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 17, 2016
Next Review Date: February 2017

Related Policies:

CP# 00.02.02 Botulinum toxin products

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

Coverage policy

Arbor Health Plan 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 twelve 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.

Arbor Health Plan 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. (see Glossary for definition.)
Limitations:

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

Note: The following CPT/HCPCS code is not listed in the Nebraska Medicaid fee schedule:

C1878 - Vocal cord medialization material, implantable

Alternative covered services:

Physician office visit and evaluation by ENT, 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 this unilaterally. 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. 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 medicalization 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 hydroxylapatite (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. 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 to form 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.
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, so 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. Wright et al. 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.
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.

The use of supraglottoplasty has been proposed for adults and children with obstructive sleep apnea. However, there are no controlled studies and this has been limited to small observational reports. Chan et al. reported on a series of 22 children with obstructive sleep apnea who had supraglottoplasty. They ranged from age 2 to 17. The group was divided into two with one group having only supraglottoplasty and the other with a staged procedure that included tonsillectomy, adenoidectomy and/or turbinate resection. This was a very small sample and there were sufficient differences between patients that conclusions could not be drawn reliably.

Methods

Searches

Arbor Health Plan 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 8, 2015, using the terms supraglottoplasty, laryngoplasty, obstructive sleep apnea, laryngoplasty and vocal cord paralysis.

Included were:
- 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

In patients with unilateral vocal fold paralysis, use of a medialization surgical procedure or injection laryngoplasty have equivalent results. 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.
The use of supraglottoplasty either as a cold-steel or laser-based surgery is indicated only in those rare cases
of laryngomalacia that are causing physiologic harm. Generally, laryngomalacia will resolve over time as the
laryngeal cartilaginous structures become more firm with maturity. This generally occurs at age 6 to
8 months. However, if the infant has evidence of documented hypoxia, hypercapnia, failure to thrive,
infantile sleep apnea, cor pulmonale or pulmonary hypertension, then a surgical approach is warranted.
Otherwise it is the responsibility of the primary care physician to continue evaluation with reassurance to
the parents if the child is otherwise with a normal examination.

Summary of clinical evidence:

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

Glossary

Conservative management—A phrase related to professionally supervised care that may consist of physical/environmental management (e.g. humidification of air, oxygen, etc); medication therapy; or use of durable medical equipment (e.g. positive pressure devices, special bed, etc.) The duration of conservative management is determined individually by the treating physicians and the patient/care giver.

Hoarseness (dysphonia) — “A disorder characterized by altered vocal quality, pitch, loudness, or vocal effort that impairs communication or reduced voice-related quality of life” (American Academy of Otolaryngology).

Injection augmentation laryngoplasty — A procedure performed while the patient is fully asleep in the operating room. This involves injecting a material deep into the vocal cords using special instrumentation. Typically, fat is used and is frequently obtained from the patient’s belly using a liposuction device.

Laryngeal electromyogram — A procedure that measures electrical impulses from the nerves innervating the vocal folds.

Medialization laryngoplasty — A procedure designed to push the vocal cords together by placing pieces of surgical grade plastic or other material deep into the vocal cords.

Medically Necessary - A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

References

Professional society guidelines/others:

Peer-reviewed references:

Laryngoplasty


Supraglottoplasty


Clinical trials:


Treatment of Children With Obstructive Sleep Apnea and Laryngomalacia: the Role of Laser Supraglottoplasty NCT00394550 Indiana University School of Medicine. The purpose of this study is to determine which is the best treatment for children with obstructive sleep apnea and laryngomalacia: adenotonsillectomy alone or adenotonsillectomy with laser supraglottoplasty (removal of tissue on top of the voice box to open the airway). https://clinicaltrials.gov/ct2/show/NCT00394550?term=supraglottoplasty&rank=1 Accessed Jan. 10, 2015.

Centers for Medicare & Medicaid Services (CMS) national coverage determination:

There are no NCDs for laryngoplasty or for supraglottoplasty.

Local coverage determinations:

There are no LCDs for laryngoplasty or for supraglottoplasty.
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>
</tr>
</thead>
<tbody>
<tr>
<td>31400</td>
<td>Arytenoidectomy or arytenoidopexy, external approach</td>
</tr>
<tr>
<td>31513</td>
<td>Laryngoscopy, indirect; with vocal cord injection</td>
</tr>
<tr>
<td>31560</td>
<td>Laryngoscopy, direct, operative with arytenoidectomy</td>
</tr>
<tr>
<td>31570</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic</td>
</tr>
<tr>
<td>31571</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic with operating microscope or telescope</td>
</tr>
<tr>
<td>31588</td>
<td>Laryngoplasty, not otherwise specified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>327.23</td>
<td>Obstructive sleep apnea (adult/pediatric)</td>
</tr>
<tr>
<td>478.31</td>
<td>Paralysis of vocal cords, unilateral, partial</td>
</tr>
<tr>
<td>478.32</td>
<td>Paralysis of vocal cords, unilateral, complete</td>
</tr>
<tr>
<td>770.81</td>
<td>Sleep apnea of newborn</td>
</tr>
<tr>
<td>770.82</td>
<td>Obstructive sleep apnea of newborn</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G47.33</td>
<td>Obstructive sleep apnea (adult/pediatric)</td>
</tr>
<tr>
<td>J38.01</td>
<td>Paralysis of vocal cords, unilateral</td>
</tr>
<tr>
<td>P28.3</td>
<td>Obstructive sleep apnea of newborn</td>
</tr>
<tr>
<td>P28.4</td>
<td>Obstructive apnea of newborn</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1878</td>
<td>Vocal cord medialization material, implantable</td>
</tr>
</tbody>
</table>
