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**: 4/1/2024
Policy Number: ccp.1157	**Effective Date:** 4/2015 **Revision Date:** March 1, 2024
Policy Name: Supraglottoplasty and laryngoplasty	

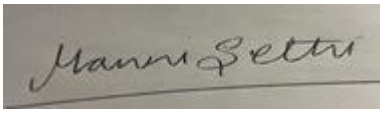
Type of Submission – Check all that apply:

New Policy
X 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:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Supraglottoplasty and laryngoplasty

Clinical Policy ID: CCP.1157

Recent review date: 3/2024

Next review date: 7/2025

Policy contains: Laryngoplasty; obstructive sleep apnea; supraglottoplasty; vocal cord paralysis laryngomalacia, glottis insufficiency, recurrent laryngeal nerve, dysphonia.

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

Coverage policy

Laryngoplasty for unilateral vocal cord paralysis is clinically proven and, therefore, may be 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

Laryngoscopy and laryngeal electromyography.

Background

Vocal cord paralysis may be the result of recurrent and/or superior laryngeal nerve damage or less commonly vagus nerve damage that may be permanent or reversible depending on cause and treatment. In such cases, nerve function to adduct the vocal cords for voice production and cough is affected unilaterally or bilaterally and the glottis fails to adequately function leading to increased risk of aspiration (Courey, 2020).

Injection laryngoplasty, also known as injection augmentation, involves the injection of bulking agents into the lateral aspect of the paralyzed vocal fold to move the vibrating surface towards the midline, to enhance glottic closure (Courey, 2020). Injection laryngoplasty may be performed in an outpatient, hospital or ambulatory surgical facility under conscious sedation or in a surgeon's office with local anesthesia. Injection laryngoplasty can serve as a bridge during the healing period after laryngeal nerve injury (Chandrasekhar, 2013).

Medialization laryngoplasty is a treatment for vocal cord paralysis, involving an incision of the neck exposing the larynx and placement of an implant. Nearly 80% of patients with vocal cord paralysis have unilateral paralysis. The surgical intervention decision is made by the physician, based on medical history, etiology and response to initial therapy (American Academy of Otolaryngology-Head and Neck Surgery, 2020). The surgery typically follows a "watchful waiting" period of 6-9 months (Williamson, 2023). About 60% of patients with idiopathic unilateral vocal cord paralysis will have resolution within a year of presentation (Lakhani, 2012).

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).

Laryngomalacia is a congenital softening of the voice tissues of the larynx above the vocal cords. It's the most common cause of noisy stridorous infant breathing (affecting 45%-75%) due to the laryngeal structure being malformed and floppy causing a collapse of the tissue to fall over and partially obstruct the airway resulting in obstructive sleep apnea. Obstructive sleep apnea and central sleep apnea are a common finding in infants with laryngomalacia (Ratanakorn, 2021). Those affected with Down syndrome are of special concern due to their hypotonia and airway issues.

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, stridor disappears. Both obstructive and central sleep apnea improved with increasing age regardless of supraglottoplasty, but the timing of resolution was dependent presence of neurological diseases, congenital anomalies and genetic syndromes (Ratanakorn, 2021).

Supraglottoplasty is a surgical procedure for laryngomalacia. 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

The American Academy of Otolaryngology-Head and Neck Surgery Foundation developed a guideline based on patients whose hoarseness (dysphonia) impaired their quality of life. One of the options recommended was performing laryngoplasty at any time in a patient with hoarseness (Schwartz, 2009). With vocal fold scarring utilizing medialization techniques to treat glottic gap plus injection augmentation or implantation was recommended. 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).

A consensus of recommendations for treating infants with laryngomalacia was developed by the International Pediatric Otolaryngology Group, including indications for performing supraglottoplasty (Carter, 2016).

Large Reviews-Laryngoplasty

A systematic review/meta-analysis of 26 studies (n = 959, of whom 615 had dysphagia) compared outcomes for injection laryngoplasty and laryngeal framework surgery for patients with unilateral vocal fold immobility. Success rates were similar (90% versus 92%), but the complication rate was lower for laryngoplasty (7% versus 15%); most complications were minor (Coulter, 2023).

A systematic review/meta-analysis of 22 studies assessed treatment of children with unilateral vocal fold paralysis (n = 267). Cases treated with injection laryngoplasty showed an improvement of 84.5% in swallowing and 81.4% in voice. Improvements for those treated with laryngeal reinnervation were 91.6% and 96.8%, both considered effective by authors (Aires, 2020).

A systematic review of 14 studies (n = 582) revealed that in 11 retrospective studies, had improvement diet intake after injection laryngoplasty for iatrogenic unilateral vocal fold paralysis. Authors note that no article used a control group, and thus did not address placebo or Hawthorne effects (Pan, 2022).

A systematic review/meta-analysis of 14 studies of hyaluronic acid injection laryngoplasty for patients with unilateral vocal fold paralysis evaluated changes in voice-related quality of life. Authors reported improvements in glottal closure insufficiency, maximal phonation time, perceptual vocal evaluations, and quality of life, but noted duration of treatment varied by study (Wang, 2020).

A systematic review/meta-analysis of 24 studies (n = 713) of young children (mean age 33.7 months) with type 1 laryngeal clefts reported 38% of patients received injection laryngoplasty as a primary therapy. After an average 6.8 month follow-up, 90% of parents reported symptom improvement (Reddy, 2020).

A systematic review/meta-analysis of 21 studies of persons with unilateral vocal fold paralysis showed improvement in functional status (mean GRBAS-I scale) from 2.33 to 0.41 after injection, and mean maximum phonation time from 4.78 and 12.50 after injection. Results were comparable with those treated with open surgery (Granato, 2019).

A systematic review of 17 studies of adults found favorable outcomes for four interventions (including injection laryngoplasty) for unilateral vocal fold paralysis, with no significant differences among acoustic, quality of life, perceptual and laryngoscopic outcomes. The other treatments were medialization thyroplasty, 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 – indicating similar improvement (Shen, 2013).

A systematic review of 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).

Large Reviews - Supraglottoplasty

A 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).

Obstructive sleep apnea in adults is a common topic for supraglottoplasty studies. One review of 11 studies (n = 121) analyzed the apnea-hypopnea index, which had overall success rates 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 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. The greatest improvement was 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 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).

A systematic review of nine studies (n = 922) of infants and children (mean age = 5.65 months) who underwent supraglottoplasty revealed 19% required post-surgical admission to a pediatric intensive care unit. Factors linked to elevated risk of intensive care included neurological disease, perioperative oxygen saturation < 95%, prolonged surgical time, and age less than two months. Authors agree that while the intensive care admission rate is low, it can be further reduced by better understanding risk factors when selecting patients (Kang, 2023).

References

On December 14, 2023, 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, vocal fold paralysis, recurrent laryngeal nerve injury, laryngomalacia, thyroplasty.” 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

12/2016: Policy references updated.

12/2017: Policy references updated.

12/2018: Policy references updated. Policy number changed to CCP.1157.

3/2020: Seven references added to the policy.

3/2021: Policy references updated.

3/2022: Policy references updated.

3/2023: Policy references updated.

3/2024: Policy references updated.