Clinical Policy Title: Supraglottoplasty and laryngoplasty

Clinical Policy Number: CCP.1157

Effective Date: April 1, 2015
Initial Review Date: January 21, 2015
Most Recent Review Date: March 5, 2019
Next Review Date: March 2020

Policy contains:
- Laryngoplasty.
- Obstructive sleep apnea.
- Supraglottoplasty.
- Vocal cord paralysis.

Related policies:
CCP.1020 Botulinum toxin products

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

**Coverage policy**

Prestige Health Choice considers the use of laryngoplasty for 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 a Food and Drug Administration-approved bulking agent.
  - Medialization thyroplasty/type 1 thyroplasty.
  - Arytenoid adduction surgery (Schwartz, 2009).

Prestige Health Choice 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 two or younger.
There is documented hypoxia, hypercapnia, failure to thrive, infantile sleep apnea, cor pulmonale or pulmonary hypertension unresolved with conservative management (Carter, 2016; Kaditis, 2017).

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/

All other uses of supraglottoplasty or laryngoplasty, or both, are not clinically proven, and therefore, not medically necessary, including the use of supraglottoplasty for treating obstructive sleep apnea.

Alternative covered services:

Office visit and evaluation by otolaryngologist, laryngoscopy and laryngeal electromyography.

Background

Laryngoplasty is a treatment for vocal cord 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, the recurrent laryngeal nerve or, less commonly, the vagus nerve. Such damage may be reversible or permanent. The determination, made by the physician, is based on review of history, etiology and response to initial therapy (American Academy of Otolaryngology-Head and Neck Surgery, 2015). About 60 percent of patients with idiopathic unilateral vocal cord paralysis will have resolution within a year of presentation (Lakhani, 2012).

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. Surgical management of laryngeal dystonia has fallen out of favor because botulinum toxin injections can resolve 80 percent of adductor spasmodic dysphonia (American Academy of Otolaryngology-Head and Neck Surgery, 2015).

Injections of bulking agents is also an accepted treatment for paralyzed vocal cords. Injection laryngoplasty may be performed in an outpatient hospital or ambulatory surgical facility under conscious sedation or in the surgeon’s office with local anesthesia. Injection laryngoplasty can serve as a bridge during the healing period after laryngeal nerve injury (Chandrasekhar, 2013). Supraglottoplasty is a surgical procedure for laryngomalacia, the most common airway disease in infants.

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, because with greater maturity of cartilage and growth, which enlarges the diameter of the upper airways, the stridor
disappears. 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 (Wright, 2012). Surgical approaches to manage 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. Surgery most commonly involves ablation or division of the aryepiglottic fold or arytenoid mucosa.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Cochrane Reviews.

We conducted searches on November 29, 2018, using the terms “laryngoplasty,” “obstructive sleep apnea,” “supraglottoplasty,” 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 typically uses medialization techniques to treat glottic gap plus injection augmentation or implantation. Newer techniques, such as anxiolytic lasers, laser technology with ultrafine excision and ablation properties or tissue engineering, are still in trials according to a review by the European Laryngological Society Phonosurgery Committee (Friedrich, 2013).

A 2017 systematic review by the European Respiratory Society Task Force of children age 1 to 23 months with obstructed sleep disorder breathing concluded that among interventions targeting specific conditions, supraglottoplasty is most often used for laryngomalacia (Kaditis, 2017).
Consensus recommendations for treating infants with laryngomalacia were developed by the International Pediatric Otolaryngology Group, including indications for performing supraglottoplasty (Carter, 2016).

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 nine months compared with just five 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 percent and 97 percent, respectively), along with complication rates (3 and 2 percent, respectively). The use of injection in patients who remained awake rose from 11 percent to 43 percent from 2003 to 2008, respectively (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 among 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 the voice outcome of calcium hydroxylapatite injection laryngoplasty with silicone medialization thyroplasty. The mean voice handicap inventory scores after one year before and after injection laryngoplasty were 68.36 and 32.24, respectively, with comparable results before and after medialization thyroplasty of 72.22 and 34.02, respectively (Shen, 2013).

A systematic review four studies followed subjects for two weeks to 12 months after injection laryngoplasty. Voice outcomes improved in each study, and no outcomes differences were observed in procedures performed in operating rooms versus offices (Ballard, 2018).

A systematic review/meta-analysis of four studies (n = 275) reported that subjects receiving an injection laryngoscopy after a diagnosis of unilateral vocal fold paralysis had a lower chance of subsequent permanent thyroplasty. Authors recommend that injection laryngoplasty should be offered to patients diagnosed with this condition (Vila, 2018).

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. Authors conclude that injection laryngoplasty is a safe, effective but non-permanent option for children with vocal cord paralysis (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 for persistent or significant aspiration of surgical patients undergoing supraglottoplasty was 4.33 \((P = .02)\) for those with associated comorbidities compared with those who had none, while the overall risk ratio for surgical failure was 7.14 \((P < .001)\) (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, which had an overall success rate of 28 percent and 72 percent for patients with an apnea–hypopnea index of <1 and <5, respectively. Children who underwent the procedure as a primary treatment had a similar postoperative apnea–hypopnea index as those with secondary treatment (primary treatment: 33 percent versus 19 percent for postoperative apnea–hypopnea index of <1; secondary treatment: 77 percent versus 61 percent for postoperative apnea–hypopnea index of <5), and there was a significant reduction of 8.9 apnea–hypopnea events per hour (Lee, 2016).

A meta-analysis of four studies \((n = 33\) children) with laryngomalacia and obstructive sleep apnea who had supraglottoplasty found the apnea–hypopnea index improved by a mean of 12.5 points and was considered an effective treatment, even though 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 the apnea–hypopnea index and lowest oxygen saturation decreased both for children with sleep exclusive laryngomalacia and congenital laryngomalacia, with the greatest improvement being a reduction of the apopnea–hypopnea index from 14 to 3.3 (sleep exclusive) and 20.4 to 4 (congenital) events per hour, but the majority of them are not cured (Camacho, 2016).

**Policy changes:**

The number of this policy was changed from 07.03.02 to CCP.1157.

A total of two guidelines/other and two peer-reviewed references were added to, and two guidelines/other and seven peer-reviewed references removed from this policy in December, 2018.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


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

No National Coverage Determinations identified as of the writing of this policy.

**Local coverage determinations:**

No Local Coverage Determinations 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.
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<td></td>
<td>transoral), unilateral</td>
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<td>L8607</td>
<td>Injectable bulking agent for vocal cord medialization, 0.1 ml, includes shipping and necessary supplies</td>
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