



# CIGNA HEALTHCARE COVERAGE POSITION

**Subject Injections for Unilateral Vocal Cord Paralysis (UVCP)**

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## Coverage Position

**CIGNA HealthCare covers laryngeal fat injections or other bulking agents approved by the U.S. Food and Drug Administration (FDA) for the treatment of unilateral vocal cord paralysis as medically necessary when the patient is not a surgical candidate.**

## General Background

Vocal fold (or cord) paresis or paralysis is a result of abnormal nerve input to the voice box muscles (i.e., laryngeal muscles). Paresis results when there is a partial interruption of nerve impulse resulting in weak or abnormal motion of the laryngeal muscle(s). Paralysis is a result of total interruption of nerve impulse with no movement of the muscle. Vocal cord paresis/paralysis can occur at any age from a variety of causes (e.g., inadvertent injury during surgery; complication from endotracheal intubation; blunt chest or neck trauma; tumors involving the skull base, neck or chest; viral infections) (American Academy of Otolaryngology Head and Neck Surgery [AAOHNS], 2004).

Vocal cord muscle movements are controlled by the brain through a set of nerves called the superior laryngeal nerve (SLN) and the recurrent laryngeal nerve (RLN). The recurrent laryngeal nerve is involved in the majority of vocal cord paresis/paralysis cases. Because of the long length of the RLN, it is at greater risk of injury from a variety of causes. The major complaint with RLN nerve paralysis is a breathy and weak voice. The incomplete glottic closure can result in aspiration and cough with the risk of developing pneumonia from aspiration (AAOHNS, 2004; Laccourreye, et al., 1999).

The symptoms of vocal cord paralysis/paresis are voice changes, and airway and swallowing problems. Glottic insufficiency, which may be secondary to vocal cord paralysis, atrophy, or scarring, is a condition

that leaves patients with phonatory compromise in both voice frequency and intensity. Vocal cord paralysis is diagnosed by an otolaryngologist-head and neck surgeon who examines the voice box to determine whether one or both vocal folds are affected. Testing which may be performed includes laryngeal electromyography (LEMG), computed tomography (CT) scans, and magnetic resonance imaging (MRI) to identify the cause of vocal cord paralysis. A speech-language pathologist may use an acoustic spectrograph that measures voice frequency and clarity (AAOHNS, 2004; National Institute for Clinical Excellence [NICE], 2005; National Institute on Deafness and Other Communication Disorders [NIDCD], 2007).

One or both of the vocal cords may be affected by vocal cord paresis. Bilateral vocal cord paralysis is manifested by both vocal folds remaining near the midline position. Patients with bilateral vocal cord paralysis maintain a strong voice, since the vocal folds continue to vibrate, but they may suffer from life-threatening airway obstruction and stridor and may require immediate reintubation or tracheotomy. Unilateral vocal cord paralysis (UVCP) is more common than bilateral vocal cord paralysis. Various techniques have been proposed for managing vocal cord paralysis, including voice therapy, laryngeal framework surgery, reinnervation surgery, and injection laryngoplasty (Kwon, et al., 2004; Lorenz, et al., 2004; NIDCD, 2007).

Conservative management by voice therapy can be a treatment of choice for UVCP if the laryngeal muscles can be developed through vocal exercise. In some cases, the patient's voice can return without treatment during the first year after damage. Doctors might delay corrective surgery for at least a year to be sure the voice does not recover spontaneously. Laryngeal framework surgery, including medialization thyroplasty or type I thyroplasty, is considered to be the surgical procedure of choice for the long-term management of the paralyzed vocal fold. The procedure can be performed alone or in conjunction with arytenoid adduction or reinnervation procedures. Type I thyroplasty is considered reversible, but the voice quality after the removal of implants has not been studied. The decision for surgery is dependent on the severity of symptoms, vocal needs of the patient, position of the paralyzed vocal folds, prognosis for recovery, and the cause of paresis/paralysis, if known. When there is documentation of denervation by electromyography (EMG), medialization thyroplasty is generally considered early in the presence of aspiration or severe dysphonia. If there is evidence of recovery visually or by EMG, medialization by injection using a resorbable material can be considered as a temporizing procedure (Kwon, et al., 2004; Lorenz, et al., 2004; Flint, et al., 2005; NIDCD, 2007).

Injection medialization laryngoplasty techniques with a variety of injectable substances have been proposed for the treatment of UVCP. The injection of a substance reduces the space between the vocal cords so the nonparalyzed vocal cord can make closer contact with the paralyzed cord, thus improving the voice. Injection laryngoplasty is used in clinical situations in which the paralyzed vocal fold is expected to fully recover. Additionally, in patients with a history of previous laryngeal irradiation or in patients with active or obstructing nonoperative disease (e.g., lymphoma, extensive fibrosis), injection laryngoplasty has an advantage over laryngeal framework surgery. Injection laryngoplasty is not recommended for patients with large glottic gaps. For these patients, an open surgical approach is the recommended treatment. The reported advantages of injection laryngoplasty compared to other procedures includes lower morbidity, reducing the risk of aspiration, avoidance of open surgical procedures, and minimal anesthetic requirements in an outpatient clinic setting. Complications of vocal cord injections include under-injection of material, requiring repeat procedures; over-injection of material with possible airway compromise; potential for stenosis; and improper placement, causing subglottal extension (Kwon, et al., 2004; Lorenz, et al., 2004; Flint, et al., 2005; NIDCD, 2007).

Textbook literature by Flint et al. (2005) states vocal cord paralysis with a favorable prognosis occurs after blunt trauma, idiopathic vocal cord paralysis, endotracheal intubation, and paralysis associated with viral pathogens. The severity of aspiration, dysphonia, and EMG findings determines the choice of procedure in patients with a favorable prognosis. Vocal cord paralysis with a poor prognosis for recovery includes patients with injury after complete nerve section during surgical resection of tumor, invasion of cranial nerves by tumor, paralysis associated with thoracic aneurysm, and paralysis due to progressive neurologic disorders. These patients have increased difficulty with dysphonia, aspiration, and dysphagia. Therefore, where denervation is documented or the patient prognosis reveals potential for a poor outcome, early medialization by thyroplasty is required. Percutaneous medialization by injection is generally considered in those patients with short life expectancy and aspiration or severe dysphonia. The

authors discuss the materials used for vocal fold medialization by injection stating, "Autologous fat and Cymetra (human micronized AlloDerm) are the most common materials used today. Cymetra has been shown to provide excellent phonatory results lasting 6–12 months with little or no inflammatory response. The hyaluronic acid formulations such as Hylan B gel used as an injectable material for medialization has also been shown to have favorable viscoelastic properties. Collagen, although not specifically approved by the U.S. Food and Drug Administration for laryngeal injections, has been shown to be effective for management of vocal fold paralysis, sulcus vocalis, and soft tissue deficits. Inflammatory changes associated with soft tissue response after bovine collagen injection can result in increased tissue stiffness and less than satisfactory results. Permanent adverse effects are unlikely to occur, however, since the collagen is ultimately resorbed. The use of Teflon paste (Polytef) for vocal fold injection is discouraged unless long-term patient survival is not anticipated. Adverse effects due to development of Teflon granuloma are well documented and include dysphonia caused by soft tissue reaction and airway obstruction from mass effect."

### **Injectable Materials**

**Autologous Fascia:** The use of autologous fascia for UVCP was introduced in 1998. Fascia is placed in the form of a free graft or can be injected by mincing it into small pieces with a scalpel. The ability to make reliable conclusions about the effectiveness of autologous fascis is limited by the relatively short follow-up. The results have not been correlated with patient satisfaction ratings or compared in studies with other injection methods (Courey, 2004).

**Literature Review:** Rihkanen et al. (2004) assessed the glottal closure and the traveling mucosal wave by videostroboscopy after autologous fascia augmentation in UVCP. Fourteen patients with mean age 59 were studied. A large glottal gap and poor voice after voice therapy were the criteria for performing an injection laryngoplasty. Videostroboscopy and voice recording were carried out before and after the operation. Mean follow-up was 13 months with a significant reduction in glottal gap and improvement in voice acoustics. Two patients failed the procedure with residual glottal gap.

**Autologous Fat:** Autologous fat injections have been used as an injection material since the later 1980s and early 1990s. The effectiveness, availability, biocompatibility, and low rate of complications of the autologous fat have contributed to its widespread use. Fat offers similar viscoelastic properties to those of the vocal cord tissue. The disadvantage of fat injection is the unpredictable rate and degree of resorption, which limits the predictability of long-term outcomes, and repeat injections are often required (Courey, 2004; Kwon, et al., 2004).

**Literature Review:** Umeno et al. (2005) evaluated 41 patients with UVCP who underwent autologous intravocal fold injection of fat due to injury to the RLN. Fat was harvested from the lower abdomen by liposuction. Voice function dramatically improved compared to parameters examined before the procedure. Vocal function improved as time passed during the second year after injection. The authors concluded that autologous fat injection is a simple, useful treatment for patients with UVCP caused by RLN injury.

Laccourreya et al. (2003) conducted a retrospective case series study (n=80) with previously nonsurgically treated unilateral laryngeal nerve paralysis (ULNP) patients. The authors documented the long-term results achieved with intracordal injection of autologous fat according to the patient's self-assessment. The authors concluded that intracordal injection of autologous fat is a useful and safe procedure. However, the impossibility of exactly predicting the amount of resorption and duration of the results of the injected fat led the authors to limit the current use of the injection of fat mainly to patients in whom a high suspicion for recovery after the initial trauma exists, and to use medialization thyroplasty in the remaining patients. The authors noted that, according to reported case series based on small cohorts with a short duration of follow-up, the average long-term success rate after autologous fat injection in patients with ULNP is 79%. According to the authors, long-term clinical data (>12 months) is scarce and conflicting.

McCulloch et al. (2002) evaluated the results of autologous fat injection laryngoplasty in the long-term management of 44 patients with UVCP. Forty-one percent required additional procedures to achieve acceptable voice outcomes. The median time to failure was 163 days. At two years, the treatment failure was 30% and reached 45% by four years. The authors concluded that fat injection laryngoplasty reliably

improves the voice over the short term in certain clinical situations, but the long-term outcome is unpredictable. Surgeries to treat subsequent voice deterioration are common. The limited success may be due to the early deaths of many of the patients. The authors state that patients who may benefit from fat injections are those with a poor prognosis or those who are not good candidates for surgery (e.g., heavily irradiated neck or altered anatomy).

In a prospective study, Laccourreya et al. (1999) analyzed the results of intracordal autologous fat injection for aspiration in 20 patients with RLN paralysis. Swallowing of pureed food was documented during nasofibroscope. The injection of fat after one year resulted in 85% successful rehabilitation of swallowing. One of three patients who failed the initial rehabilitation of swallowing was managed successfully when fat was reinjected. In all the patients, speech and voice were immediately improved after injection. In patients with unilateral nerve palsy after pulmonary resection, incomplete glottic closure and non-efficient cough are at risk for developing pneumonia from aspiration which can be fatal in this patient population. The authors concluded that intracordal autologous fat injection is a safe and valuable treatment option in patients with aspiration after RLN paralysis.

**Calcium Hydroxylapatite:** Synthetic calcium hydroxylapatite (CaHA) has biocompatibility properties that create no antigenic or inflammatory responses. CaHA is formed from calcium and phosphorus ions, which are natural to human teeth and bones (Rosen, 2004). Radiesse™ and Juliesse™ (BioForm Medical, Inc., San Mateo, CA) have received 510(k) United States Food and Drug Administration (FDA) approval as Class II devices for use as resorbable implant materials placed via percutaneous injection under local anesthesia. These implants aid in surgical reconstruction as a space-occupying material in laryngeal surgical procedures for vocal cord medialization and augmentation. These are temporary implants and resorb in 3–6 months. The gel material is being used as a carrier for calcium hydroxylapatite (FDA, 2003; Kwon, et al., 2004; FDA, 2006).

**Literature Review:** In a multicenter prospective study, Rosen et al. (2007) evaluated the effectiveness of CaHA injection for patients with glottal incompetence. Voice-related outcome measures were collected for pre-injection and at one, three and six months. Sixty-eight patients were available for evaluation. Fifty percent of the injection procedures were done in the office setting. Fifty-seven percent were diagnosed with unilateral paralysis and 42% with glottal incompetence with mobile vocal folds. Patient satisfaction at six months post-procedure showed 56% had significantly improved voice, and 38% reported moderately improved voice. Information regarding the value and results of CaHA vocal fold augmentation beyond six months are presently not available but will be forthcoming with the 12- and 24-month reports from this prospective, open-label clinical trial.

Belafsky et al. (2004) prospectively evaluated 23 patients concerning indications, technique, functional outcome, and complications with CaHA. The authors concluded that initial experience with vocal fold augmentation using CaHA is promising, but long-term safety needs to be established.

In a preliminary report on vocal cord augmentation with injectable CaHA, Rosen et al. (2004) concluded that vocal fold injection of CaHA for UVCP improved voice quality and reduced mean airflow rates in this patient group with short-term results.

**Collagen:** A variety of collagen products have been used in studies such as purified bovine or biochemically cross-linked products. Collagen is used for injection laryngoplasty because it is readily available and lasts for several months to years. Injection of bovine collagen has a reported hypersensitivity incidence of 3%; therefore, skin testing is required before injection. Bovine collagen has not been approved by the FDA for intralaryngeal injection. Purified human forms of collagen (e.g., autologous collagen) have been evaluated. Clinical objections to the use of allograft material include donor site morbidity, long processing time delaying availability of implant, and high cost involved with individual graft preparation. Purified forms of human collagen from cadaveric skin have been developed. A micronized form of Alloderm tissue, Cymetra® (LifeCell Corporation, Branchburg, NJ) has been studied for injection laryngoplasty. Cymetra® has not received FDA approval for laryngeal injection due to lack of controlled clinical trials. Preliminary studies show it appears to be a safe injection material for injection laryngoplasty, but long-term results are pending. Laryngeal abscess is one complication that has been reported with Cymetra® (Flint, et al., 2005; Zapanta, et al., 2004; Courey, 2004; Pearl, et al., 2002).

**Literature Review:** Milstein et al. (2005) retrospectively reviewed the long-term results of Cymetra injection laryngoplasty in patients with vocal fold paralysis. Over a three-year period, 20 patients underwent Cymetra injection laryngoplasty. The causes of vocal cord paralysis included idiopathic, viral, intrathoracic surgery or malignancy. The range in amount of time between onset of vocal fold paralysis and time of injection was 4–216 months, with an average of 45.1 months. Follow-up after injection ranged from 1–35 months, with an average of 11.2 months. Voice quality and voice fold bowing were all improved after injection. Eight patients showed improvement for more than 12 months after injection. The authors state that further investigation is needed, but if Cymetra is found to have long-term improvement, it may become the material of choice for injection laryngoplasty. Cymetra offers the best combination of vocal benefit, biocompatibility, length of outcome, easy handling, and lack of donor-site morbidity.

The National Institute for Clinical Excellence (NICE, 2005) issued an Interventional Procedure Guidance overview of collagen injection for vocal cord augmentation. The authors stated, “Not many good-quality studies have been carried out on collagen injections into the vocal cord, but NICE considers that there is enough evidence to support use of these injections in people who need short-term relief of problems affecting the vocal cords.”

**Gelfoam®:** Gelfoam (Pharmacia and Upjohn, Kalamazoo, MI) injection is proposed as treatment for vocal fold paralysis when the recovery status of the vocal fold paralysis is unknown. The injection involves mixing gelatin powder with a buffered saline solution to form a paste that is used for a lateral vocal fold injection. This gelatin sponge is naturally degraded in the body. The injection lasts approximately 6–8 weeks, depending on the amount of saline used to make the injectate and the amount injected (Rosen, 2000).

Currently, Gelfoam is not FDA approved for the treatment of vocal cord paralysis. The FDA intended use/indications state, “Gelfoam Sterile Powder, saturated with sterile sodium chloride solution is indicated in surgical procedures including those involving cancellous bone bleeding as a hemostatic device when control of capillary, venous, and arterial bleeding by pressure, ligature and other conventional procedures is either ineffective or impractical” (FDA, 2000).

**Hyaluronic Acid:** Hyaluronan is a polysaccharide which occurs naturally in the extracellular matrix of human tissue. One commercially available product, Hylaform (hylan B gel) (Genzyme Corp., Cambridge, MA) is contraindicated for implantation into bone, tendon, ligament, or muscle per FDA safety and effectiveness data. It is currently approved for dermal augmentation (FDA, 2004).

**Silicone:** Silicone paste was introduced as a substance for injection laryngoplasty in 1965 by Rubin. Due to the availability of Teflon®, silicone paste was never widely studied (Courey, 2004). In 1991, the FDA made the use of injectable silicone illegal, but it is still used in other countries (Kwon, et al., 2004).

**Teflon®:** From the 1960s to early 1990s, Teflon® paste injection was the main treatment for dysphonia due to UVCP. Multiple long-term side effects were reported. Complications were related to over-injection, improper placement, concerns regarding migration of Teflon® particles, giant cell foreign body reaction with granuloma formation, and difficulty in revising patients with poor outcomes. Teflon® has been excluded as a treatment technique, with the exception of a few selected cases in which permanent augmentation is desired without concern for long-term side effects (O’Leary, et al., 2006; Kwon, et al., 2004; Courey, 2004).

**Literature Review:** Iseli et al. (2001) evaluated survival and functional outcomes in a group of 57 patients who underwent vocal cord medialization with Teflon™ or a modified Isshiki type I thyroplasty for UVCP secondary to malignant disease. Eighty-six percent of the patients who underwent Teflon laryngoplasty had satisfactory phonation after two months. Type I thyroplasty patients maintained 100% satisfactory voice outcomes after two months. The authors concluded that with the increasing popularity of thyroplasty, there has been a move away from Teflon injection, but Teflon injection still has a role in the treatment of neoplastic UVCP.

## Summary

The prerequisites for successful injection laryngoplasty are proper patient selection, an understanding of laryngeal anatomy and physiology, and knowledge of injection materials. Laryngeal framework surgery is

considered the gold standard for the long-term treatment of unilateral vocal cord paralysis (UVCP). Studies have concluded that in carefully selected patients, some injection materials may be beneficial for short-term treatment. Long-term clinical studies are needed to assess the safety of the materials used for injection laryngoplasty. Outcome studies that compare the injection materials are needed.

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

### Covered when medically necessary:

CPT®*	Description
31570	Laryngoscopy, indirect; with injection into vocal cord(s), therapeutic
31571	Laryngoscopy, indirect; with injection into vocal cord(s), therapeutic; with operating microscope

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
478.31	Paralysis of vocal cords or larynx, unilateral, partial
478.32	Paralysis of vocal cords or larynx, unilateral, complete

\*Current Procedural Terminology (CPT®) ©2006 American Medical Association: Chicago, IL.

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