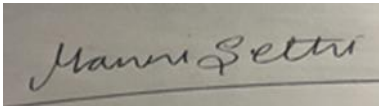


Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 4/1/2025
Policy Number: ccp.1157	Effective Date: 4/2025 Revision Date: 3/2025
Policy Name: Supraglottoplasty and laryngoplasty	
Type of Submission:	Type of Policy:
☒ New Policy	☒ Prior Authorization Policy
☐ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☐ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy 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: 3/2025

Next review date: 7/2026

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 is clinically proven and, therefore, may be medically necessary for members with glottic insufficiency who have not achieved an adequate response to conservative treatment, when one of the following procedures is performed (American Academy of Otolaryngology-Head and Neck Surgery Foundation [Stachler, 2018]):

- Unilateral or bilateral injection medialization using a U.S. Food and Drug Administration-approved bulking agent.
- Unilateral or bilateral lateral framework medialization with or without arytenoid adduction.

Supraglottoplasty is clinically proven and, therefore, may be medically necessary when all of the following criteria are met (Carter, 2016; Kaditis, 2017):

- 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.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Laryngoscopy and laryngeal electromyography.

Background

Vocal cord paralysis refers to complete vocal cord immobility, while vocal cord paresis refers to reduced vocal cord mobility. Vocal cord paralysis may be the result of recurrent or superior laryngeal nerve damage or, less commonly, of 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, and the glottis fails to adequately function, leading to an increased risk of aspiration. The most common type of vocal cord paralysis is unilateral (Singh, 2024).

In the absence of aspiration or other serious pathology, conservative intervention with speech therapy and a 12-month observation period may be appropriate to see if the patient can recover vocal and swallowing interventions. More aggressive approaches may be indicated to protect the airway and prevent aspiration. Surgical interventions include temporary or permanent vocal fold injection augmentation, medialization laryngoplasty, laryngeal reinnervation, and arytenoid adduction (Singh, 2024).

Injection laryngoplasty, also known as injection augmentation, involves the injection of bulking agents (e.g., hyaluronic acid) into the lateral aspect of the paralyzed vocal fold to move the vibrating surface towards the midline and enhance glottic closure. 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. Medialization laryngoplasty is an open surgical procedure that exposes the larynx for implant placement (Singh, 2024).

Laryngomalacia is a congenital anomaly affecting the laryngeal structure most commonly in infants, although it may occur in older children and some adults. It primarily involves a structural weakness in the soft tissues of the larynx in the supraglottic area. During inspiration, the larynx may collapse and partially obstruct the airway, resulting in the characteristic stridor heard in infants. Frequently, laryngomalacia is self-limiting that improves with age as the laryngeal structures mature, and requires only conservative management such as feeding upright, antireflux therapy, and close observation of respiratory symptoms. In severe cases, surgical intervention may be needed to address symptoms of hypoxia, hypercapnia, failure to thrive, infantile sleep apnea, cor pulmonale, or pulmonary hypertension (Klinginsmith, 2024).

Supraglottoplasty is a surgical procedure that removes excess tissue and reshapes the structures of the upper larynx. The supraglottoplasty procedure may consist of several procedures, broadly categorized as debulking of arytenoids, division of aryepiglottic folds, and epiglottis surgery (Del Do, 2018).

Findings

Guidelines

According to the American Academy of Otolaryngology-Head and Neck Surgery Foundation's guideline on patients with dysphonia, surgery is generally not the primary treatment for the majority of patients with dysphonia and should be targeted at specific pathologies. Medialization techniques are indicated for glottic insufficiency, for which there are several etiologies, including impaired vocal fold mobility (e.g., paralysis or paresis), bowing, and vocal fold soft tissue defects. Medialization techniques consist of injection medialization with a bulking agent or laryngeal framework medialization with or without arytenoid adduction. These techniques may be performed unilaterally or bilaterally. For spasmodic dysphonia and other types of laryngeal dystonia, botulinum toxin injections are preferred (Stachler, 2018).

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 severe laryngomalacia was developed by the International Pediatric Otolaryngology Group, including indications for performing supraglottoplasty (Carter, 2016).

Evidence review

Laryngoplasty

Overall, the best evidence supporting the safety and efficacy of laryngoplasty procedures consists of nonrandomized studies of patients with unilateral vocal fold paralysis. There is insufficient evidence to determine the superiority of one laryngoplasty procedure over another. Choice of procedure will depend on several factors including patient preferences and expectations, laryngoscopy findings, the possibility for spontaneous recovery, need for immediate effect, airway compromise, and surgeon's preference.

In adults, both injection laryngoplasty and laryngeal framework medialization improve perceptual, acoustic, quality of life, and laryngoscopic outcomes, and compare favorably to other surgical options such as arytenoid adduction and laryngeal reinnervation (Coulter, 2023; Granato, 2019; Siu, 2016). One systematic review found injection laryngoplasty had lower complication rates than medialization laryngoplasty (7% versus 15%), but complications were generally minor (Coulter, 2023).

In other systematic reviews, injection laryngoplasty improved dietary intake (Pan, 2022) and reduced the need for permanent thyroplasty (Vila, 2018). There were no differences in outcomes based on procedural setting (operating room versus office procedure) (Ballard, 2018). The choice of injection material, volume, and timing of the intervention can impact the effectiveness of the procedure, particularly vocal quality (Safia, 2024).

In pediatric populations, the main causes of unilateral vocal fold paralysis are trauma due to cardiac surgery and idiopathic paralysis. Recovery is often prolonged, placing the child at risk for aspiration and dysphonia. Speech therapy, injection laryngoplasty, medialization laryngoplasty, and laryngeal reinnervation are corrective options. While laryngoplasty outcomes are less established in children, systematic review evidence shows generally favorable improvements in phonation and dysphagia outcomes, and the results are comparable to laryngeal reinnervation (Aires, 2020; Marvin, 2023). A limited meta-analysis demonstrated a mean improvement after laryngoplasty intervention in 79% (95% confidence interval 67% to 91%) of children, with an overall complication rate of 15% (Marvin, 2023).

Laryngeal cleft is a rare congenital disorder where the larynx and esophagus fail to fully fuse. A systematic review analyzed the outcomes of 713 young children (mean age 33.7 months) with type 1 laryngeal clefts, and 38% of patients received injection laryngoplasty as a primary therapy. After an average 6.8 month follow-up, 90% of parents reported symptom improvement. These results compare favorably to formal surgical repair (Reddy, 2020).

Evidence supporting laryngoplasty procedures for treating bilateral vocal fold paralysis is very limited. Various surgical techniques, including laryngoplasty, have been studied in adults and children with the goals of either avoiding tracheostomy with small changes to both voice parameters or deglutition, decannulating the tracheostomy tube, or improving breathing function. The evidence does not permit conclusions regarding the optimal surgical intervention for this condition (Al-Khatib, 2024; de Almeida, 2023; Nemry, 2024).

Supraglottoplasty

Laryngomalacia is a common cause of swallowing disorders. Evidence from systematic reviews and meta-analyses of supraglottoplasty consists of nonrandomized studies in pediatric populations. The mean age of children presenting with laryngomalacia is less than 12 months, and children often present with other comorbidities, most commonly gastroesophageal reflux. Despite heterogeneous samples, supraglottoplasty appears to be an effective treatment option for resolving symptoms of dysphagia in children presenting with

severe laryngomalacia (Mills, 2024, Rossoni, 2024). A portion may require intensive care post-operatively. Factors linked to elevated risk of intensive care included neurological disease, perioperative oxygen saturation < 95%, prolonged surgical time, and age less than two months (Kang, 2023).

One systematic review included 18,317 infants with laryngomalacia. The mean age was 10.6 months (range 0 to 252 months) with a 1.4:1 male to female ratio. Following supraglottoplasty, complete resolution of symptoms occurred in 73.6% of participants and the apnea-hypopnea index was reduced in those with concurrent sleep disordered breathing, but not resolved (mean difference -10.0, 95% confidence interval 15.6 to -4.5 events per hour) (Mills, 2024). Another meta-analysis (n = 311, mean age four months) found supraglottoplasty reduced the prevalence of oropharyngeal dysphagia by 59% when measured immediately postoperatively (Rossoni, 2024).

Laryngomalacia in children with Down syndrome presents additional challenges, as airway obstruction and hypotonia may occur at multiple levels and significant comorbidities are often present. While the evidence is very limited in this population, Salloum's review found 20 of 32 patients were successfully treated with supraglottoplasty. The duration of follow-up ranged from 12 to 102 days (Salloum, 2021).

There is very limited evidence supporting supraglottoplasty as a surgical option for isolated, persistent pediatric obstructive sleep apnea in the absence of laryngomalacia. Supraglottoplasty may reduce but not resolve apneic events. (Leonard, 2024; Mills, 2024).

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, whereas bilateral procedures were associated with a slightly higher risk of supraglottic stenosis (0% versus 1.2%, $P = .011$) (Avillion, 2019).

In 2025, we reorganized the findings, updated the references, and modified medical necessity criteria for laryngoplasty based on updated guideline criteria.

References

On January 22, 2025, 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 (MeSH), "laryngoplasty," "supraglottoplasty," "thyroplasty," "vocal cord paralysis," "vocal fold paralysis," "recurrent laryngeal nerve injury," and "laryngomalacia." 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.

3/2025: Policy references updated.