Clinical Policy Title: Uvulopalatopharyngoplasty (UPPP)

Clinical Policy Number: 10.03.05

Effective Date: October 1, 2015
Initial Review Date: June 17, 2015
Most Recent Review Date: July 20, 2016
Next Review Date: July 2017

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

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

Coverage policy

Keystone First 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.

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 (Qaseem 2013, Randerath 2011, Aurora 2010). However, overall compliance with CPAP and MADs is quite low (50 percent to 60 percent), particularly among those with less severe impairment.

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**

Keystone First 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 10, 2016. 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:

None.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Balk (2011)</td>
<td>Key points:</td>
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<tr>
<td>Comparative</td>
<td>• Systematic review of studies of</td>
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<tr>
<td>effectiveness review</td>
<td>treatment of OSA in adults (variable numbers of patients).</td>
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<tr>
<td>for AHRQ</td>
<td>• Overall quality: low with high</td>
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<td></td>
<td>risk of bias and unclear reporting</td>
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<td>of design elements and outcomes.</td>
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<td></td>
<td>• UPPP versus conservative</td>
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<td>treatment: Significant improvement</td>
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<tr>
<td></td>
<td>in daytime somnolence (p &lt; 0.05)</td>
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<td></td>
<td>observed after 12 months; no</td>
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<td></td>
<td>difference in cognitive function.</td>
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<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| - 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% – 15% of patients. Largest surgical cohort study reported no long-term complications (not including perioperative death or cardiovascular complications). |
| Caples (2010) for the AASM Surgical modifications of the upper airway for OSA in adult | Key points:  
- Systematic review of two RCTs (UPPP versus oral appliances or lateral pharyngoplasty) and 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 — 1 year.  
  - Overall 33% reduction in AHI (95% confidence interval [CI] 23% – 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% – 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. |

**Glossary**

**Apnea-hypopnea index (AHI)** — The number of apneic episodes (obstructive, central and mixed) and hypopneic episodes per hour of sleep. Only full polysomnography and portable monitors that measure airflow directly measure AHI.

**Hypopnea** — A partial reduction in breathing of at least 30 percent that lasts at least 10 seconds during sleep. This is measured by a nasal pressure transducer.

**Obstructive sleep apnea (OSA)** — A life-threatening and life-altering condition that causes a person to stop breathing repeatedly during sleep caused by a mechanical obstruction of the airway, such as a semi-collapsed trachea, tongue relaxed to the back of the throat or a large amount of tissue in the uvula area.

**Palate** — Roof the mouth comprising:
- **Hard palate** — Bony anterior portion of the palate, separating the oral and nasal cavities.
- **Soft palate** — Fleshy part of the palate, extending from the posterior edge of the hard palate separating the mouth and the pharynx; the uvula projects from its free inferior border.

**Pharynx** — Throat (the passageway leading from the mouth and nose to the esophagus and larynx) comprising three parts:
- **Nasopharynx** — Upper part of the pharynx; posterior portion of the nasal cavity.
- **Oropharynx** — Back of the mouth from the soft palate to the superior border of the epiglottis.
- **Hypopharynx** — Lower part of the pharynx; below the upper edge of the epiglottis, opening into the larynx and esophagus.

**Phased testing** — Process of diagnosing OSA using simple tests, followed by more intensive tests in selected patients.

**Polysomnography (PSG) or overnight sleep study** — Standard method of detecting sleep disorders and evaluating treatments in sleeping children and adults. PSG measures information such as airflow, brain activity (EEG), respiratory effort, eye movements (EOG), leg movements (EMG), blood oxygen saturation and unusual behavior. May be facility-based or portable.

**Respiratory disturbance index/respiratory distress index (RDI)** — A formula used in reporting the frequency of respiratory events during sleep. Calculated as the number of events (including apneas and hypopneas) per hour of recording.

**Uvula (palatine)** — Small, fleshy mass hanging from the soft palate above the root of the tongue.

**Uvulopalatopharyngoplasty (UPPP)** — A surgical procedure performed on the soft tissues of the soft palate and pharyngeal area in the treatment of OSA.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Clinical trials:**

Searched clinicaltrials.gov on June 10, 2016 using terms “obstructive sleep apnea,” uvulopalatopharyngoplasty or UPPP | Open studies. One study found, but not available in the U.S.

**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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