**Prior Authorization Review Panel**

**MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

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<th>Plan: Aetna Better Health</th>
<th>Submission Date: 07/01/2018</th>
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<td><strong>Policy Number:</strong> 0253</td>
<td><strong>Effective Date:</strong> 05/04/2018</td>
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<td><strong>Policy Name:</strong> Vocal Cord Paralysis/Insufficiency Treatments</td>
<td><strong>Revision Date:</strong> 05/04/2018</td>
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**Type of Submission – Check all that apply:**

- [ ] New Policy
- [X] Revised Policy*
- [ ] Annual Review – No Revisions

*All revisions to the policy **must** be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0253 Vocal Cord Paralysis/Insufficiency Treatments**
This CPB has been revised to state that botulinum toxin injection is considered experimental and investigational for the treatment of vocal cord paralysis.

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<th>Name of Authorized Individual (Please type or print):</th>
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<tr>
<td>Dr. Bernard Lewin, M.D.</td>
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Vocal Cord Paralysis/Insufficiency Treatments

Number: 0253

Policy

I. Aetna considers injections of bulking agents medically necessary for members with unilateral vocal cord paralysis using agents that are cleared by the Food and Drug Administration for this indication. This procedure has been shown to improve vocal quality and prevent recurrent aspiration pneumonia in individuals with unilateral vocal cord paralysis.

Aetna considers injections of bulking agents into the vocal cords experimental and investigational for all other indications because their effectiveness for indications other than the one listed above has not been established.

Policy History

Last Review 02/22/2018
Effective: 05/26/1998
Next Review: 02/28/2019

Definitions

Additional Information

Clinical Policy Bulletin Notes
II. Aetna considers medialization thyroplasty (also known as type 1 thyroplasty) medically necessary for vocal cord paralysis. A Gore Tex/silastic implant is considered medically necessary for this indication.

III. Aetna considers posterior cricoarytenoideus re-innervation and pacing experimental and investigational for the treatment of bilateral vocal fold paralysis because its effectiveness for this indication has not been established.

IV. Aetna considers Radiesse (calcium hydroxylapatite and hyaluronic acid gel) medically necessary for the treatment of permanent vocal cord paralysis/insufficiency.

V. Aetna considers Radiesse injection for the treatment of velopharyngeal/velopalatal insufficiency experimental and investigational because its effectiveness for this indication has not been established.

VI. Aetna considers harvesting and injection of autologous fat medically necessary for the treatment of vocal cord paralysis/insufficiency.

VII. Aetna considers injection of Cymetra (micronized AlloDerm tissue), or Restylane (cross-linked hyaluronic acid) medically necessary for the management of voice loss and aspiration in cases where unilateral vocal cord paralysis is anticipated to be short-term (e.g., in cases of post-thyroidectomy unilateral paralysis where the recurrent nerve is known to be intact).
VIII. Aetna considers laryngeal electromyography (EMG) medically necessary for the evaluation of vocal fold paralysis.

IX. Aetna considers botulinum toxin injection experimental and investigational for the treatment of vocal cord paralysis because its effectiveness for this indication has not been established. See CPB 113 -- Botulinum Toxin.

Background

The vocal cords, also known as vocal folds, are two bands of flexible tissue located within the larynx (voice box) at the top of the trachea (windpipe). They are open during inhalation and close during swallowing and phonation (producing sound or speech). Closure of the vocal folds is imperative to protect the lower airway during swallowing. When closed, the vocal folds are able to vibrate and regulate the expelled airflow from the lungs to produce speech and singing. The rest of the time, they are relaxed in an open position, to allow for breathing.

Abnormal functioning or impaired movement of the vocal folds is generally referred to as vocal cord dysfunction and may be caused by disease, injury or may be idiopathic (cause unknown). Symptoms of vocal cord dysfunction may include changes in voice (breathiness or hoarseness), repetitive throat clearing, coughing or difficulty swallowing. Dysphonia is a general descriptive term that encompasses any voice impairment, including the quality or volume of the sound, increased vocal effort, fatigue, pain or discomfort associated with speaking or singing.
Vocal fold mobility disorders are a type of vocal cord dysfunction involving decreased movement of one (unilateral) or both (bilateral) vocal cords. Vocal cord insufficiency (also called glottic insufficiency) is most often used to describe this condition. Other associated terms include vocal fold paresis, paralysis or weakness.

Vocal cord insufficiency involves the incomplete closure of vocal cords and inappropriate escaping of air during phonation. Vocal folds are generally classified as hypomobile or immobile until the condition persists beyond six months with no other mechanical explanation. After that time, the cause is assumed to be from a permanent neurological cause and the terms paralysis or paresis are used.

Resting the voice is often the first conservative measure for individuals with symptoms indicative of vocal cord dysfunction. Voice (speech) therapy may also be recommended. Vocal cord paralysis determined to be bilateral or permanent generally requires surgical intervention.

The recurrent laryngeal nerves of the vagus nerves are the primary innervators of the abductors and adductors of the vocal folds. Isolated injury of the recurrent laryngeal nerve results in paralysis of the vocal cord in the para-median position on one side, 2 to 3 mm lateral to the laryngeal midline. Combined injury of the recurrent and superior laryngeal nerves paralyzes the vocal cord in the intermediate position, several millimeters lateral to the para-median position.

Vocal cord paralysis may be unilateral or bilateral, central or peripheral. Unilateral left vocal cord paralysis is most common. Less than 20% of cases are bilateral. Thyroidectomy is by far the most common cause of bilateral vocal cord paralysis. Central causes include
brain stem and supranuclear lesions and account for only 5% of all cases. Supranuclear or cortical causes of vocal cord paralysis are exceedingly rare, owing to the bilateral crossed neural innervation to the brain stem medullary centers in the nucleus ambiguus. The most frequent central cause is vascular insufficiency or a stroke affecting the brain stem. Congenital central lesions are usually secondary to Arnold-Chiari malformation or brain stem dysgenesis and are often associated with additional cranial neuropathies.

Most cases of peripheral vocal cord paralysis are secondary to thyroidectomy or non-laryngeal neoplasms, including bronchogenic, esophageal, and thyroid carcinoma. Other less common lesions causing paralysis of the vocal cord include tumors of the deep lobe of the parotid gland, carotid body tumors, glomus jugulare and vagale tumors, and neurogenic neoplasms of the tenth nerve and jugular foramen. External penetrating wounds to the neck or prolonged endotracheal intubation may also traumatize the recurrent laryngeal nerve, producing vocal cord paralysis. Finally, toxic neuropathy and idiopathic causes account for a few cases.

In adults, unilateral recurrent laryngeal nerve paralysis generally produces hoarseness and a weak, breathy voice with varying amounts of aspiration. The normal vocal cord may cross the midline to approximate the paralyzed vocal cord in the para-median position. In children, varying degrees of inspiratory stridor may also be present. Bilateral vocal cord paralysis is commonly associated with inspiratory stridor, shortness of breath, and dyspnea on exertion.

Injection laryngoplasty/injection augmentation of the vocal cords has been proposed as an alternative to conventional surgical insertion of a permanent synthetic implant lateral to the vocal fold (medialization
Injection laryngoplasty is a purportedly less invasive, nonsurgical procedure to treat unilateral vocal cord insufficiency by temporarily adding volume or bulk to facilitate vocal fold closure. Substances proposed for injection include, but may not be limited to, the following: autologous fat; collagen or gelatin based bulking agent; skin/tissue substitute (micronized human acellular dermis [Cymetra]); soft tissue fillers including calcium hydroxyapatite gel (eg, Prolaryn, Radiesse, VF Gel/Gel Plus), hyaluronic acid gel (eg, Hyalaform, Restylane), and Teflon.

Management of unilateral vocal cord paralysis due to lesions of the recurrent laryngeal nerve includes the injection of Teflon paste or Gelfoam under local anesthesia into the paralyzed vocal cord, mobilizing it medially. Medialization is valuable in the therapy of aspiration and results in dramatic improvement in voice quality. Other injection options for glottic insufficiency include bovine collagen, calcium hydroxylapatite, injectable fat, and Gelfoam. An assessment by the National Institute for Clinical Excellence (NICE, 2005) concluded that there are no major safety concerns regarding collagen injections for vocal cord augmentation and that they provide short-term symptom relief. However, evidence on long-term efficacy is lacking. Belafsky and Postma (2004) stated that initial experience with vocal fold augmentation using calcium hydroxylapatite is promising. However, its long-term safety and effectiveness needs to be established. Medialization of the paralyzed cord may also be accomplished externally via a thyroidotomy and placement of a Silastic wedge implant inside the thyroid cartilage in a small pocket deep to the paralyzed vocal cord.
The upper airway obstruction caused by bilateral vocal cord paralysis usually requires a tracheostomy initially. Subsequent improvement in the airway can be obtained with an arytenoidectomy.

Cymetra (micronized AlloDerm tissue) has been studied for soft tissue augmentation. In a preliminary report on voice quality as well as quality-of-life following Cymetra injection laryngoplasty in patients with unilateral vocal cord paralysis (n = 14), Pearl et al (2002) stated that Cymetra appears to be a safe new material that is suitable for injection laryngoplasty. However, long-term results are pending.

In a study with 10 patients with breathy dysphonia caused by unilateral vocal fold paralysis, Karpenko and colleagues (2003) examined the effectiveness of transoral injection of Cymetra for this indication. Each patient underwent pre-operative and post-operative acoustic analysis, aerodynamic measures, taped voice sampling, and videostroboscopy. Significant improvements were identified in maximum phonation time, relative glottal area, and subjective judgment of glottal competency. However, these results were not maintained at the 3-month study interval. No significant change in quantitative or subjective voice quality was noted for the study group during the investigation. The investigators stated that resorption of Cymetra may play a significant role in contributing to these findings.

Milstein and colleagues (2005) noted micronized AlloDerm (Cymetra) is a relatively new product used for vocal fold augmentation. Previous studies evaluating possible long-term effectiveness of this product have shown mixed results. These investigators re-assessed possible long-term results of Cymetra injection laryngoplasty (IL) in patients with unilateral vocal fold paralysis (UVFP). Pre-operative voice samples and
videostroboscopic findings were compared with the most recently available post-operative data to assess effectiveness of the procedure. A panel of voice experts analyzed both vocal and vibratory function in these samples. In addition, pre- and post-operative voice-related quality of life measures and patients' self-ratings of voice outcomes were compared. A total of 20 patients (7 males, 13 females; 14 with left-sided paralysis, 6 with right-sided paralysis) were identified in the study population. Cymetra injection was performed an average of 45.1 months after onset of vocal fold paralysis, and average follow-up post-injection was 11.2 months. Comparing pre- and post-operative measures, voice quality (p < 0.0001), glottal closure (p < 0.0001), and degree of vocal fold bowing (p < 0.0001) were all improved by injection. Quality of life measures and patients' self-perceptions of vocal quality were also improved (p < 0.01). Fifteen (75 %) patients showed long-lasting results; 8 patients showed improvement for more than 12 months after injection. The authors concluded that Cymetra IL offers improved vocal and vibratory function to patients with UVFP. The benefits of such medialization may be longer lasting than previously reported; and further long-term study is needed.

Tirado et al (2010) reviewed the clinical results of office-based injection laryngoplasty with 2 different therapeutic materials in patients with vocal fold paralysis and history of radiation therapy to the larynx. These investigators performed chart review of 11 patients who underwent office-based injection laryngoplasty with calcium hydroxylapatite or micronized Alloderm. All patients had a history of radiation therapy to the neck, with the larynx included in the radiation field. Voice analyses, clinical outcomes, and complications were reviewed. Effectiveness of the procedure was evaluated by comparing pre- and post-injection mean phonation
time (MPT) results from voice analysis data. A total of 15 injections were performed in 11 patients with vocal fold paralysis (1 female, 10 males; mean age of 62 years). Data from voice analyses before and after the procedure were available for 9 injections. The MPT was significantly increased among patients undergoing the procedure (p < 0.05). All procedures were successful, and only 1 self-limited complication was reported. The authors concluded that office-based injection laryngoplasty is a safe procedure with acceptable clinical results in patients with vocal fold paralysis who have a history of radiation therapy to the larynx.

Aviso et al (2010) stated that IL is a temporary intervention for UVFP. Injection laryngoplasty is often performed in patients with a potentially recoverable recurrent laryngeal nerve insult while awaiting spontaneous recovery, compensation, or definitive intervention. These researchers investigated the long-term outcomes of subjects treated with an IL. A single-institution, retrospective review was performed from January 2004 to July 2008; subjects with potentially recoverable UVFP who underwent an IL were included. The following etiologies were noted for the 42 subjects included: idiopathic in 13 (31 %), iatrogenic in 25 (60 %), infectious in 2 (5 %), traumatic in 1 (2 %), and stroke in 1 (2 %). Ten subjects (24 %) had full recovery of their paralysis, 4 (10 %) partially recovered movement with adequate recovery of voice, 16 (40 %) had no recovery of motion but compensation with adequate recovery of voice, 12 (29 %) required further definitive intervention in the form of laryngeal framework surgery. Voice-related quality of life scores improved for all patients surveyed after IL and improved more for those who ultimately recovered or compensated. The authors concluded that the majority
of subjects with potentially recoverable UVFP recover vocal fold motion and/or adequate voice after IL without permanent intervention.

Prendes et al (2012) noted that patients with UVFP treated with temporary IL have a decreased rate of permanent medialization laryngoplasty (ML) compared to UVFP patients initially treated by observation. These researchers examined if the lower rate of ML corresponded with improved quantifiable measures. Examinations at presentation and follow-up of 14 IL patients and 24 observation patients were analyzed for laryngoscopic features and Consensus Auditory-Perceptual Evaluation of Voice (CAPE-V) scores. The groups were similar at presentation. At follow-up, the IL group showed significant improvement in 11/18 laryngoscopic criteria and 7/12 CAPE-V parameters compared to the observation group (p < 0.05). The observation group underwent ML more frequently than the IL group (75 % versus 29 %, p = 0.008). The authors concluded that the lower rate of permanent ML in patients undergoing temporary IL corresponds with improvements in CAPE-V scores and laryngoscopic features, and improvements persisted beyond the accepted time frame for temporary graft resorption.

Lee and colleagues (2010) investigated the effectiveness of IL in the management of post-thyroidectomy vocal cord paralysis (VCP). From March 2005 to December 2008, a total of 174 consecutive injection laryngoplasties were performed in patients with unilateral glottic insufficiency. This included 34 patients with post-thyroidectomy VCP: 15 with temporary VCP and 19 with permanent VCP. Percutaneous injection was performed under local anesthesia into the vocalis muscle, using disposable 25G-long needles through the cricothyroid membrane or directly through the thyroid cartilage. Patients completed the acoustic, aerodynamic,
perceptual, stroboscopic, and voice handicap index evaluations before and at 3 and 6 months after the injection. All IL could be performed under local anesthesia without morbidity. Acoustic and perceptual parameters (overall grade of hoarseness, roughness, breathiness, asthenia, and strain), maximum phonation time, jitter, and shimmer, voice handicap index, and grades of mucosal waves and glottic closure were significantly improved after the injection and they remained stable over 6 months in both the temporary VCP and permanent groups (p < 0.05). The authors concluded that based on these results, IL improved the voice, and voice-related quality of life in patients with post-thyroidectomy VCP. It is a simple, safe, and useful method for rehabilitating post-thyroidectomy VCP patients.

Lau et al (2010) (i) determined the correlation between voice handicap index and quantitative videostroboscopy for patients undergoing IL for UVFP; and (ii) evaluated which videostroboscopy measurements correlate best with voice handicap index in patients demonstrating progressive improvement beyond 6 months following IL. Patients underwent outpatient injection laryngoplasty with hyaluronic acid between 2005 and 2007. A total of 28 patients were assessed pre-operatively and post-operatively using voice handicap index and videostroboscopy. Various videostroboscopy measurements were quantified: glottic open area (ratio of open to total glottic area during closed phase of phonation), glottic closed phase (frame ratio of closed phase to total glottic cycle), supraglottic compression (percent encroachment of supraglottis onto best-fit ellipse around glottis), wave amplitude (difference in glottic open area between open
and closed phases), and wave duration (number of frames per glottic cycle). Correlation coefficients were calculated using Spearman's r. A total of 117 separate recordings were analyzed. Correlation coefficients between voice handicap index (normalized to preoperative values) and glottic closed phase showed moderate-strong correlation ($r = -0.733$, $p < 0.001$), while glottic open area and wave duration showed weak-moderate correlation ($r = 0.465$, $p < 0.001$ and $r = -0.404$, $p < 0.001$ respectively). Other parameters showed poor correlation. A subset of 25 recordings from 8 patients with progressive voice handicap index improvement beyond 6 months showed highest correlation with supraglottic compression ($r = 0.504$, $p < 0.05$). The authors concluded that voice handicap index correlates best with glottic closed phase, suggesting duration of vocal fold closure during the glottic cycle best represents patients' subjective outcome post-procedure. Progressive improvement in voice handicap index beyond 6 months may relate to gradual reduction in compensatory supraglottic compression, with moderate correlation.

Reiter and Brosch (2012) noted that augmentation of vocal fold with hyaluronic acid (Restylane) is used as a therapeutic option for insufficient glottic closure in UVFP. Analysis of the optimal glottic width, effectiveness (long-term voice improvement as a consequence of longevity of Restylane), and safety of this new method was made. In a prospective clinical cohort study, 19 consecutive patients with UVFP who received vocal fold augmentation with Restylane were examined pre-operatively; 6 weeks, 6, and 12 months post-operatively by laryngostroboscopy; and their voice was evaluated by subjective, objective, and self-
assessment (Voice Handicap Index). In 11 of 19 (58 %) patients, a subjectively and objectively acceptable voice quality was observed in a follow-up of 12 months; 8 of 19 (42 %) patients had a considerable impairment of the voice after 6 weeks (range of 1 to 24 weeks). Therefore, another intervention (e.g., IL or thyroplasty) was recommended. An impairment of voice was mainly observed if the pre-operative glottal gap during phonation was more than 1 mm. The authors concluded that a long duration (up to 12 months) of acceptable quality of voice was achieved by augmentation with Restylane, if the glottal gap was 1 mm or less videolaryngostroboscopically during phonation. The authors recommend this therapy for temporary voice improvement and to augment vocal therapy, if spontaneous recovery of voice is likely.

Upton et al (2013) prospectively evaluated the safety and clinical effectiveness of office-based IL of Juvederm Ultra Plus gel (hyaluronic acid gel) in patients with glottic insufficiency. A total of 30 patients met the criteria for study inclusion and were treated with unsedated office-based IL of hyaluronic acid gel over a 20-month period. The pre-injection acoustic and aerodynamic measures, Voice Handicap Index, Glottal Function Index, and Dysphonia Severity Index were compared with values recorded at 1 and 4 months after injection. Data for 27 patients were available for follow-up analysis at 1 month, and 12 patients' data were available at 4 months. Significant improvements, compared to pre-injection levels (p < 0.02), were shown in all outcome measures at 1 and 4 months. One patient required intravenous steroid therapy for delayed glottic inflammation that resolved without permanent sequelae. The authors concluded that injection of hyaluronic acid gel is a relatively safe procedure that allows for short-term improvements in objective and subjective outcome measures of vocal function in patients with glottic
insufficiency, provided the surgeon remains alert to the possibility of post-procedural injection site inflammation.

Verma and Dailey (2014) stated that office-based injection laryngoplasty (OBIL) is a common method of addressing glottal insufficiency. These investigators identified the demographics, laterality, technique, success rate, injectates, and complications of OBIL performed over a 3-year period at a single institution. All OBILs performed for the management of UVFP by the senior author over 3 years (2007 to 2009) were identified from billing records. The age, gender, laterality, underlying disease process, augmentation material, route of injection, and complications were recorded. A total of 82 OBILs were attempted on 57 patients. The most common route of access was transoral (85.6%). All OBILs were able to be completed. Injectates used were hyaluronic acid derivatives (57.3%), calcium hydroxyapatite (16%), and Cymetra (16.5%). A total of 3 complications (3.7%) occurred; 30% of patients ultimately elected for thyroplasty or ansa reinnervation, 22% found their condition to self-resolve, 14% died, and 25% were lost to follow-up. The authors concluded that using a variety of approaches, OBIL is possible in almost all patients. The single surgeon transoral route using a rigid angled telescope and curved injection needle was the most commonly used approach. Multiple injectates can be used and have good safety records.

Furthermore, an UpToDate review on “Hoarseness in adults” (Bruch and Kamani, 2015) states that “Unilateral paralysis -- Surgical procedures are available for unilateral fold paralysis to reposition (medialize) the immobile vocal fold in order to achieve adequate glottal closure and improve voice as well as swallowing and cough. Techniques include transoral or transcervical
injection (injection laryngoplasty) of permanent or resorbable material, such as autologous fat, collagen, hyaluronic acid, or hydroxylapatite, lateral to the vocal fold. Medialization thyroplasty involves transcervical placement of an implant (usually silicone or Gortex) through a surgically created window in the thyroid cartilage”.

Rees and colleagues (2008) reviewed the clinical results of the thyrohyoid approach for in-office vocal fold augmentation with calcium hydroxylapatite (CaHA/Radiesse). The charts of all patients who underwent in-office thyrohyoid vocal fold augmentation between June 1, 2005 and June 1, 2007 were reviewed. Information with respect to patient demographics, indications, complications, and clinical outcome was abstracted. A total of 51 thyrohyoid vocal fold augmentations were performed in 33 patients (26 men; mean age of 66 years). Six (13 %) procedures were aborted as a result of an inability to achieve an appropriate injection angle. Two (6 %) self-limited complications included a vasovagal episode and a small ulcer near the petiole of the epiglottis. Pre- and post-procedure data were available for 62.5 %. The mean 10-item Voice Handicap Index (VHI) improved from 27.9 (+/- 8.40) pre-procedure to 13.5 (+/- 10.52) post-procedure (p < 0.001). The authors concluded that in-office vocal fold augmentation with the use of the thyrohyoid approach demonstrates excellent clinical results. It has become these investigators’ technique of choice for vocal fold medialization with the patient under local anesthesia in the office setting. Complications are rare.

Rosen et al (2009) evaluated the long-term effectiveness of CaHA vocal fold injection for patients with glottal insufficiency. Each patient served as his/her own control. Voice-related outcome measures were collected
for pre-injection, 1, 3, 6, and 12 months. A total of 63 patients were available for evaluation; 53% of the injection procedures were done in the office and 57% of patients were diagnosed with unilateral paralysis and 43% with glottal incompetence with mobile vocal folds. Patient satisfaction 12 months after injection showed 67% reporting a significant improvement in voice and 81% reporting at least a moderate improvement in voice. Utilizing the VHI-10, visual analog scale (vocal effort), Consensus Assessment Perceptual Evaluation V (judgments of voice severity), and objective voice measures of glottal closure (maximum phonation time and S:Z ratio), paired-t tests showed significant improvements after treatment. A 22% further treatment rate was found at the 12-month time point. The authors concluded that 1-year results in this large cohort of patients with glottal incompetence treated with CaHA vocal fold injection demonstrate that excellent clinical results were achieved.

In a multi-institutional retrospective review, Sulica et al (2010) identified contemporary indications, treatment principles, technique, injection materials, complications, and success rates of vocal fold injection augmentation. Records of patients undergoing injection augmentation at 7 university medical centers from July 2007 through June 2008 were reviewed for information regarding diagnosis, unilateral or bilateral injection, route of injection, anesthesia, treatment site (office or operating room), material used, reason for technique selected, and technical success. In 12 months, 460 injections were performed, 236 (51%) in awake, unsedated patients, and 224 (49%) under general anesthesia. Indications included vocal fold paralysis (248; 54%), paresis (97; 21%), atrophy (68; 15%) and scar (47; 10%). Scar was more likely to be treated in the operating room (p = 0.000052). In awake patients, 112 (47%) injections were performed by transcricothyroid approach, 55 (23%...
by peroral approach, 49 (21%) by trans-thyrohyoid membrane approach, and 20 (8%) by trans-thyroid cartilage approach. Neither technical success rate (99% versus 97%) nor complication rate (3% versus 2%) differed between awake and asleep techniques. The most common materials in the clinic setting were methylcellulose (35%), bovine collagen (28%), and CaHA (26%); in the operating room these were CaHA (36%) and methylcellulose (35%). Calcium hydroxylapatite was more likely to be used under general anesthesia (p = 0.019). Five-year data show that the use of injection in the awake patient rose from 11% to 43% from 2003 to 2008. The authors concluded that injection augmentation remains a safe, effective, and clinically practical treatment with a high rate of success, whether performed in the awake or asleep patient. The rapid adoption of awake injection over the past 5 years speaks to its clinical utility. Complication rates are low and equivalent to those under general anesthesia.

Medialization thyroplasty (MT), also known as type 1 thyroplasty, is one of the several surgical procedures that are employed for the treatment of unilateral vocal fold paralysis (UVFP). It entails the trans-cervical placement of an implant through a surgically created window in the thyroid cartilage to achieve medialization of the vocal fold so that better closure can be achieved.

Laccourreye and colleagues (2005) documented the long-term results achieved with the Montgomery implant in 96 patients with a unilateral laryngeal nerve paralysis (ULNP). Data regarding morbidity and functional results were obtained at regular visits to the clinic. All patients were followed for a minimum of 6 months or until death. A total of 42 patients had a minimum of 12 months of follow-up. Early in the study, 36 patients were prospectively recorded under similar conditions before placement of the Montgomery implant.
and at 1, 3, 6, and 12 months post-operatively. None of the 96 patients died in the immediate post-operative period. The peri-operative course was unremarkable in 94.8% of cases. Peri-operative problems included failure to obtain a satisfactory phonatory result in 3 patients, difficulty to stabilize the implant posteriorly in 1 patient, and fracture of the inferior rim of the thyroid cartilage window in another patient. The primary immediate post-operative problem (within the first post-operative month) was laryngeal dyspnea, noted in 4 patients. According to the patient's subjective assessment, speech and voice was always improved in the immediate post-operative period. However, 3 patients had secondary degradation of speech and voice. Revision surgery under local anesthesia resulted in a 97.9% ultimate speech and voice success rate.

According to the patient's subjective assessment, adequate swallowing in the immediate post-operative period was achieved in 94.2% of cases that had swallowing problems pre-operatively. A significant statistical increase in the duration parameters (phonation time, phrase grouping, speech rate) together with a statistical significant decrease in both the jitter and shimmer values was noted when comparing the pre-operative and the post-operative values at 1 month. Analysis of the evolution of the speech and voice parameters at 1, 3, 6, and 12 months post-operatively showed a significant decrease in the fundamental frequency and noise-to-harmonic ratio values but did not demonstrate any significant differences for the other speech and voice parameters. The authors concluded that type I thyroplasty with Montgomery implant insertion is a safe and reproducible method to treat ULNP. Furthermore, this system achieves very good and stable phonatory results. Finally, the use of this technique and implant system appears safe in patients from various cultures with ULNP from a variety of causes and severe comorbidity. Over the past decade
at the authors' department, this procedure progressively replaced the use of the intra-cordial injection of autologous fat injection that was initially advocated in patients with ULNP.

Lam et al (2007) reported on the use of MT in patients (n = 87) with symptomatic cancer-related UVFP. There were no significant differences between the cancer-related and benign groups in terms of the speech and swallowing rehabilitation outcome and the peri-operative complication rate (p > 0.05). The median survival time of cancer-related UVFP patients from the date of medialization to death was 129 days. Age greater than 65 years was identified as the only factor for a shorter survival period after medialization (p = 0.040). The authors concluded that MT restores satisfactory speech and swallowing and has a low peri-operative complication rate in patients with cancer-related UVFP. Furthermore, post-medialization survival period was also reasonable.

In a prospective observational cohort study, Storck and associates (2007) assessed functional results of MT using a hydroxyapatite implant (VoCoM) for the treatment of UVFP. A total of 26 patients (19 men, 7 women) were enrolled in the study. To evaluate voice function, the following parameters were measured pre-operatively and post-operatively: mean fundamental frequency, mean sound pressure level, frequency and amplitude range (voice range profile), and maximum phonation time. A perceptual assessment of hoarseness was conducted using the Roughness, Breathiness, Hoarseness scale. Furthermore, the magnitude of voice related impairment of the patient's communication skills was rated on a 7-point scale. A combined parameter called the Voice Dysfunction Index (VDI) was used to rate vocal performance. All patients showed a statistically significant improvement in the VDI, in
perceptual voice analysis, in maximum phonation time, and in the dynamic range of voice. One patient experienced a post-operative wound hemorrhage as a minor complication. No further complications or implant extrusions were observed. The authors concluded that MT using a hydroxyapatite implant is a secure and efficient phono-surgical procedure. Voice quality and patient satisfaction improve significantly after treatment.

Chrobok et al (2008) implemented MT with a customized silicone implant in a total of 43 operations (36 patients). In 5 of these patients, the MT was combined with cricothyroid subluxation (3 cases) or adduction of arytenoid cartilage (3 cases). One patient received MT, cricothyroid subluxation and adduction of arytenoid cartilage. Post-operatively, 36 patients reported substantial reduction of their complaints, 5 patients found their voice improved and only 2 patients (5.6 %) stated that their voice had not changed. The subjective evaluation was consistent with the findings of laryngoscopy and the pre-operative and post-operative phonation parameters (maximum phonation time, maximum sound pressure level, jitter and shimmer). Average maximum phonation time was 6.5 seconds before surgery and 12.5 seconds after surgery. Maximum vocal sound pressure level was, on average, about 4 dB higher after surgery. Jitter was reduced from 5.3 % to 3.7 % and shimmer from 32.3 % to 18.6 %. The differences between pre-surgical and post-surgical parameters in this study were all statistically significant, indicating voice improvement. The authors concluded that MT with a silicone implant was proven to be a successful and safe surgical method for the treatment of vocal fold paralysis.
Dursun and co-workers (2008) examined the early and long-term functional results of type I thyroplasty and injection laryngoplasty using fat or calcium hydroxylapatite. A total of 30 patients with glottic insufficiency were included and followed-up between 1 to 7 years. Patients with glottic bowing or sulcus vocalis were selected for injection augmentation of the vocal folds, while those with UVFP underwent MT. Perceptual and acoustic analysis of voice, and videolaryngostroboscopy were performed before and after surgery. After the surgery, GRBAS (grade, rough, breathy, asthenic, strained) scale (where 0 = normal, 1 = mild, 2 = moderate and 3 = severe) of all patients demonstrated significant change in grade of severity, roughness, and breathiness. Acoustic analysis showed significant change in fundamental frequency (Fo), jitter, shimmer, noise to harmonic ratio, and maximum phonation time (MPT) in thyroplasty group, while those demonstrated significant change in Fo (lowest) and jitter, and MPT in injection augmentation group. The authors concluded that MT is the gold standard for the management of glottic insufficiency, regardless of the severity of glottic gap. However, injection augmentation of the vocal folds may be considered as an alternative in the treatment of patients with small glottic gap.

Broniatowski and colleagues (2010) examined if respiratory compromise from bilateral vocal fold impairment (paralysis) can be objectively alleviated by re-innervation and pacing. A patient with paramedian vocal folds and synkinesis had a tracheotomy for stridor after bilateral laryngeal nerve injury and Miller Fisher syndrome. One posterior cricoarytenoideus (PCA) received a nerve-muscle pedicle fitted with a perineural electrode for pacemaker stimulation. The airway was evaluated endoscopically and by spirometry for up to 1 year. Bilateral vocal fold patency during quiet breathing was reversed to active vocal fold adduction during
tracheal occlusion. Peak inspiratory flows were significantly higher \((p < 0.001)\) after re-innervation. Peak inspiratory flows as well as glottic apertures increased further under stimulation \((42 \text{ Hz}, 1 \text{ to } 4 \text{ mA}, 42 \text{ to } 400 \text{ microsec})\); although the differences were insignificant. The authors concluded that based on these preliminary data, PCA re-innervation and pacing offer promise for amelioration of respiratory compromise after paradoxical adduction in bilateral vocal fold paralysis.

Fang et al (2010) analyzed outcomes following fat injection laryngoplasty in patients with unilateral vocal cord paralysis. A total of 33 consecutive patients with unilateral vocal cord paralysis undergoing autologous fat injection laryngoplasty with pre-operative and serial post-operative follow-up were included in this analysis. Main outcome measures were voice laboratory measurements, Voice Outcome Survey, and 36-item Short Form Health Survey. Except for the physical functioning dimension of global health, voice-related subjective outcomes and acoustic variables of the patients significantly improved after surgery \((p < 0.05)\). Compared with population norms, the mean \((SD)\) scores of patients were inferior on the 36-item Short Form Health Survey dimensions of physical functioning \((80.7 [22.3] \text{ versus } 90.2 [17.4])\) and role functioning-physical problems \((65.0 [36.2] \text{ versus } 80.2 [36.2])\). Overall, 88.9 % \((24 \text{ of } 27)\) of the patients were satisfied with their surgery. The authors concluded that fat injection laryngoplasty seems to be effective in enhancing acoustic and quality of life outcomes in patients with unilateral vocal cord paralysis. The effect is sustainable over 12 months.

Zhang et al (2011) evaluated the effect of combination of autologous fascia and fat injection into vocal fold for the treatment of patients with unilateral vocal fold
paralysis and observed the long-term effectiveness of this procedure. A total of 26 unilateral vocal fold paralysis patients underwent vocal fold injection under general anesthesia, meanwhile, the mucosa of the injected point was sutured through laryngoscope under direct vision. There were 6 patients underwent autologous fat injection into vocal fold (group A), and 20 patients underwent autologous anterior rectus sheath fascia and fat injection (group B). Therapeutic efficacy were evaluated by videostroboscopy, voice-related parameters analysis and voice evaluation before and after treatment. Clinical analysis of this procedure was retrospectively performed in this serial of patients. All patients were followed-up for 24 months. On the third day after operation, there was an acute inflammatory reaction induced by the graft. This reaction disappeared 3 months later. In all 20 cases, videolaryngostroboscopy showed significant improvement of the glottic closure, the improvement in acoustical parameters was statistically significant (p < 0.01). Perceptual evaluation of GRBAS scale showed significant improvement of phonatory function on G, B, A scale. The results remained stable 6 to 24 months after operation and were not changed by the length of follow-up. And in the 6 cases, videolaryngostroboscopy showed significant improvement of the glottic closure at 3 months compared with pre-operative observation, a little spindle-shaped disclosure. The improvement in acoustical parameters was significant statistically at 3, 6 and 24 months (p < 0.05 or < 0.01), the voice quality decreased significantly at 6 and 24 months compared with 3 months (p < 0.05 or < 0.01). The significant differences were not observed between 6 and 24 months (p > 0.05). No complications were observed in all patients peri-operatively or during the follow-up period. Voice-related parameters jitter, normalized noise energy and maximum phonation time showed significant differences between Group A and Group B on 24
months \( (p < 0.05 \text{ or } < 0.01) \). The authors concluded that the combination of autologous fascia and fat vocal fold injection is an effective procedure for the treatment of unilateral vocal fold paralysis, and the stable results can be achieved during the follow-up period for 24 months.

Mazzola et al (2011) stated that minimally-invasive autologous fat injection of the head and neck region can be considered a valid alternative to major invasive surgical procedures both for aesthetic and functional purposes. The favorable outcomes of autologous fat injection in otolaryngological practice are due to the filling of soft tissue and, mainly, to the potential regenerative effect of adipose-derived mesenchymal stem cells. Herewith, some important biological preliminary remarks were described underlying the potential of autologous fat injection in regenerative medicine, and personal experience in using it for both consolidated clinical applications, such as fat grafting to the face and vocal fold augmentation in the treatment of glottic incompetence, and more recent applications including the treatment of post-parotidectomy Frey syndrome and velopharyngeal insufficiency. The authors noted that vocal fold augmentation by means of autologous fat injections for glottic incompetence has been standardized and used in their clinic for several years.

Radiesse, originally approved as a wrinkle filler, received additional clearance from the Food and Drug Administration for the treatment of vocal cord insufficiency (2007). Radiesse is injected lateral to the vocal folds and the vocalis muscle. The bulking effect of the implant medializes the vocal folds, facilitating speech and preventing inadvertent aspiration of liquids, as well as correcting shortness of breath caused by laryngeal incompetence. The Radiesse injection procedure can be performed percutaneously or trans-
orally with endoscopic guidance, with local or topical anesthetic as required. Since the procedure can be performed in-office with the patient awake and able to talk, patients' speech can be evaluated immediately and the amount of material needed for optimal correction can be more accurately determined.

Carroll et al. (2011) reported the long-term effectiveness of CaHA/Radiesse as a vocal fold injectable by assessing data from a cohort of patients who underwent injection for glottal insufficiency. Patients who underwent CaHA injection for glottal insufficiency of any etiology were considered for inclusion in the study. The change in VHI-10 scores between pre-injection scores and best post-injection scores as well as between the pre-injection and the most recent VHI-10 scores were used as primary outcome measures to determine the persistence of benefit or the time to loss of benefit. Complications among the cohort were identified. A total of 90 patients who underwent 108 vocal fold injections with CaHA were evaluated for inclusion. Twenty patients with 22 injections met the criteria for inclusion. Fourteen of 22 (64%) subjects showed loss of benefit of the CaHA material. The average length of benefit was 18.6 months, with a range of 8 to 36 months. Three complications were identified among the original cohort of 108 injections. The authors concluded that CaHA remains a safe and effective long-term vocal fold injectable with an average length of benefit of 18.6 months. Three complications were seen among 108 CaHA injections. They stated that CaHA is a long-term injectable with an excellent track record that does not appear to warrant concern for permanent or late complications.

Yung and colleagues (2011) examined if temporary vocal fold injection affects the need for permanent medialization laryngoplasty in patients with UVFP. A
total of 175 patients with dysphonia resulting from UVFP were identified. Patients with documented recovery of vocal fold mobility, less than 9 months of follow-up after diagnosis of UVFP, previous treatment at other institutions, neoplastic disease involving the larynx, or history of radiation to the larynx were excluded. A total of 54 patients met all inclusion/exclusion criteria. Rates of permanent medialization laryngoplasty in patients undergoing vocal fold injection were compared with those of patients who chose observation or voice therapy. A total of 35 % of patients underwent temporary injection medialization, and the remaining 65 % chose conservative management. Five of 19 of the temporary injection medialization patients subsequently underwent permanent intervention compared to 23 of 35 of the conservative management group (p = 0.0131). The authors concluded that UVFP patients who underwent vocal fold injection with an agent intended to provide temporary medialization were statistically significantly less likely to undergo permanent medialization laryngoplasty compared to those patients who were treated with conservative management only.

Song et al (2010) noted that a variety of materials as well as approaches have been used to treat glottic insufficiency, but the ideal procedure has yet to be determined. The goal of this study was evaluate the safety and effectiveness of cross-linked hyaluronic acid (HA; Restylane) for office-based injection laryngoplasty for the treatment of vocal fold (VF) immobility. These researchers performed a retrospective chart review of 27 patients with VF immobility; 25 received Restylane VF injections in the office setting via percutaneous, trans-thyrohyoid injection with distal chip endoscopic guidance. Two patients received injections using suspension microlaryngoscopy under general anesthesia. Voice outcomes were followed using the Voice-Related
Quality of Life Survey and the Voice Outcome Survey. Four patients were lost to follow-up immediately after injection; 20 of 23 patients (87%) reported subjective improvement in voice. Analysis of subjective surveys from 9 patients revealed a trend toward improvement of V-RQOL from 34 to 23 (p = 0.083); but did not reach significance. After compilation of all VOS questions, 69% of all follow-up responses noted improvement of symptoms, 24% were unchanged and 7% were worse. The authors concluded that office-based injection laryngoplasty with Restylane appears to be a safe procedure that improves vocal function in patients with glottal insufficiency due to impaired VF mobility. Moreover, they stated that further studies are needed to quantify the benefits and to compare the effects with other injectable materials.

In a prospective study, Wang et al (2012) examined the feasibility of using an injectable needle electrode to guide VF injection (VFI) of HA during laryngeal electromyography (LEMG) for unilateral VF paralysis (UVFP). From March to June 2010, a total of 20 UVFP patients received LEMG examination. Before completion of LEMG, 1.0 cc of HA (Restylane Perlane®; Q-Med, Uppsala, Sweden) was injected via a 26-gauge monopolar injectable needle electrode into paralyzed thyroarytenoid muscle. After injection, 20 patients completed 3-month follow-up and 16 patients completed 6-month follow-up. The data before, 1 week, 3 months, and 6 months after injection, including the normalized glottal gap area (NGGA) from videostroboscopy, maximal phonation time (MPT), mean airflow rate (MAFR), phonation quotient (PQ), perceptual evaluation of voice (grade, roughness, breathiness, asthenia, strain [GRBAS] scale), Voice Handicap Index (VHI), and self-grading of choking (grade 1 to 7), were analyzed by the Wilcoxon signed rank test. All of the patients completed the procedure
without complications. After injection, mean NGGA was significantly reduced from 8.28 units to 0.52 units (1 week), 1.79 units (3 months), and 1.36 units (6 months). The mean MPT was prolonged from 5.66 seconds to 11.73, 11.25, and 11.93 seconds, respectively. Voice Handicap Index HI was reduced from 76.05 to 38.10, 37.40 and 35.00, respectively. Other analyzed data (PQ, MAFR, GRBAS scale, and choking severity) also showed statistically significant improvement. The authors concluded that LEMG-guided HA VFI provides UVFP patients with neuromuscular function evaluation and treatment in one step. This clinical technique is feasible, and the short-term results are satisfactory. These preliminary findings need to be validated by well-designed studies with more patients and longer follow-up.

In a Cochrane review, Lakhani et al (2012) evaluated the effectiveness of alternative injection materials in the treatment of UVFP. These investigators searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; ICTRP and additional sources for published and unpublished trials. The date of the most recent search was March 23, 2012. Randomized controlled trials (RCTs) of injectable materials in patients with UVFP were selected for analysis. The outcomes of interest were patient and clinician-reported improvement, and adverse events. Two authors independently selected studies from the search results and extracted data. They used the Cochrane 'Risk of bias' tool to assess study quality. These researchers identified no RCTs that met the inclusion criteria for this review. They excluded 18 studies on methodological grounds: 16 non-randomized studies; 1 RCT due to inadequate randomization and inclusion of non-UVFP
patients; and 1 RCT that compared 2 different particle sizes of the same injectable material. The authors concluded that there is currently insufficient high-quality evidence for, or against, specific injectable materials for patients with UVFP. They stated that future RCTs should aim to provide a direct comparison of the alternative materials currently available for injection medialization.

A Food and Drug Administration’s MAUDE Adverse Event Report on “Q-MED AB. Restylane injectable gel injectable dermal filler” (FDA, 2007; last updated 1/31/2013) noted that vocal cord paralysis is not an approved indication for Restylane use.

The consensus report on “Vocal fold scars” by the Phonosurgery Committee of the European Laryngological Society (Friedrich et al, 2013) stated that scarring of the vocal folds leads to a deterioration of the highly complex micro-structure with consecutively impaired vibratory pattern and glottic insufficiency. The resulting dysphonia is predominantly characterized by a reduced vocal capacity. Despite the considerable progress in understanding of the underlying pathophysiology, the treatment of scarred vocal folds is still an unresolved chapter in laryngology and phonosurgery. Essential for a successful treatment is an individual, multi-dimensional concept that comprises the whole armamentarium of surgical and non-surgical (e.g., voice therapy) modalities. An ideal approach would be to soften the scar, because the reduced pliability and consequently the increased vibratory rigidity impede the easiness of vibration. The chosen phonosurgical method is determined by the main clinical feature: Medialization techniques for the treatment of glottic gap, or epithelium freeing techniques for improvement of vibration characteristics often combined with injection augmentation or implantation. In severe cases, buccal
mucosa grafting can be an option. New developments, include treatment with anxiolytic lasers (e.g., pulse dye laser [PDL]; potassium titanyl phosphate [KTP] laser), laser technology with ultrafine excision/ablation properties avoiding coagulation (Picosecond infrared laser, PIRL), or techniques of tissue engineering. However, the authors concluded that despite the promising results by in-vitro experiments, animal studies and first clinical trials, the step into clinical routine application has yet to be taken.

**Injection Pharyngoplasty with Calcium Hydroxyapatite (Radiesse) for the Treatment of Velopharyngeal//Velopalatal Insufficiency:**

In an observational case-series study, Sipp and colleagues (2008) evaluated the effectiveness of injectable CaHA for treatment of velo-palatal insufficiency (VPI). A total of 7 patients treated with injectable CaHA for VPI and followed for 10 to 24 months were included in this analysis. Subjects were children aged 6 to 16 years with clinically significant VPI stemming from documented small VP gaps and who did not benefit from speech therapy were treated with CaHA injection pharyngoplasty. Treatment success was defined as (i) speech improvement to the degree that parents felt no additional treatment was needed, and (ii) meeting post-operative nasometric measures. Treatment failure was defined as parental report of insufficient improvement in speech. Complications and additional treatments for VPI were noted. There were no major complications in any of the 7 children injected with CaHA. There was 1 minor complication: 1 patient was re-admitted for post-operative pain and dehydration. Of the 7 patients, 4 experienced a
satisfactory result for up to 17 months. Findings from post-operative nasometry were either within reference range, or less than 1 SD greater than the reference range, for all sounds. There were 3 treatment failures, each with pre-existing craniofacial abnormality. Two patients in the group that failed treatment later underwent revision superior pharyngeal flap surgery without complication or hindrance from the CaHA injection; 4 children underwent subsequent magnetic resonance imaging evaluations up to 1 year after injection, which revealed no evidence of migration. The authors concluded that the findings of this small series suggested that posterior pharyngeal wall injection with CaHA was safe and may be effective in treating select patients with VPI. They stated that further longitudinal studies, with a larger series of patients, examining the safety, effectiveness, and patient selection are needed to better understand the possible use of posterior pharyngeal wall injection of CaHA in children with symptomatic VPI.

Brigger et al (2010) identified children who may benefit from CaHA injection pharyngoplasty for symptomatic VPI. Children with symptomatic VPI as defined by abnormal speech associated with subjective and objective measures of hyper-nasality were included in this study. Main outcome measure was nasalence scores recorded as number of standard deviations (SDs) from normalized scores, and perceptual scoring recorded as standardized weighted score and caretaker satisfaction from direct report. A total of 12 children who had undergone injection pharyngoplasty with CaHA were identified. Of the 12 children, 8 showed success at 3 months as defined by nasalence (less than 1 SD above normal nasalence scores), perceptual scoring (decrease
in weighted score), and overall caretaker satisfaction. Four children were followed up for more than 24 months and continued to demonstrate stable success. The 4 children who failed the procedure all failed before the 3-month evaluation and demonstrated increased baseline severity of VPI as defined by increased pre-operative nasalance scores (5.25 SD versus 2.4 SD above normalized scores), perceptual scores (weighted score, 4.25 versus 3.85), and characteristic nasendoscopy findings of a broad-based velopharyngeal gap or unilateral adynamism; 3 of the 4 treatment failures occurred early in the senior author's (C.J.H.) experience with the technique. The authors concluded that injection pharyngoplasty with CaHA is a useful adjunct in the treatment of children with mild VPI. Safety and effectiveness have been demonstrated more than 24 months after injection. Patient selection and operative technique are critical to the success of the procedure. Success is seen most often in children with mild VPI and small well-defined velopharyngeal gaps consistent with touch closure. This was a small study (n = 12); and there may have been overlapping of patients with the study by Sipp et al (2008) because the senior author of both studies appeared to be C.J.H. These preliminary findings need to be validated by well-designed studies.

**Laryngeal EMG for the Evaluation of Vocal Fold Paralysis:**

Munin and colleagues (2016) developed an evidence-based consensus statement regarding use of LEMG for diagnosis and treatment of vocal fold paralysis after recurrent laryngeal neuropathy (RLN). Two questions regarding LEMG were analyzed: (i) Does LEMG predict recovery in patients with acute unilateral or bilateral vocal fold paralysis? and (ii) Do LEMG
findings change clinical management in these individuals? A systematic review was performed using American Academy of Neurology criteria for rating of diagnostic accuracy. Active voluntary motor unit potential recruitment and presence of poly-phasic motor unit potentials within the first 6 months after lesion onset predicted recovery. Positive sharp waves and/or fibrillation potentials did not predict outcome. The presence of electrical synkinesis may decrease the likelihood of recovery, based on 1 published study; LEMG altered clinical management by changing the initial diagnosis from RLN in 48% of cases. Cricoarytenoid fixation and superior laryngeal neuropathy were the most common other diagnoses observed. The authors concluded that if prognostic information is needed in a patient with vocal fold paralysis that is more than 4 weeks and less than 6 months in duration, then LEMG should be performed. Moreover, they stated that LEMG may be performed to clarify treatment decisions for vocal fold immobility that is presumed to be caused by RLN.

**Botulinum Toxin Injection:**

Benninger and associates (2016) noted that bilateral vocal fold paralysis most commonly results from iatrogenic trauma to the recurrent laryngeal nerve during surgical procedures in the anterior neck. Patients may require tracheostomy because of acute or gradual onset of dyspnea and airway compromise. The intra-laryngeal injection of Botox has been considered as a possible therapy for these airway symptoms of bilateral vocal fold paralysis. Chronic unopposed activity of intact cricothyroid muscles
could potentially result in gradual medialization of the vocal folds in patients with bilateral recurrent laryngeal nerve paralysis. This case series described 3 patients who successfully underwent injections of botulinum toxin (BTX) into the bilateral cricothyroid muscles to offer sustained relief of dyspnea resulting from bilateral vocal fold paralysis.

Woisard and colleagues (2017) stated that data regarding the use of BTX in laryngeal dyspnea, are scarce, coming from some cases reports in the literature, including Vocal fold paralysis, laryngeal dystonia, vocal cord dysfunction also called paradoxical motion of the vocal fold (PMVF), and post-neuroleptic laryngeal dyskinesia. There is no consensus regarding the muscles and the doses to inject. In a retrospective study, these researchers presented a review of patients treated in their ENT Department by BTX injection in this indication. Patients who underwent an injection of BTX for laryngeal dyspnea in the ENT Department from 2005 to 2015 years. The inclusion criteria were a dyspnea associated with a laryngeal dysfunction, confirmed by flexible fiberoptic nasopharyngolaryngoscopy. Information concerning the causes of the dyspnea, the BTX injections procedure, post-injection follow-up, and respiratory outcome were collected for all patients included. A total of 13 patients included; the main cause identified as principal factor linked with the short breath was: a bilateral VF paralysis, laryngeal dystonia, anxiety syndrome associated with unilateral vocal fold paralysis or asthma, and an isolated asthma; 9 out of the 13 patients improved following the injections. A BTX-induced stable benefit for 4
patients led them to stop the injections in the follow-up. Good outcome was observed in 5 other patients (main cause: bilateral VP paralysis), allowing a progressive lengthening of the delay between BTX injections; 4 patients did not report a positive risk/benefit ratio after BTX injections; 2 of them (with bilateral VF paralysis), because of respiratory side effects and lack of benefit without the side effects for the 2 others. This failure of effect was not related with BTX doses injected. The authors concluded that this study provided support for using BTX injections as a symptomatic treatment of periodic laryngeal dyspnea, regardless of the etiologic context. They suggested that a small starting dose (about 4 units of BTX) could be enough for a first injection to obtain a good benefit. The target muscle should be determined by the EMG analysis. These preliminary findings need to be validated by well-designed studies.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<td></td>
<td>Injections of bulking agents and medialization thyroplasty:</td>
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<td></td>
<td>CPT codes covered if selection criteria are met:</td>
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<tr>
<td>31513</td>
<td>Laryngoscopy, indirect; with vocal cord injection</td>
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<tr>
<td>31570</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic</td>
</tr>
<tr>
<td>31571</td>
<td>with operating microscope or telescope</td>
</tr>
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<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------</td>
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<tr>
<td>31591</td>
<td>Laryngoplasty, medialization, unilateral</td>
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Other CPT codes related to the CPB:

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<th>Code Description</th>
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<tr>
<td>60210</td>
<td>Thyroidectomy</td>
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<td>60271</td>
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HCPCS codes covered if selection criteria are met:

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<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>C1878</td>
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<td>C9742</td>
<td>Laryngoscopy, flexible fiberoptic, with injection into vocal cord(s), therapeutic, including diagnostic laryngoscopy, if performed</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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<tr>
<td>Q3031</td>
<td>Collagen skin test</td>
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ICD-10 codes covered if selection criteria are met:

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<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>J38.01</td>
<td>Paralysis of vocal cords and larynx, unilateral</td>
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<tr>
<td>J38.3</td>
<td>Other diseases of vocal cords [vocal cord insufficiency]</td>
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</table>

Posterior cricoarytenoideus re-innervation and pacing:

CPT codes not covered for indications listed in the CPB:

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<td>31590</td>
<td>Laryngeal reinnervation by neuromuscular pedicle [posterior cricoarytenoideus re-innervation and pacing]</td>
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<tr>
<td>Code</td>
<td>Code Description</td>
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<tr>
<td>---------</td>
<td>----------------------------------------------------------------------------------</td>
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<tr>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrodes; cranial nerve [posterior cricoarytenoideus re-innervation and pacing]</td>
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HCPCS not covered for indications listed in the CPB [posterior cricoarytenoideus re-innervation and pacing]:

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<tr>
<th>Code</th>
<th>Code Description</th>
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<td>C1767</td>
<td>Generator, neurostimulator (implantable), nonrechargeable</td>
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<tr>
<td>C1778</td>
<td>Lead, neurostimulator, (implantable)</td>
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<tr>
<td>C1816</td>
<td>Receiver and/or transmitter, neurostimulator (implantable)</td>
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<tr>
<td>C1883</td>
<td>Adaptor/extension, pacing lead or neurostimulator lead (implantable)</td>
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<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
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<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
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<td>--------</td>
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<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
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<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
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<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implanted neurostimulator, replacement only</td>
</tr>
<tr>
<td>L8695</td>
<td>External recharging system for battery (external) for use with implanted neurostimulator, replacement only</td>
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ICD-10 codes not covered for indications listed in the CPB:

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Radiesse:

HCPCS codes covered if selection criteria are met:

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ICD-10 codes not covered for indications listed in the CPB:

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<td>Other congenital malformations of pharynx</td>
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Autologous Fat Injection:

CPT codes covered if selection criteria are met:

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<th>Code</th>
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<td>31570</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic</td>
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<td>Code</td>
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<td>31571</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope</td>
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<td>Laryngoscopy, flexible; with therapeutic injection(s) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral</td>
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<td>Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral</td>
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Other CPT codes related to the CPB:

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ICD-10 codes covered if selection criteria are met:

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Restylane:

No specific code

ICD-10 codes not covered for indications listed in the CPB:

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<td>J38.00</td>
<td>Paralysis of vocal cords and larynx</td>
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<tr>
<td>J38.02</td>
<td>Paralysis of vocal cords and larynx</td>
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<td>J38.3</td>
<td>Other diseases of vocal cords [vocal cord insufficiency]</td>
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Cymetra (micronized AlloDerm tissue):

http://qawww.aetna.com/cpb/medical/data/200_299/0253_draft.html

06/13/2018
The above policy is based on the following references:


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<th>Code</th>
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<td>Q4112</td>
<td>Cymetra, injectable, 1 cc</td>
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<tr>
<td>R49.1</td>
<td>Aphonia</td>
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</table>


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AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0253 Vocal Cord Paralysis/Insufficiency Treatments

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania

revised 05/04/2018