

## Bulking Agents for Vocal Cord Insufficiency

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<u>Effective Date</u>	1/2011
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<u>Coverage Policy</u>	Medical 153
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**All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual [\\*](#).**

### Purpose:

This policy addresses the medical necessity of Bulking Agents for Vocal Cord Insufficiency

### Description & Definitions:

Bulking agents are substances in the form of a gel like product used to fill in gaps for indications of vocal cord paralysis, weak vocal cords or other vocal insufficiencies.

Bulking agents for Vocal cord insufficiency include the harvesting and injection of autologous fat.

Bulking agents for Unilateral vocal cord paralysis (UVCP) include the use of FDA approve vocal cord implants.

Types of bulking agents may include, but are not limited to:

- Calcium hydroxylapatite (e.g., Radiesse™ Voice, Prolaryn™ Plus)
- Collagen
- Cymetra (micronized AlloDerm tissue)
- Restylane (cross-linked hyaluronic acid)
- Prolaryn and Prolaryn Plus (formerly the Radiesse Laryngeal Implant).

### Criteria:

Bulking Agents for Vocal Cord Insufficiency are considered medically necessary for individuals with **1 or more of the following**:

- Vocal cord insufficiency
- Glottis insufficiency resulting from 1 of the following:
  - Unilateral vocal cord paralysis (UVCP)

- Vocal fold paralysis
- Vocal fold paresis
- Vocal fold atrophy
- Vocal fold scar
- Vocal fold sulcus vocalis
- Vocal fold bowing
- Presbylaryngis
- Abductor muscle spasmodic dysphonia
- Parkinson's disease

Bulking Agents for Vocal Cord Insufficiency is considered **not medically necessary** for any use other than those indicated in clinical criteria.

### Coding:

Medically necessary with criteria:

Coding	Description
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), therapeutic; with operating microscope or telescope
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral
L8607	Injectable bulking agent for vocal cord medialization, 0.1 ml, includes shipping and necessary supplies
Q2026	Injection, Radiesse, 0.1 ml
Q4112	Cymetra, injectable, 1 cc

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

### Document History:

Revised Dates:

- 2021: December
- 2019: November
- 2016: March
- 2014: February, July
- 2013: July
- 2011: September

Reviewed Dates:

- 2023: September
- 2022: September
- 2020: December
- 2019: December
- 2018: June
- 2016: July
- 2015: July
- 2012: August

Effective Date:

- January 2011

## References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2023). Retrieved Aug 16, 2023, from MCG 26th Edition: <https://careweb.careguidelines.com/ed26/index.html>

(2023). Retrieved Aug 16, 2023, from CMS: <https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=bulking+agent+for+vocal+cord&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all>

(2023). Retrieved Aug 16, 2023, from American Academy of Otolaryngology—Head and Neck Surgery AAO-HNS: <https://www.entnet.org/?s=glottic+insufficiency&site=>

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Procedure Fee Files & CPT Codes. (2023). Retrieved Aug 16, 2023, from Department of Medical Assistance Services: <https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/> & <https://www.dmas.virginia.gov/for-providers/cardinal-care-transition/>

Radiesse Voice Injectable Implant (Merz Aesthetics Inc.) For Treatment of Glottic Insufficiency Including Vocal Cord Paralysis. (n.d.). Retrieved Aug 16, 2023, from Hayes: <https://evidence.hayesinc.com/report/htb.radiesse1294>

SILK VOICE. (2023). Retrieved Aug 16, 2023, from SOFREGEN: <https://www.sofregen.com/silk-voice>

## Special Notes: \*

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice.

Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to “correct or ameliorate” (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

### Keywords:

SHP Bulking Agents for Vocal Cord Insufficiency, Radiess voice gel injection, shp medical 153, vocal cord, Glottis insufficiency, vocal cord fold, vocal fold injection, VFI, VFI bulking agents, Injection laryngoplasty, Voice Injectable Implant, vocal cord augmentation, Injection Augmentation