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 20, 2017
Next Review Date: July 2018

Related policies:

CP# 07.01.01 Treatment for obstructive sleep apnea in adults
CP# 07.01.05 Diagnosing obstructive sleep apnea in adults

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ 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 AmeriHealth Caritas 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. AmeriHealth Caritas’ 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. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers uvulopalatopharyngoplasty (UPPP) as a single or in-phased surgery to be clinically proven and, therefore, medically necessary when all of the following criteria are met:

- Adult diagnosed with obstructive sleep apnea (OSA) (See Clinical Policy #07.01.05: Diagnosing obstructive sleep apnea in adults).
- Failure to tolerate positive airway pressure (PAP) therapy or mandibular advancement devices (MADs).
- Failure of PAP therapy or MADs to eliminate OSA after a six-month trial.
- Evidence of retropalatal or combination retropalatal/retrolingual obstruction as the cause of OSA.

Limitations:

All other uses of UPPP are not medically necessary, including, but not limited to:
Treating snoring without significant OSA.
Improving adherence to OSA treatment with PAP.

UPPP is not medically necessary in pediatric populations.

**Alternative covered services:**

See Clinical Policy # 07.01.01: Treatment for obstructive sleep apnea in adults.
- PAP therapy.
- MAD devices (oral appliances).
- Palatal implants.
- Weight management programs.

**Background**

OSA is an important public health issue, with associated morbidity and mortality risks. Untreated OSA 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. OSA affects all age groups, especially middle-aged and elderly people. OSA rates are increasing, most likely associated with escalating obesity rates (Balk, 2011).

The standard diagnostic test for OSA is polysomnography performed at a sleep laboratory. Results are reported as the apnea-hypopnea index (AHI) or respiratory disturbance index (RDI). The AHI is a strong and independent predictor of all-cause mortality over several years of follow-up, with the association being strongest among people with severe OSA (Balk, 2011). The American Academy of Sleep Medicine (AASM) classifies OSA severity according to AHI 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 AHI that indicates the need for treatment.

The goal of OSA treatment is to alleviate airway obstruction during sleep. Tonsillectomy and adenoidectomy are the first-line treatments for OSA in children. In adults, treatment of OSA includes behavioral therapy (e.g., weight loss), drug therapy, continuous positive airway pressure (CPAP), dental or MADs, palatal implants, and surgery (upper airway or bariatric). CPAP is the first-line therapy for adults with severe OSA, but overall compliance with CPAP and MADs is quite low (50 percent to 60 percent), particularly among those with less severe impairment (Qaseem, 2013; Randerath, 2011; Aurora, 2010).

Some adults whose OSA has been treated inadequately may benefit from surgical procedures that remodel the upper airway to repair upper airway obstruction causing airway collapse and OSA. The location of collapse (i.e., nasopharyngeal, oropharyngeal, or hypopharyngeal) and the specific structures causing obstruction guide surgical intervention that may involve shrinking, stiffening, or removing excess tissue in the nose, mouth, and throat, or resetting the lower jaw.
UPPP is a surgical procedure that increases the oropharyngeal airspace by removing throat tissue, including the uvula, soft palate, tonsils, adenoids, and/or pharynx (Adil, 2015). In the United States, it is the most common surgery for adults with OSA. UPPP 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**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s (AHRQ) National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on June 27, 2017. Search terms were: “palate/surgery,” “uvula/surgery,” “sleep apnea, obstructive/surgery,” and “uvulopalatopharyngoplasty (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 (RCT) (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 RCTs of surgical treatments for OSA. Rarely, UPPP has been used to treat snoring in the absence of documented OSA 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 makes the relative risks and benefits of UPPP for people with OSA difficult to determine.

Overall, study subjects were mostly male, less than 50 years of age, with severe OSA (AHI > 40/hour) (Balk, 2011; Caples, 2010). Studies of elderly, minority, and female populations are scarce. Trials of isolated UPPP
surgery included patients with a body mass index (BMI) of less than 30kg/m². In studies of UPPP 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 AHI or RDI with excessive daytime somnolence (EDS), 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 UPPP and surgical success have been unreliable (Qaseem, 2013).

Isolated pharyngeal/soft palatal interventions reduced the AHI inconsistently, resulting in many patients having a significant level of residual OSA postoperatively, even in those with mild to moderate OSA at baseline (Balk, 2011; Caples, 2010; Browaldh, 2013). 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 most often associated with UPPP (Balk, 2011; Caples, 2010). Significant improvements in AHI were reported in some small series of multi-level surgeries with and without UPPP. 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 OSA are rarely curative (Qaseem, 2013; Aurora, 2010; Epstein, 2009). Surgery, including UPPP, is considered secondary treatment for OSA when the outcome with CPAP or oral appliances is inadequate. Therefore, patients with severe OSA should initially be offered CPAP, while those with moderate OSA should initially be offered either CPAP 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 UPPP as a sole treatment. Primary surgical treatment may be considered in people with mild OSA who have severe obstructing anatomy that is surgically correctable (Epstein, 2009). A position statement by the American Academy of Otolaryngology — Head and Neck Surgery (AAO) supports the effectiveness of surgical modification of the velopharynx if the area has been shown to collapse (AAO, 2015).

**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 UPPP (Tang, 2017). Foreign body sensation and a dry pharynx were the most common complaints reported in surgical case series, 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 UPPP. 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, BMI, or preoperative AHI, 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.

Summary of clinical evidence:

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<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| **Tang (2017)** Long-term incidence of velopharyngeal insufficiency (VPI) and other sequelae following UPPP | **Key points:**  
  - Systematic review of 24 studies.  
  - Complications included VPI (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%), VPI (8.1%).  
  - Limited long-term data suggest that complications such as VPI are more common than previously reported. Other sequelae, such as foreign body sensation, may be one of the most frequently expected complications after UPPP surgery. |
| **Choi (2016)** Predicting outcomes after UPPP for adult OSA | **Key points:**  
  - 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 (OR 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, BMI, preoperative AHI, and other cephalometric measurements were not significant. |
| **Balk (2011)** Comparative effectiveness review for AHRQ | **Key points:**  
  - Systematic review of studies of treatment of OSA in adults (variable numbers of patients).  
  - Overall quality: low with high risk of bias and unclear reporting of design elements and outcomes.  
  - UPPP versus conservative treatment: Significant improvement in daytime somnolence (\( p < 0.05 \)) observed after 12 months; no difference in cognitive function.  
  - UPPP versus CPAP (two RCTs, three observational studies): Effects on mortality, AHI, daytime sleepiness, and sleep quality inconclusive.  
  - UPPP versus MADs (one RCT): Significantly more patients using MADs achieved 50% reductions in AHI at one year and significantly lower AHI at four years.  
  - Adverse events associated with UPPP (10 studies, including one large cohort study of 3,130 patients):  
    - Mostly perioperative, including perioperative death in about 1.5% in two studies.  
    - 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). |
| **Caples (2010) for the AASM** | **Key points:**  
  - Systematic review of two RCTs (UPPP versus oral appliances or lateral pharyngoplasty) and |
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| Surgical modifications of the upper airway for OSA in adults | 13 prospective or retrospective observational studies of UPPP (950 total patients).  
- Overall quality: low, with high risk of bias. Inconsistent or unreported patient selection criteria, surgical protocols, outcome measures, and adverse events.  
- UPPP only:  
  - Mean age 44 years, 91.9% males, average BMI 29 kg/m²; average baseline AHI 40.3 events/hour. Follow-up duration: three months to one year.  
  - Overall 33% reduction in AHI (95% confidence interval [CI] 23% to 42%). Postoperative residual AHI 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 UPPP and other procedures:  
  - Mean baseline AHI > 40. Significant improvements in AHI 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:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**


**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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