APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

Clinical Coverage Guideline

Original Effective Date: 8/1/2013 - Revised: 11/7/2013, 11/6/2014, 11/5/2015
TRANSCUTANEOUS INJECTION LARYNGOPLASTY
HS-212

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. Note: Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com – select the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

Transcutaneous injection laryngoplasty is an office-based procedure that allows immediate reduction of symptoms. The procedure requires only local anesthesia with no need for an intravenous line or monitoring of vital signs. Two people are required to perform the procedure. An assistant passes the nasopharyngoscope through the patient's nasal passage and suspends it above the larynx so that the surgeon can view the inside of the throat. The surgeon then passes a needle connected to a syringe filled with augmentation material transcutaneously into the vocal fold. Injectate is then deposited into the vocal fold. (MedScape, 2013).

Vocal fold injection (VFI) has recently re-emerged as a valuable treatment for laryngeal disorders. Advances in injection materials have broadened the indications for this technique, while the increasing capabilities of endoscopic technology have increased the number of available approaches and precision of injection delivery. Basic indications for VFI include vocal fold paralysis, paresis, atrophy, and scar or sulcus. VFI includes procedures that target the superficial (subepithelial space) aspect of the vocal fold. The procedure involves injection of a substance as a lamina propria replacement. Useful for mild-to-moderate vocal fold scar and lamina propria defects, superficial injection provides correction of vibratory defects rather than global augmentation. VFI refers to deep or lateral injection, as a means for vocal fold augmentation. Deep injection allows for placement of a filler substance in the lateral aspect of the thyroarytenoid/lateral cricoarytenoid muscle complex (medial aspect of the paraglottic space). The result is a medially displaced free edge of the vocal fold, akin to laryngeal framework surgery, or type I thyroplasty. The procedure allows for correction of glottal insufficiency from a variety of causes, and is typically used to treat temporary or permanent mild-to-moderate glottal insufficiency (<1 to 3 mm glottal gaps). For the purposes of this review, VFI will refer to this latter method of deep vocal fold injection augmentation. (Mallur & Rosen, 2010).

Temporary vocal fold injection is currently the treatment of choice for the treatment of glottic incompetence when prognosis for recovery is unclear. This is best illustrated in the case of acute unilateral vocal fold paralysis or paresis. During the time for potential recovery of function, usually up to 6-months post-onset, vocal fold injection with a shorter duration substance has been shown to alleviate voice symptoms and improve swallowing until function recovers or the patient is a candidate for a more permanent treatment option. In this setting, injection with collagen, HA, or Radiesse Voice Gel provides the best treatment option (Anderson & Mirza, 2001; Kwon, Rosen & Gartner-Schmidt, 2005; Mallur & Rosen, 2010; Remacle & Lawson, 2007).

Vocal fold injection may also be used to treat permanent causes of mild-to-moderate glottic insufficiency. Specifically, this has been successfully used to treat vocal fold atrophy, paralysis, paresis, and augmentation after previous framework surgery. Specifically, results with calcium hydroxylapatite (Belafsky & Postma, 2004; Sulica & et al., 2010) and autologous fat injections (Hartl & et al., 2009) have proven acceptable in the treatment of atrophy, paralysis, and paresis. Though some have reported inconsistent results with fat when compared to type I thyroplasty in cases of unilateral vocal fold paralysis many may find better results with the ability to "fine tune" serial injections for progressive vocal fold atrophy and presbylarynx. Additionally, results are promising for those requiring injection augmentation for recalcitrant glottic insufficiency after type I thyroplasty with or without arytenoid adduction (Umemo & et al., 2008).

Materials for Injection

Materials for deep augmentation injection are typically described as temporary, and permanent/long lasting. Long lasting, and sometimes, permanent injectable materials include autologous fat, calcium hydroxylapatite, and autologous fat injections (Hartl & et al., 2009).
(Radiesse™), polydimethylsiloxane (PDMS or particulate silicone), and historically, and polytetrafluoroethylene (PTFE or Teflon™). Temporary injection materials include bovine gelatin (Gelfoam™, Surgifoam™), collagen-based products (Cymetra™, Zyplast™, Cosmoplast/Cosmoderm™), hyaluronic acid (Restylane™, Hylaform™), and carboxymethylcellulose (Radiesse Voice Gel™). The materials vary in the duration of integration and are thought to vary in their specific viscoelastic properties and biocompatibility. (Mallur & Rosen, 2010).

**POSITION STATEMENT**

**Applicable To:**
- Medicaid
- Medicare

**Exclusions**

The following are not considered a covered benefit:
- Injections of bulking agents into the vocal cords for indications other than listed above;
- Materials that have not received FDA approval (list may not be inclusive): Juviderm, Hylaform, Restylane, Cymetra, Captique, methylcellulose injections, Sculptra, Teflon and/or collagen products such as CosmoDerm/ Zyplast/Zyderm

**Coverage**

Use of injection materials (e.g., Radiesse Voice, Radiesse Voice Gel, steroids or autologous fat) in the office setting are considered medically necessary and a covered benefit when the following criteria are met:

1. Vocal fold paralysis resulting from:
   - Prior neck or chest surgery that damaged the vagus or recurrent laryngeal nerve
   - Complications from endotracheal intubation
   - Tumor invasion causing nerve damage
   - Blunt trauma to the neck or chest
   - Viral/inflammatory processes or
   - Degenerative neural disorders

OR,

2. Vocal cord paresis; OR,
3. Vocal fold scarring; OR,
4. Presbylaryngitis (age-related loosening of the vocal cords aka vocal cord atrophy); OR,
5. Parkinson’s disease

The following should be considered for office-setting procedures:
- Patients with a strong gag reflex
- Avoidance of general anesthesia in patients with significant comorbidities
- Symptoms that do not merit the risk of general anesthetic
- Treatment trials in situations of uncertain benefit and when the diagnosis is uncertain

**CODING**

**Covered CPT®* Codes**

- 31513 Laryngoscopy, indirect; with vocal cord injection
- 31570 Laryngoscopy, direct, with injection into vocal cord(s); therapeutic
- 31571 Laryngoscopy, direct, with injection into vocal cord(s); with operating microscope or telescope

**Covered HCPCS®* Codes**

- C1878 Material for vocal cord medialization, synthetic (implantable)
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C9742  Laryngoscopy, flexible fiberoptic, with injection into vocal cord(s), therapeutic, including diagnostic laryngoscopy, if performed
Q2026  Injection, Radiesse, 0.1 ml

Non-Covered HCPCS® Codes
Q4112  Cymetra, injectable, 1 cc

Covered ICD-9-CM Diagnosis Codes
332.0 - 332.1  Parkinson’s disease
478.30 - 478.34  Paralysis of vocal cords or larynx
478.40 – 478.6  Polyp of vocal cords or larynx
478.70 - 478.79  Other diseases of larynx, not elsewhere classified
646.80 – 646.84  Other specified complications of pregnancy
668.81 – 668.84  Other complications of anesthesia or other sedation in labor and delivery
909.3  Late effect of complications of surgical and medical care
999.9  Other and unspecified complications of medical care, not elsewhere classified
V58.89  Other specified aftercare

Covered 2015 ICD-10-CM Diagnosis Codes
G20  Parkinson’s disease
G21.11-G21.9  Other drug-induced secondary parkinsonism
J38.00-J38.7  Diseases of vocal cords and larynx, not elsewhere classified
O29.60 – O29.63  Failed or difficult intubation for anesthesia during pregnancy
O74.7  Failed or difficult intubation for anesthesia during labor and delivery
O89.6  Failed or difficult intubation for anesthesia during the puerperium
T88.4XXA-T88.4XXS  Failed or difficult intubation


REFERENCES

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date  Action
11/5/2015  Approved by MPC. Coding updates only.
11/6/2014  Approved by MPC. No changes.
11/7/2013  Approved by MPC. Added references of specialty organizations/colleges via Hayes.
8/1/2013  Approved by MPC. New.