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on May 17, 2018. Search terms were: “palate/surgery,” (MeSH) “uvula/surgery,” (MeSH), “pharynx/surgery,” (MeSH), and “sleep apnea, obstructive/surgery” (MeSH).

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

For this policy, we identified two systematic reviews (Balk, 2011; Caples, 2010), one new randomized controlled trial (Browaldh, 2013), and three evidence-based guidelines (Qaseem, 2013; Aurora, 2010; Epstein, 2009). The evidence primarily consists of small observational surgical case series and few randomized controlled trials of surgical treatments for obstructive sleep apnea. Rarely, uvulopalatopharyngoplasty has been used to treat snoring in the absence of documented obstructive sleep apnea when non-surgical treatments have failed. However, it may not completely cure snoring, and the risks of surgery may be higher than the small benefit gained. The overall quality of the evidence base is low and limited by inconsistencies in, or incomplete reporting of, selection criteria, baseline characteristics across study populations, surgical protocols, chosen outcomes, and adverse effects, which make the relative risks and benefits of uvulopalatopharyngoplasty for people with obstructive sleep apnea difficult to determine.

Overall, study subjects were mostly male, less than 50 years of age, with severe obstructive sleep apnea (apnea-hypopnea index > 40/hour) (Balk, 2011; Caples, 2010). Studies of elderly, minority, and female populations are scarce. Trials of isolated uvulopalatopharyngoplasty surgery included patients with a body mass index of less than 30 kg/m². In studies of uvulopalatopharyngoplasty combined with other
procedures, selection criteria included the presence of bulky lateral oropharyngeal tissues and lateral pharyngeal wall collapse (Caples, 2010). Indications for surgical treatment included an elevated apnea-hypopnea index or respiratory disturbance index with excessive daytime somnolence, oxygen desaturations below 90 percent, medical comorbidities including hypertension and arrhythmias, anatomic abnormalities of the upper airway, and failure of medical treatment (Caples, 2010). However, attempts to identify prognostic indicators that would improve patient selection for uvulopalatopharyngoplasty and surgical success have been unreliable (Qaseem, 2013).

Isolated pharyngeal/soft palatal interventions reduced the apnea-hypopnea index inconsistently, resulting in many patients having a significant level of residual obstructive sleep apnea postoperatively, even in those with mild-to-moderate obstructive sleep apnea at baseline (Browaldh, 2013; Balk, 2011; Caples, 2010). Serious adverse events were rare but associated with perioperative complications, including perioperative death of about 1.5 percent in two studies. Long-term adverse events from smaller studies included speech or voice changes, difficulty swallowing, airway stenosis, and others in 2 percent – 15 percent of patients (Balk, 2011; Caples, 2010). Significant improvements in apnea-hypopnea index were reported in some small series of multi-level surgeries with and without uvulopalatopharyngoplasty. The efficacy was attributed, in part, to careful patient selection, namely retropalatal or combination retropalatal/retrolingual obstruction. Self-selection of patients who willingly returned for a subsequent surgical procedure biased the results of multi-phase surgery (Balk, 2011; Caples, 2010).

Evidence-based guidelines agree that, except for tracheotomy, surgical procedures for obstructive sleep apnea are rarely curative (Qaseem, 2013; Aurora, 2010; Epstein, 2009). Surgery, including uvulopalatopharyngoplasty, is considered secondary treatment for obstructive sleep apnea when the outcome with continuous positive airway pressure or oral appliances is inadequate. Therefore, patients with severe obstructive sleep apnea should initially be offered continuous positive airway pressure, while those with moderate obstructive sleep apnea should initially be offered either continuous positive airway pressure or oral appliances. Use of multi-level or step-wise surgical procedures is acceptable in patients with narrowing of multiple sites in the upper airway, particularly if they have failed uvulopalatopharyngoplasty as a sole treatment.

Primary surgical treatment may be considered in people with mild obstructive sleep apnea who have severe obstructing anatomy that is surgically correctable (Epstein, 2009). A position statement by the American Academy of Otolaryngology — Head and Neck Surgery (2014) supports the effectiveness of surgical modification of the velopharynx if the area has been shown to collapse.

**Policy updates:**

In 2017, we found two new systematic reviews for this policy. The pooled results from multiple case series identified several long-term complications following uvulopalatopharyngoplasty (Tang, 2017). Foreign body sensation and a dry pharynx were the most common complaints reported, followed by difficulty swallowing, voice changes, taste disturbances, and velopharyngeal insufficiency. The authors hypothesized that these complications occurred more frequently than previously thought.
Choi (2016) systematically reviewed 15 retrospective case series to clarify the uncertainty surrounding valid predictors of outcome following uvulopalatopharyngoplasty. Low-quality evidence from 15 retrospective case series suggests anatomic factors such as Friedman stage and hyoid position were stronger predictors of outcome than age, body mass index, or preoperative apnea-hypopnea index, reinforcing the need for surgeons to carefully consider anatomic factors in their preoperative assessment. These results do not alter the previous findings; however, the anatomical region causing the obstruction is mentioned in Medicare’s local coverage determination criteria (L34526) and needed to be clarified in this policy statement, warranting a policy modification.

In 2018, we added one evidence-based guideline of managing obstructive sleep apnea in pediatric populations (Roland, 2011), which is consistent with current policy. We made one minor change to the policy statement that allows any criterion (not all criteria) to be met with adults diagnosed with obstructive sleep apnea, to be consistent with current guidelines.

Summary of clinical evidence:

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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Tang (2017)</td>
<td>Key points:</td>
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| Long-term incidence of velopharyngeal insufficiency and other sequelae following uvulopalatopharyngoplasty | - Systematic review of 24 studies.  
- Complications included velopharyngeal insufficiency (24 studies, 191 subjects), difficulty swallowing (seven studies, 83 patients), taste disturbances (four studies, 10 patients), voice changes (seven studies, 46 patients), foreign body (nine studies, 427 patients), and dry pharynx (seven studies, 150 patients).  
- Foreign body sensation (31.2%), difficulty swallowing (17.7%), dry pharynx (23.4%), voice changes (9.5%), taste disturbances (8.2%), and velopharyngeal insufficiency (8.1%).  
- Limited long-term data suggest that complications are more common than previously reported. Other sequelae, such as foreign body sensation, may be one of the most frequently expected complications after uvulopalatopharyngoplasty surgery. |
| Choi (2016)            | Key points:                        |
| Predicting outcomes after uvulopalatopharyngoplasty for adult obstructive sleep apnea | - Meta-analysis of 15 retrospective case series.  
- Overall quality: low with high risk of bias.  
- Friedman stage I is a strong positive predictor (odds ratio [OR] 4.429, range 2.316 to 8.486, P < .001), but Friedman stage III (odds ratio 0.164, range 0.040 to 0.663, P = .011) and low hyoid position (standard mean difference 20.397, range 20.658 to 20.136, P = .003) are negative predictors (three studies, 361 patients).  
- Age, body mass index, preoperative apnea-hypopnea index, and other cephalometric measurements were not significant. |
| Balk (2011)            | Key points:                        |
| Comparative effectiveness review for Agency for Healthcare Research and Quality’s | - Systematic review of studies of treatment of obstructive sleep apnea in adults (variable numbers of patients).  
- Overall quality: low with high risk of bias and unclear reporting of design elements and outcomes. |
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<thead>
<tr>
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<tr>
<td>• Uvulopalatopharyngoplasty versus:</td>
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<td>- Conservative treatment: Significant improvement in daytime somnolence (p &lt; 0.05) observed after 12 months; no difference in cognitive function.</td>
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<td>- Continuous positive airway pressure (two randomized controlled trials, three observational studies): Effects on mortality, apnea-hypopnea index, daytime sleepiness, and sleep quality inconclusive.</td>
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<td>- Mandibular advancement devices (one randomized controlled trial): Significantly more patients using mandibular advancement devices achieved 50% reductions in apnea-hypopnea index at one year and significantly lower apnea-hypopnea index at four years.</td>
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<td>• Adverse events associated with uvulopalatopharyngoplasty (10 studies, including one large cohort study of 3,130 patients):</td>
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<td>- Mostly perioperative, including perioperative death in about 1.5% in two studies.</td>
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<td>- Long-term adverse events from smaller studies included speech or voice changes, difficulties swallowing, airway stenosis, and others in 2% to 15% of patients. Largest surgical cohort study reported no long-term complications (not including perioperative death or cardiovascular complications).</td>
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**Key points:**

- Systematic review of two randomized controlled trials (uvulopalatopharyngoplasty versus oral appliances or lateral pharyngoplasty) and 13 prospective or retrospective observational studies of uvulopalatopharyngoplasty (950 total patients).
- Overall quality: low, with high risk of bias. Inconsistent or unreported patient selection criteria, surgical protocols, outcome measures, and adverse events.
- Uvulopalatopharyngoplasty only:
  - Mean age 44 years, 91.9% males, average body mass index 29 kg/m²; and average baseline apnea-hypopnea index 40.3 events/hour. Follow-up duration: three months to one year.
  - Overall 33% reduction in apnea-hypopnea index (95% confidence interval 23% to 42%). Postoperative residual apnea-hypopnea index remained elevated, averaging 29.8/hour.
  - Adverse events: difficulty swallowing/nasal regurgitation, taste disturbances, voice changes; lower complication rates reported in more recent studies. Large Veterans Administration survey reported a 1% to 2% risk of life-threatening adverse events and 0.2% risk of death. Overall mortality 0% to 16%. Two cases of postoperative bleeding.
- Combined uvulopalatopharyngoplasty and other procedures:
  - Mean baseline apnea-hypopnea index > 40. Significant improvements in apnea-hypopnea index in small surgical series of multi-level surgeries attributed in part to careful patient selection. Impact of standardized clinical measures and/or imaging studies on improved patient selection and surgical outcomes requires further research.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

None identified as of the writing of this policy.

**Local Coverage Determinations:**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
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<td>42145</td>
<td>Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)</td>
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<tr>
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<th>Description</th>
<th>Comment</th>
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<tr>
<td>G47.33</td>
<td>Obstructive sleep apnea (adult) (pediatric)</td>
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<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
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