I. POLICY

It is the policy of MedStar Health, Inc. to cover Office-based Laryngeal Injections for Vocal Cord Augmentation when it is medically necessary as detailed in this policy and covered under the member's specific benefit plan.

II. DEFINITIONS

Videostroboscopy: using specialized cameras, stroboscopic light slows down the speed of vibrations of the vocal folds so they can be easily visualized and interpreted.

III. PURPOSE

The purpose of this policy is to outline the indications for coverage of Laryngeal Injections for Vocal Cord Augmentation.

IV. SCOPE

This policy applies to various MedStar Health, Inc. departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to: Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description / Background
Glottal incompetence and vocal cord/fold insufficiency can cause a disruption in voice production. This can be characterized by a weak, breathy voice and vocal fatigue caused by loss of air through the vocal cords that are not positioned properly. Other common symptoms include a weak cough, shortness of breath and dysphagia (difficulty swallowing). This incompetence/insufficiency can also affect swallowing and coughing abilities which may be dramatically compromised leading to inability to control secretions or fluids resulting in aspiration or aspiration pneumonia.

An evaluation for these symptoms by an otolaryngologist or head/neck surgeon would include:

- Medical history including onset and severity of symptoms
- Voice handicap index questionnaire
- Laryngeal examination including videoendoscopy with videostroboscopy
- Transnasal fiberoptic laryngoscopy
- Baseline voice laboratory studies and/or
- Laryngeal electromyelography if applicable (can provide definitive diagnostic information and vital prognostic information in some cases)

Treatment of glottal incompetence/vocal cord insufficiency depends on the patient’s symptoms and severity and consists of any of the following:

- Voice therapy (a short term option)
- Surgical procedures such as laryngeal framework surgery aimed at repositioning the paralyzed cord to a more medial position
- Food and Drug Administration (FDA) approved injectable bulking agents or autologous fat injections for vocal cord augmentation. The injected material moves the affected vocal cord into a more medial position to allow for structural vibrations.

There are now multiple techniques (i.e. percutaneously, transorally, transthyrohyoid, transcricothyroid), improved endoscopic equipment and multiple injectable substances available for vocal cord injection. Complications of injection augmentation may result in permanent hoarseness, airway obstruction, aspiration, airway hemorrhage or injury to perilaryngeal structures and, therefore, visualization of the larynx and injection placement are of utmost importance.

Trial augmentation, typically performed with a short-lived injectable, can often be used as a diagnostic trial in cases of vocal cord scar, vocal cord atrophy or suspected vocal cord paresis. If the effect of the injection is satisfactory, then the procedure can be performed later for definitive treatment.

Radiesse Voice and Radiesse Voice Gel laryngeal implant are FDA approved for vocal cord medialization and vocal fold/cord insufficiency. These materials augment
the size of the displaced or deformed vocal fold so it may meet the opposing fold at the midline for improved phonation.

A form of AlloDerm called Cymetra (LifeCell Corporation) has also been used for injection laryngoplasty. It is processed from human tissue obtained from tissue banks and therefore it falls under the broader FDA guidelines for banked human tissue.

Autologous fat injections have been used as a bulking agent as they have similar properties to that of vocal cord tissue and may be beneficial for short-term treatment for vocal cord paralysis, paresis, scar and atrophy.

Vocal cord augmentation can be administered in an office or outpatient setting. Injection in the office setting is minimally invasive and performed under local or topical anesthesia without sedation and has become a new trend due to the availability of a variety of injectable materials adapted for laryngeal use and with the introduction of distal video-chip laryngoscopy which enables greater visualization of the larynx.

**B. Indications**

Coverage of Radiesse Voice, Radiesse Voice Gel, Cymetra, steroids or autologous fat injection augmentation for glottal/vocal cord insufficiency includes any of the following:

- Vocal fold paralysis resulting from but not limited to:
  - 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
- Vocal cord paresis
- Vocal fold scarring
- Presbylaryngitis (age-related loosening of the vocal cords aka vocal cord atrophy) or
- Parkinson’s disease

**AND**

Indications for office setting augmentation include all of the following:

- Cooperative 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

Note: The setting for the procedure is usually based on the general indication, patient safety and individual surgeon preference.

C. Limitations/Exclusions include the following:
• Injections of bulking agents into the vocal cords for indications other than listed above
• Non FDA approved laryngeal implant materials such as: Juvederm, Hylaform, Restylane, Captique, methylcellulose injections, Sculptra, Teflon and/or collagen products such as CosmoDerm/Zyplast/Zyderm
• See policy RX.PA.025.PH regarding botulinum toxin for adductor laryngeal dystonia

D. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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E. Variations

N/A

F. Quality Audit

Quality Audit monitors policy compliance and/or billing accuracy at the request of the MedStar Health, Inc.’s Assessment Committee or the Benefits Reimbursement Committee.

G. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health, Inc. Policy and Procedure for Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten (10) years from the date of recording.

H. References

Medical Literature/Clinical Information:

1. ECRI Institute: Product Brief: Radiesse Voice and Voice Gel (BioForm Medical Inc.) for Vocal Cord Augmentation. Published 03/15/2011. [Link]

Regulatory/Government Source:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077277.htm

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