MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

Policy Number: MP.112.MH Last Review Date: 02/04/2016 Effective Date: 03/01/2016 Renewal Date: 02/01/2017

MP.112.MH – Office-based Laryngeal Injections for Vocal Cord Augmentation

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar MA DSNP CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers office-based Laryngeal Injections for Vocal Cord Augmentation medically necessary for the following 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:

- a) Vocal fold paralysis resulting from but not limited to:
 - Prior neck or chest surgery that damaged the vagus or recurrent laryngeal nerve
 - Lung or thyroid cancer
 - Complications from endotracheal intubation
 - Tumors of the skull base, neck, or chest
 - Blunt trauma to the neck or chest
 - Infections (ie Lyme disease)
 - Stroke
 - Neurological conditions (ie Multiple Sclerosis, Parkinson's Disease)
- b) Vocal cord paresis;
- c) Vocal fold scarring;
- d) Presbylaryngitis (age-related loosening of the vocal cords aka vocal cord atrophy); or
- e) Parkinson's disease

Indications for office setting augmentation include all of the following:

- a) Cooperative patients with a strong gag reflex;
- b) Avoidance of general anesthesia in patients with significant comorbidities:
- c) Symptoms that do not merit the risk of general anesthetic;
- d) Treatment trials in situations of uncertain benefit and when the diagnosis is uncertain



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

Limitations

 Injections of bulking agents into the vocal cords for indications other than listed above and non-FDA approved laryngeal implant materials such as, but not limited to: Juviderm, Hylaform, Restylane, Captique, methylcellulose injections, Sculptra, Teflon and/or collagen products such as CosmoDerm/Zyplast/Zyderm

Background

The left and right vocal fords of the larynx muscle move away or towards one another in order to open and close the glottis. Glottal incompetence is the inability of the vocal folds to close the glottis adequately, resulting in vocal abnormalities, shortness of breath while talking, and an inability to produce an adequate cough.

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 10 item scale (VHI-10)
- Digital videostroboscopic laryngeal examination
- Transnasal flexible 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
- Surgery if therapy is inadequate
- Food and Drug Administration (FDA) approved injectable bulking agents into the affect vocal fold to augment medialize the folds

Radiesse Voice and Radiesse Voice Gel laryngeal implant are FDA approved for vocal cord medialization and vocal fold/cord insufficiency. Radiesse is an injectable calcium hydroxylapatite (CaHA) implant with a smoothing effect lasting about six months.



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Codes:

Codes.	
CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
CPT codes	
<i>31</i> 513	Laryngoscopy, indirect; with vocal cord injection
31570	Laryngoscopy, direct, with injection into vocal cords(s), therapeutic
31571	Laryngoscopy, direct with injection into vocal cords(s) therapeutic with operating microscope or telescope
31599	Unlisted Procedure of larynx
C9742	Laryngoscopy, flexible fiberoptic, with injection into vocal cord(s), therapeutic, including diagnostic laryngoscopy, if performed
ICD-9 codes of	covered if selection criteria are met:
478.31	Paralysis of vocal cords or larynx, unilateral, partial
478.32	Paralysis of vocal cords or larynx, unilateral, complete
478.33	Paralysis of vocal cords or larynx, bilateral, partial
478.34	Paralysis of vocal cords or larynx, bilateral, complete
478.75	Laryngeal spasm
784.42	Dysphonia
ICD-10 codes	covered if selection criteria are met:
J38.01	Paralysis of vocal cords and larynx, unilateral
J38.02	Paralysis of vocal cords and larynx, bilateral
J38.5	Laryngeal spasm
R49.0	Dysphonia

References

- 1. Hayes Health Technology Brief. Radiesse Voice Injectable Implant (Merz Aesthetics Inc.) for Treatment of Glottic Insufficiency Including Vocal Cord Paralysis). Annual Review October 15, 2015.
- 2. Mallur P, Rosen CA. Vocal fold injection: review of indications, techniques, and materials for augmentation. Clin Exp Otorhinolaryngol. 2010 Dec; 3(4): 177-182. doi: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3010535/



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- 3. National Institute on Deafness and Other Communication Disorders (NIDCD). Vocal Fold Paralysis. Updated October 2011. http://www.nidcd.nih.gov/health/voice/pages/vocalparal.aspx
- 4. Sulica L, Rosen CA, Postma GN, et al. Current practice in injection augmentation of the vocal cords: indications, treatment principles, techniques, and complications, Laryngoscope. 2010 Feb; 120(2): 319-325. doi: 10.1002/lary.20737 http://www.ncbi.nlm.nih.gov/pubmed/19998419
- Rosen CA., Performing Radiesse™ Trans-Oral Vocal Cord Fold Augmentation InjectionVia Flexible Nasopharyngoscopic Guidance "Drip Laryngeal Anesthesia" – Tips and Pearls. White Paper on Injection Techniques. [Personal Communication]. http://www.radiesse-voice.com/docs/ML00113.pdf
- U.S. Food and Drug Administration (FDA). Radiesse Laryngeal Implant Approval. P050052. Dated: December 22, 2006. Last Updated: 09/05/2013 http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077277.htm

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