Clinical Policy Title: Supraglottoplasty and laryngoplasty

Clinical Policy Number: 07.03.02

Effective Date: April 1, 2015
Initial Review Date: January 21, 2015
Most Recent Review Date: February 15, 2017
Next Review Date: February 2018

Related Policies:

CP# 00.02.02 Botulinum toxin products

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

Coverage policy

AmeriHealth Caritas District of Columbia considers the treatment of unilateral vocal cord paralysis to be clinically proven and, therefore, medically necessary when the following criteria are met:

- The patient has unilateral vocal cord paralysis.
- The patient has been managed conservatively for 12 months from the date of determination of dysphonia.
- One of the following procedures is performed:
  - Injection of an FDA-approved bulking agent.
  - Medialization thyroplasty/Type 1 thyroplasty.
  - Arytenoid adduction surgery.

AmeriHealth Caritas District of Columbia considers the use of supraglottoplasty to be clinically proven and, therefore, medically necessary when the following criteria are met:

- The diagnosis is laryngomalacia in a child age 2 or younger.
- There is documented hypoxia, hypercapnia, failure to thrive, infantile sleep apnea, cor pulmonale or pulmonary hypertension unresolved with conservative management.
Limitations:

All other uses of supraglottoplasty and/or laryngoplasty are not medically necessary, including the use of supraglottoplasty for treatment of obstructive sleep apnea

Alternative covered services:

Office visit and evaluation by otolaryngologist, laryngoscopy, and laryngeal electromyography (LEMG).

Background

Management of clinical conditions associated with airway disease in the region of the larynx may be handled medically or by surgical approaches. This policy reviews the evidence behind two of the invasive procedures for airway management.

Laryngoplasty:

The fibrous bands within the larynx that are termed the vocal cords are essential for proper phonation, swallowing and breathing. Paralysis of one or both cords will cause hoarseness and may lead to increased risk of aspiration of solids and liquids. Bilateral vocal cord paralysis may inhibit effective respirations. Normal vocal cord function causes these bands to open during inhalation, allowing air to enter the trachea. The vocal cords close during swallowing and during phonation. In the latter situation the cords vibrate to modulate the airflow, allowing speech. These functions are reduced with unilateral cord paralysis and non-functioning if there is bilateral paralysis.

Nearly 80 percent of patients with vocal cord paralysis have unilateral paralysis. Vocal cord paralysis may be the result of damage to the superior laryngeal nerve (SLN), the recurrent laryngeal nerve (RLN), or, less commonly, the vagus nerve. Such damage may be reversible or permanent. The determination is made by the physician based upon history, etiology and response to initial therapy. Vocal cord paralysis may be the result of inadvertent injury to the RLN during head or neck surgery, a complication from endotracheal intubation, blunt trauma, tumors of the skull base, neck or chest (both malignant and benign); but nearly half of vocal cord paralysis is idiopathic. The presumption is that viral infections are the cause of a significant percentage of these idiopathic cases.

Diagnosis of vocal cord paralysis is made based upon careful history, physical examination, laryngeal electromyography (LEMG) and laryngoscopy to verify absence of vocal cord movement. The LEMG is used both diagnostically and prognostically based upon the nerve pattern responses. A Cochrane Collaboration review of the literature indicates that conservative treatment is appropriate unless a tumor is found, as 60 percent of patients with idiopathic unilateral vocal cord paralysis (UVCP) will have resolution within a year of presentation (Lakhani, 2012). Speech therapy provides patient education of vocal hygiene, phonation and breathing.
However, surgical intervention is indicated early in patients when there are clinical signs of aspiration or respiratory difficulties, or if the individual must have a clear voice for work. Direct surgery on benign soft tissue lesions such as recurrent respiratory papilloma (RRP) or on malignant tumors may be appropriate steps. Surgical management of laryngeal dystonia has fallen out of favor as botulism toxin injections can resolve 80 percent of adductor spasmodic dysphonia.

Treatment of glottis insufficiency caused by vocal cord paralysis may be performed through a direct intervention with static positioning of the weak vocal cord into the midline. This is termed medialization laryngoplasty. Another surgical approach is arytenoid adduction. The results from these surgical procedures may not be as good as that from injection of resorbable bulking material into the vocal folds or surrounding tissue to force the weak cord into a medial position. This latter therapy is termed injection laryngoplasty. A variety of agents have been used in trials, including silicone, bovine gelatin (Gelfoam®, Surgifoam®), carboxymethylcellulose (Radiesse® Voice) and hydroxyapatite (Radiesse®), resulting in phonation improvement in 94 percent to 100 percent of patients in various series. The use of hyaluronic acid (Restylane®, Hylaform®), polytetrafluoroethylene (Teflon®) and of autologous fat do not have sufficient clinical trials to ascertain long term effectiveness.

Injection laryngoplasty:

The injection of bulking agents to force the weakened or paralyzed vocal cord to the midline is now accepted in the ENT literature. However, a 2012 Cochrane Collaboration review of 230 reference sources failed to find any medical articles meeting their criteria for scientific acceptability (Lakhani, 2012). The evidence for the use of bulking agents has been largely based upon small and medium-sized series without blinding of the results. The American Academy of Otolaryngology — Head and Neck Surgery formed its recommendation based upon observational studies demonstrating a benefit of injection laryngoplasty and a preponderance of benefit over harm. The wide variation in agents used in the injections suggests there is as yet no consensus on a preferred agent.

Injection laryngoplasty may be performed in an outpatient hospital/ambulatory surgical facility under conscious sedation or in the surgeon’s office with local anesthesia. The former offers the advantage of patient comfort and airway management but has the disadvantage that the patient is unable to speak or test the effectiveness of the therapy. Office based therapy does allow the operator to know immediately if there has been adequate medialization of the vocal cord as judged by the patient’s phonation. The injection of the bulking material may be performed transorally or transcutaneously. Injected agents may remain in place for several months, allowing time to observe the patient’s phonation recovery before making a decision for future, longer-lasting injection or open surgical procedures such as medicalization thyroplasty. Agents such as Radiesse are potentially much longer and more suitable to office-based treatment.
Permission requested from the illustrator.

**Supraglottoplasty:**

Laryngomalacia is the most common airway disease in infants, manifesting itself with stridor. Laryngomalacia is characterized by collapse of the laryngeal cartilage with glottic obstruction. Delayed maturation of the cartilaginous structures of the larynx, including the arytenoid and epiglottis, is felt to be the etiology. Stridor on inspiration may be either low or high pitched based upon the areas of greatest flexibility within the laryngeal structures. Based upon the anatomic area of greater weakness, laryngomalacia may be subtyped as follows:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Pathology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1 laryngomalacia</td>
<td>Tightening or foreshortening of the aryepiglottic folds.</td>
</tr>
<tr>
<td>Type 2 laryngomalacia</td>
<td>Redundant soft tissue in any area of the supraglottic region.</td>
</tr>
<tr>
<td>Type 3 laryngomalacia</td>
<td>Caused by neuromuscular disease and/or gastroesophageal reflux.</td>
</tr>
</tbody>
</table>

Despite the noisy respirations which may be frightening to parents, laryngomalacia is rarely a cause of mortality. The higher intrathoracic pressures are thought to be the reason for the higher incidence of gastroesophageal reflux. Laryngomalacia is most commonly found in infants between ages 6 and 8 months but may be found as early as age 4 to 6 weeks or as late as age 2. It is found equally among genders and ethnicities. Most infants with laryngomalacia are normally active and feeding well, and give no other appearance of illness.

No treatment is necessary for the majority of infants with laryngomalacia, as with greater maturity of cartilage and growth that enlarges the diameter of the upper airways, the stridor disappears. Some infants who have measured lower oxygen tensions appear to do better with supplemental oxygen but that has not been demonstrated in high-quality clinical trials. One report reviewed 120 sequential cases at a single institution and found that 115 cases resolved spontaneously by an average age of 7.6
months; three cases were treated with nasogastric tube feeds secondary to aspiration. In two patients with failure to thrive operative management was undertaken (Wright, 2012).

**Surgical procedures:**

Surgical approaches to management of laryngomalacia should only be entertained in severe disease that results in documented hypoxia, hypercapnia, failure to thrive, infantile sleep apnea, cor pulmonale or pulmonary hypertension. Tracheostomy is an accepted procedure but rarely performed for infants. Endoscopic supraglottoplasty has been found to relieve the obstruction but available literature all represents observational small sample sizes. Surgery most commonly involves ablation or division of the aryepiglottic fold or arytenoid mucosa. Endoscopically the surgery may be performed by laser or cold steel. Case reports do not conclude any outcome differences by technique but infants with underlying neurologic deficits or with significant gastroesophageal reflux have a greater chance of requiring a second operation.

**Searches**

AmeriHealth Caritas District of Columbia 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.

Searches were conducted on January 24, 2017, using the terms “supraglottoplasty,” “laryngoplasty,” “obstructive sleep apnea,” and “vocal cord paralysis.”

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**

Patients with hoarseness (dysphonia) that impairs quality of life were the subject of a guideline of the American Academy of Otolaryngology-Head and Neck Surgery Foundation. One option the Academy recommended was performing laryngoplasty at any time in a patient with hoarseness (Schwartz, 2009).
Vocal fold scarring is typically uses medialization techniques treating glottic gap, plus injection augmentation or implantation. Newer techniques such as anxiolytic lasers, laser technology with ultrafine excision/ablation properties, or tissue engineering, are still in trials, according to a review by the European Laryngological Society Phonosurgery Committee (Friedrich, 2013). In patients with unilateral vocal fold paralysis, use of a medialization surgical procedure or injection laryngoplasty have equivalent outcomes. This determination is, however, based upon medical citations from observational studies and is not based upon high-quality medical evidence. Experience suggests that the determination of appropriate treatment of unilateral vocal cord paralysis is initially conservative with speech therapy. Only after one year or upon evidence of aspiration, respiratory issues or tumor is a surgical approach indicated.

It is clear from published evidence that vocal fold paralysis generally does not resolve on its own or from conservative approaches. In a study of 54 patients with dysphonia from unilateral vocal fold paralysis, 23 of 35 managed with observation or voice therapy later required permanent intervention within 9 months, compared to just 5 of 19 with temporary injection medialization - (Yung, 2011). There has been a trend against using anesthesia in vocal fold injection augmentations, with similar outcomes. In a 12-month period, 460 vocal fold injection augmentations included 51 percent awake, and 49 percent under general anesthesia. Similar technical success rates were observed for the awake and anesthetized groups (99 and 97 percent), along with complication rates (3 and 2 percent). The use of injection in patients who remained awake rose from 11 to 43 percent from 2003 to 2008 (Sulica 2010).

A systematic review of 17 studies of adults found favorable outcomes for four interventions for unilateral vocal fold paralysis, with no significant differences between acoustic, quality of life, perceptual, and laryngoscopic outcomes. The four treatments were medialization thyroplasty, injection laryngoplasty, arytenoid adduction, and laryngeal reinnervation (Siu 2016).

A meta analysis of 24 studies compared voice outcome of calcium hydroxylapatite injection laryngoplasty (IL) to silicone medialization thyroplasty (MT). The mean voice handicap inventory scores after one year before/after IL were 68.36 and 32.24, with comparable results before/after MT of 72.22 and 34.02 (Shen 2013).

A systematic review of 15 studies of unilateral vocal cord paralysis found that all 36 children undergoing laryngeal reinnervation experienced improvement or resolution of dysphonia. Most of the 31 children who received injection laryngoplasty experienced improvement in voice quality, speech, swallowing, aspiration, and glottis closure. Of the 12 treated by thyroidplasty, two experienced resolution and four had some improvement (Butskiy 2015). A seven-study systematic review of 202 children treated for subglottic or laryngeal stenosis with balloon laryngoplasty documented a success rate of 68 percent, with no complications (Wentzel 2014).

Several systematic reviews have been conducted on supraglottoplasty. One review of 12 studies found the risk ratio of surgical patients undergoing supraglottoplasty was 4.33 for those with associated
comorbidities, compared to those who had none (Preciado 2012).

Treatment of obstructive sleep apnea in adults is a common topic of supraglottoplasty studies. One review of 11 studies (n=121) analyzed the apnea-hypopnea index (AHI), which had an overall success rate of 28 and 72 percent for patients with AHI <1 and <5. Children who underwent the procedure as a primary treatment had similar post-op AHI as those with secondary treatment (33 percent versus 19 percent for postoperative AHI <1, 77 percent versus 61 percent for postoperative AHI <5) (Lee 2016).

A meta-analysis of four studies (n=33 children) with laryngomalacia and obstructive sleep apnea who had supraglottoplasty found AHI improved by a mean of 12.5 points, but 29 of 33 children had residual disease after treatment (Farhood 2016). A meta-analysis of 13 studies (n=138 children) who underwent isolated supraglottoplasty for laryngomalacia with obstructive sleep apnea found AHI and lowest oxygen saturation decreased both for children with sleep exclusive laryngomalacia and congenital laryngomalacia, but the majority of them are not cured (Camacho 2016).

**Policy changes:**

This version of the policy contains an additional three clinical guidelines/other, and seven additional peer-reviewed references. A total of eight peer-reviewed references have been deleted if they are short reports or case studies, or if they are more than a decade old.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Douglas (2014)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td></td>
<td>• Gastroesophageal reflux and neurologic disease were highly associated with failure of supraglottoplasty.</td>
</tr>
<tr>
<td></td>
<td>• Study of 148 children with supraglottoplasty, with full data on 115 cases.</td>
</tr>
<tr>
<td></td>
<td>• Significant association between delayed post-op neurological disease diagnosis and failure of the surgery.</td>
</tr>
<tr>
<td></td>
<td>• In infants under age 1, reflux symptoms were associated with a higher likelihood of surgical failure</td>
</tr>
<tr>
<td>Preciado (2012)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td></td>
<td>• Relative risk of supraglottoplasty failure significantly higher in patient with medical comorbidities.</td>
</tr>
<tr>
<td></td>
<td>• Review of 12 studies, with eight meeting inclusion criteria.</td>
</tr>
<tr>
<td></td>
<td>• Overall risk ratio of surgical failure among patients with associated comorbidities was 7.14.</td>
</tr>
<tr>
<td></td>
<td>• The risk ratio of aspiration after supraglottoplasty in patients with comorbidities was 4.33; the ratio in those without comorbidities was 1.25</td>
</tr>
<tr>
<td>Chan (2012)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td></td>
<td>• The use of supraglottoplasty for obstructive sleep apnea is investigational.</td>
</tr>
<tr>
<td></td>
<td>• Study of 22 children between ages 2 and 17 with OSAS, some with neurologic disease.</td>
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<tr>
<td></td>
<td>• Two groups. Nine had supraglottoplasty alone and 13 had a staged procedure.</td>
</tr>
</tbody>
</table>
Patient differences and studies were not uniform.
Conclusions on the effectiveness of supraglottoplasty were suggested but not proven.

**Lakhani (2012)**

**Key points:**

- There is insufficient high-quality evidence for or against any specific injectable material for unilateral vocal fold paralysis.
- Review of existing RCTs on the use of bulking agents injected into the vocal folds in patients with unilateral vocal fold paralysis. None met criteria as RCT.
- At this time no bulking agent can be determined superior to others.

**Rosen (2010)**

**Key points:**

- Vocal fold injection as treatment for glottic insufficiency — pro.
- Vocal fold injection has many advantages by being a minimally invasive procedure that can be performed in the outpatient office setting.
- Unsedated in-office injection has the advantage of precision because one can perform real-time monitoring of vocal function before, during and after the procedure.
- Vocal fold injection as treatment for glottic insufficiency — con.
- No ideal study comparing Type I thyroplasty with injection laryngoplasty exists. Type I thyroplasty brings enhanced precision when augmenting glottal insufficiency.

**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):**

No NCDs identified as of the writing of this policy.

**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 in accordance with those manuals.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>31400</td>
<td>Arytenoidectomy or arytenoidopexy, external approach</td>
<td></td>
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<tr>
<td>31513</td>
<td>Laryngoscopy, indirect; with vocal cord injection</td>
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<tr>
<td>31560</td>
<td>Laryngoscopy, direct, operative with arytenoidectomy</td>
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<tr>
<td>31570</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic</td>
<td></td>
</tr>
<tr>
<td>31571</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic with operating microscope or telescope</td>
<td></td>
</tr>
<tr>
<td>31588</td>
<td>Laryngoplasty, not otherwise specified</td>
<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>G47.33</td>
<td>Obstructive sleep apnea (adult/pediatric)</td>
<td></td>
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<tr>
<td>J38.01</td>
<td>Paralysis of vocal cords, unilateral</td>
<td></td>
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<tr>
<td>P28.3</td>
<td>Obstructive sleep apnea of newborn</td>
<td></td>
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<tr>
<td>P28.4</td>
<td>Obstructive apnea of newborn</td>
<td></td>
</tr>
<tr>
<td>HCPCS Level II</td>
<td>Description</td>
<td>Comment</td>
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<tr>
<td>---------------</td>
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<tr>
<td>C1878</td>
<td>Vocal cord medialization material, implantable</td>
<td></td>
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