Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: Keystone First	**Submission Date**: March 27, 2020
Policy Number: CCP.1157	**Effective Date:** 4/2015 **Revision Date:** March 3, 2020
Policy Name: Supraglottoplasty and laryngoplasty	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☑ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

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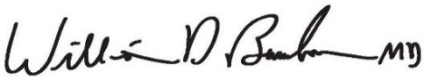
Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
William D. Burnham, MD	

Keystone First

Coverage by Vista Health Plan,
an independent licensee of the Blue Cross and Blue Shield Association.

Supraglottoplasty and laryngoplasty

Clinical Policy ID: CCP.1157

Recent review date: 3/2020

Next review date: 7/2021

Policy contains: Laryngoplasty; obstructive sleep apnea; supraglottoplasty; vocal cord paralysis.

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

Laryngoplasty for unilateral vocal cord paralysis is clinically proven and, therefore, medically necessary when all of 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).

Supraglottoplasty is clinically proven and, therefore, medically necessary when all of 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

No limitations were identified during the writing of this policy.

Alternative covered services

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

Background

Laryngoplasty is a treatment for vocal cord paralysis, involving an incision of the larynx and placing an implant. Nearly 80% 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 to undergo surgery, made by the physician, is based on review of history, etiology and response to initial therapy (American Academy of Otolaryngology-Head and Neck Surgery, 2018). The decision to conduct surgery typically follows a 6 – 9 month "watchful waiting" period (Williamson, 2019). About 60% 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% of adductor spasmodic dysphonia (American Academy of Otolaryngology-Head and Neck Surgery, 2018).

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, which affects 45% to 75% of all infants with congenital stridor (Landry, 2012).

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 (Landry, 2012).

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 conservatively with observation or voice therapy later required permanent intervention within nine months compared with just 5 of 19 with temporary injection medialization (Yung, 2011).

In a study of 136 elderly individuals who underwent medialization laryngoplasty, two measures of vocal function improved post-operative scores ($P < .05$). Most (81.6%) of patients had at least a 20% improvement, while about half (53.7%) had at least a 50% improvement. The rate of minor complications and major complications were 5.9% and zero, respectively (Philips, 2019).

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% awake and 49% under general anesthesia. Similar technical success rates were observed for the awake and anesthetized groups (99% and 97%, respectively), along with complication rates (3% and 2%, respectively). The use of injection in patients who remained awake rose from 11% to 43% 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%, 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% and 72% 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% versus 19% for postoperative apnea–hypopnea index of < 1; secondary treatment: 77% versus 61% 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).

A systematic review of 24 studies (n = 960) of children with obstructive sleep apnea compared six studies of lingual tonsillectomy (success rate 57% to 88%) and four studies with supraglottoplasty (58% to 72%) not significantly different. Authors conclude evidence is extremely limited (Manickam, 2016).

A systematic review of 11 studies (n = 75) persons who underwent supraglottoplasty for exercise-induced laryngeal obstruction revealed many beneficial outcomes, including visual verification of improvement of the laryngeal obstruction during exercise and patient self-reported symptom severity (Siewers, 2019).

A review of 20 studies (n = 1,186) compared repeat surgery rates of unilateral and bilateral supraglottoplasty for laryngomalacia. Unilateral procedures had a significantly higher rate of repeat surgery, most of which were contralateral procedures (Avillion, 2019).

Lasers can be successfully used for supraglottoplasty. A review of 79 patients (median age 12.7 months) showed an operation success rate of 86.1% after the procedure, even though over half (55.7%) of subjects had one or more comorbidities (Reinhard, 2019).

References

On December 24, 2019, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “laryngoplasty,” “obstructive sleep apnea,” “supraglottoplasty,” and “vocal cord paralysis.” We included the best available evidence according to established

evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

1/2015: initial review date and clinical policy effective date: 4/2015

3/2020: Policy updates: seven references added to the policy.