



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Injections for Unilateral Vocal Cord Paralysis (UVCP)

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[Speech/Language Therapy](#)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

CIGNA 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 individual 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], 2009).

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 (National Institute on Deafness and Other Communication Disorders [NIDCD], 2008; AAOHNS, 2004; National Institute for Clinical Excellence [NICE], 2005).

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 (Lorenz, et al., 2007; NIDCD, 2007; Kwon, et al., 2004).

Conservative management of UVCP may include voice therapy 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. Many otolaryngologists recommend waiting six months or a year to allow for vocal fold paralysis to resolve on its own before performing corrective surgery. This interval of time is determined largely by tradition since there is almost no evidence to support this practice. The appropriate interval should be determined individually in each case, based to extent of disability, likelihood of recovery and vocal demand. 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 (Lorenz, et al., 2007; NIDCD, 2007; Flint, et al., 2005; Kwon, et al., 2004).

Injection medialization laryngoplasty techniques with a variety of resorbable and long-term or permanent injectable substances have been proposed for the treatment of transient or permanent 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 (Lorenz, et al., 2007; King and Simpson, 2007; NIDCD, 2007; Flint, et al., 2005; Kwon, et al., 2004).

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.”

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. Since fascia grafts are autologous tissue, they will become permanent after a blood supply is established. 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). A small (n=14) case series study reported a significant reduction in glottal gap and improvement in voice acoustics after autologous fascia augmentation in UVCP (Rihkanen, et al., 2004).

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).

Although there is a lack of long-term comparative outcome studies of fat injections as an implant material for vocal cord medialization and augmentation, there is sufficient evidence in the published, peer-reviewed medical literature that in carefully selected patients, fat injections may be beneficial for short-term treatment for vocal cord paralysis. 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 unilateral laryngeal nerve paralysis is 79%. (Umeno, et al., 2005; Laccourreye, et al., 2003; McCulloch, et al., 2002; Laccourreye, et al., 1999).

Calcium Hydroxylapatite: Synthetic calcium hydroxylapatite (CaHA) (e.g., Radiesse™) 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).

Although there is a lack of long-term comparative outcome studies of CaHA as an implant material for vocal cord medialization and augmentation, there is sufficient evidence in the published, peer-reviewed medical literature that in carefully selected patients, CaHA may be beneficial for short-term treatment of vocal cord paralysis. Patient satisfaction 12 months after injection reported that 67% of individuals had a significant improvement in voice and 81% at least a moderate improvement in voice (Rosen, et al., 2009; Rosen, et al., 2007; Belafasky, et al., 2004; Rosen, et al., 2004).

Radiesse™ Laryngeal Implant (BioForm Medical, Inc., San Mateo, CA) has received 510(k) United States Food and Drug Administration (FDA) approval. Radiesse FDA indications for use state that it is, “indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue hulating agent. Radiesse Laryngeal Implant injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication” (FDA, 2007).

Juliesse™ Injectible Laryngeal Augmentation Implant (BioForm Medical, Inc., San Mateo, CA) was FDA approved under the 510(k) process. This product is “indicated as a resorbable implant material to aid in surgical reconstructions as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. Juliesse is a temporary implant and resorbs within a period of 3-6 months” (FDA, 2006). The predicate device for approval is the Radiesse Voice Gel™ Injectible Laryngeal Augmentation Implant ((BioForm Medical, Inc., San Mateo, CA) (FDA, 2003).

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).

CosmoDerm[™]/CosmoPlast[™] and Zyplast[™] (Allergan-Inamed, Irvine, CA) are human collagens that have been proposed for treatment of vocal cord paralysis (King and Simpson, 2007). These materials are not FDA-approved for laryngeal injection for vocal cord paralysis (FDA, 2006).

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 that, “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. Commercially available products that have been proposed as a treatment for vocal cord paralysis include Hylaform[®] (hylan B gel) (Genzyme Corp., Cambridge, MA); Juvederm[™] (Inamed Corp., Santa Barbara, CA) and Restylane[®] Injectable gel (Medicis Aesthetics, Scottsdale, AZ). Currently, none of these products are FDA-approved for the treatment of vocal cord paralysis.

Hylaform (hylan B gel) is contraindicated for implantation into bone, tendon, ligament, or muscle per FDA safety and effectiveness data. It is currently indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) (FDA, 2004).

The FDA intended use/indications state that Juvederm 30, Juvederm 24HV and Juvederm 30HV are injectable gels indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds) (FDA, 2006).

The FDA intended use/indications state that Restylane injectable gel is indicated for mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds (FDA, 2003).

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. The FDA does not address approval of Teflon as a laryngeal injection agent (O’Leary, et al., 2006; Kwon, et al., 2004; Courey, 2004).

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.

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).

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). Although the published evidence supporting the role of injection materials for the treatment of unilateral vocal cord paralysis is not robust, limited data from small studies as well as acceptance and use of some of these materials by certain specialists in the practicing community indicates that these products may improve outcomes in a carefully selected subset of patients. 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.

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

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®) © 2008 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	11/15/2007	0426	Injections for Unilateral Vocal Cord Paralysis (UVCP)

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