MEDICAL POLICY

Medical Policy Title	**Injectable Fillers for Dermal and Laryngeal Conditions**
Policy Number	**7.01.119**
Current Effective Date	**September 17, 2026**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Dermal injectable fillers approved by the U.S. Food and Drug Administration (FDA) for facial HIV-associated lipoatrophy (i.e., poly-L-lactic acid [Sculptra], calcium hydroxylapatite [Radiesse]) are considered **medically appropriate** for the treatment of documented facial lipodystrophy syndrome (LDS) due to antiretroviral therapy in HIV-infected patients.

II. Laryngeal injections using calcium hydroxylapatite (e.g., Prolaryn Plus, formerly Radiesse Voice) or autologous fat is considered **medically appropriate** for vocal fold medialization and augmentation in the management of glottic insufficiency, including when due to vocal fold paralysis or paresis.

III. Interarytenoid injection augmentation with calcium hydroxylapatite (e.g., Prolaryn Plus, formerly Radiesse Voice) is considered **medically appropriate** for the management of type 1 laryngeal cleft when there has been a failed 3-month trial of conservative therapy (e.g., feeding therapy).

IV. Injectable filler or bulking material other than those specified above is considered **not medically necessary** for any other dermal or laryngeal indication.

RELATED POLICIES

7.01.11 Cosmetic and Reconstructive Procedures

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Injectable soft tissue fillers are medical agents used to restore tissue volume for both cosmetic enhancement and therapeutic reconstruction. Administered via injection or implantation into the dermis, subcutaneous tissue, or other soft tissue planes, these fillers address volume loss caused by aging, trauma, congenital defects, or lipoatrophy. While commonly applied in facial aesthetics, certain injectable fillers are also utilized for reconstructive and functional indications.

Some fillers, such as injectable collagen and hyaluronic acid, primarily function by directly filling volume-deficient areas. Others, including calcium hydroxylapatite (CaHA) (e.g., Radiesse and Prolaryn

Plus) and poly-L-lactic acid (PLLA) (e.g., Sculptra), serve as scaffolds that stimulate the body's natural collagen production, offering longer-term structural support. CaHA also provides immediate volume replacement, whereas PLLA acts primarily through gradual collagen stimulation.

Injectable fillers are generally categorized into three main types:

- Biodegradable fillers are temporary agents that are gradually reabsorbed by the body. Examples include hyaluronic acid, collagen, calcium hydroxylapatite, and poly-L-lactic acid (PLLA).
- Permanent fillersare substances that remain in the tissue indefinitely. Common examples include polymethylmethacrylate (PMMA) microspheres, hydrogel polymers, and silicone.
- Autologous fat grafting is a technique that involves harvesting the patient's own viable fat tissue, which is then processed and reinjected to restore volume.

Facial Lipodystrophy Syndrome (LDS)

HIV-associated lipodystrophy is a complication of antiretroviral therapy (ART), characterized by abnormal redistribution of body fat. Facial lipoatrophy is often characterized by the loss of buccal and temporal fat pads, resulting in sunken cheeks, hollowing around the eyes, and visible facial musculature. This condition can have an impact on the physical appearance and psychological well-being of affected individuals. For those experiencing facial lipoatrophy, injectable gel fillers are a treatment option.

Laryngeal Cleft

Laryngeal cleft is a rare congenital anomaly of the larynx, characterized by an abnormal connection between the laryngotracheal complex and the esophagus. Clefts are classified according to the depth and extent of tissue involvement. Type 1 laryngeal cleft (LC1) involves incomplete formation of the supraglottic interarytenoid musculature, without extension into the cricoid cartilage, and does not extend inferiorly beyond the level of the true vocal cords. Initial conservative treatment includes thickening of liquids, feeding adjustments and reflux medication. Surgical interventions include endoscopic surgery or injection laryngoplasty (IL), which is a less invasive alternative to endoscopic surgery. A variety of injectable materials are available, offering therapeutic effects lasting from 6 weeks to 2 years. Injection is generally not the primary treatment for other types of laryngeal cleft, which are more severe, extending into the cricoid cartilage and trachea.

Vocal Cord Paralysis

Vocal fold mobility disorders refer to conditions characterized by reduced movement of one (unilateral) or both (bilateral) vocal cords. These disorders are commonly described as vocal cord insufficiency, also known as glottic insufficiency. Related terms include vocal fold paresis, paralysis, and weakness. Vocal cord insufficiency involves incomplete closure of the vocal cords. Vocal cord paralysis can be unilateral or bilateral. In adults, unilateral paralysis often results in hoarseness and a weak, breathy voice, sometimes accompanied by aspiration. In children, it may also present with varying degrees of inspiratory stridor. Bilateral vocal cord paralysis is typically associated with inspiratory stridor, shortness of breath, and exertional dyspnea. Among the causes of bilateral vocal cord paralysis, iatrogenic surgical injury, including thyroidectomy, is the most common.

Injection laryngoplasty, also known as injection augmentation, has been proposed as a less invasive alternative to traditional surgical medialization laryngoplasty, which involves the insertion of a permanent synthetic implant lateral to the vocal fold. This minimally invasive procedure aims to treat glottic insufficiency by increasing the volume or bulk of the vocal fold to improve closure during phonation. Injectable materials range from temporary agents lasting weeks to months to long-lasting materials such as calcium hydroxylapatite, autologous fat, and polydimethylsiloxane.

SUPPORTIVE LITERATURE

Facial Lipodystrophy Syndrome

The use of PLLA (Sculptra) and calcium hydroxylapatite (Radiesse) for HIV-associated facial lipoatrophy have been supported by several trials and observational studies that have demonstrated improvement in patient appearance and cutaneous thickness as well as overall safety (Silvers 2006; Bassichis 2012; Jagdeo 2015; Vallejo 2018; Guida 2024; Glesby 2024).

Laryngeal Cleft – Type 1

The efficacy of injection laryngoplasty (IL) for the treatment of type 1 laryngeal cleft has been reported in multiple studies (Mangat 2012; Jefferson 2015; Yeung 2017; Cole 2018; Reddy 2020; Isaac 2020; Timashpolsky 2021; Stack 2023). Given the rarity of the condition, most of the evidence comes from retrospective case series, cohort studies, and expert opinion, rather than randomized controlled trials (RCTs).

Reddy et al (2020) conducted a systematic review and meta-analysis of 24 studies (n=713 patients) to evaluate outcomes of injection laryngoplasty (IL) and endoscopic surgical repair for the treatment of type 1 laryngeal clefts (LC1). Eight studies detailed the use of IL as the primary treatment in 268 children. Overall, 38% of patients received IL as primary therapy. Prior to injection, 91% of patients aspirated on swallow evaluations, and 62% aspirated post-injection. At an average follow-up time of 6.8 months, 90% of parents reported symptom improvement. An additional 54% of patients underwent endoscopic surgical repair as primary treatment. The rate of aspiration decreased from 73% to 28% after repair. At a mean follow-up of 14.2 months, 80% reported symptom improvement. Although there are limitations to this study, the authors concluded that both IL and endoscopic surgery are efficacious treatments. The authors noted that the recurrence rate associated with IL and the subsequent need for re-injection or endoscopic surgical repair is an important factor in a physician's decision to use one treatment over the other.

Stack et al (2023) conducted a single-institution retrospective chart review of children under the age of 5 years presenting for aspiration, dysphagia, or choking. Over a period of 7 years (January 2014–October 2021), 39 met inclusion criteria and had sufficient follow-up data. Descriptive statistics and subgroup analyses were performed. Of the 39 included patients, 76.92% had clinical improvement post-injection, with the mean time to follow-up being 47 days. Thirteen patients had both pre- and post-injection video fluoroscopic swallow study (VFSS). Of these, 10/13 (76.92%) had improvement in liquid consistency safely swallowed ($p = <.0001$). There were no adverse events. Study design, small sample sizes and lack of VFSS data limit the results of this study; however, the authors concluded that interarytenoid injection augmentation is an effective and safe treatment for pediatric

feeding disorders. Further investigations are needed to explore predictors of success with IIA in this population.

Vocal Cord Paralysis

The American Laryngological Association (ALA) curriculum module was published in 2019 as an educational resource rather than a formally graded clinical practice guideline on vocal fold injection augmentation. Indications for the procedure include glottal insufficiency due to unilateral vocal fold paralysis or paresis, vocal fold atrophy, vocal fold scar, sulcus vocalis, or loss of the soft tissue of the vocal folds. Materials are broadly classified as temporary and long-lasting. Temporary materials last weeks to months. Long-lasting materials last from 1 year to "forever".

- Long-lasting injection materials include: autologous fat, calcium hydroxylapatite (Prolaryn), polydimethylsiloxane (PDMS or particulate silicone).
- Temporary materials include: bovine gelatin (Gelfoam), collagen-based products (Zyplast), micronized acellular dermal matrix (Cymetra), hyaluronic acid (Restylane, Perlane, Juvederm), and carboxymethylcellulose (Prolaryn Gel).

Balouch et al (2023) conducted a retrospective study of 172 subjects undergoing type I thyroplasty (n=100) or autologous lipoinjection medialization (n=72) for glottic insufficiency. Need for further medialization did not differ significantly between groups (34.00% vs 32.39%, P=0.870), and Voice handicap index (VHI-10) scores (available for 54 subjects) did not differ pre- or post-operatively. Implant migration or extrusion occurred significantly more often with thyroplasty (22.00% vs 5.56%, P=0.003), as did postoperative vocal fold hemorrhage (14.00% vs 2.78%, P=0.015). Explant was required in 14.00% of thyroplasty subjects versus one (1.39%) lipoinjection subject (P=0.005). The authors concluded that both techniques provide effective medialization with similar reoperation rates, and that benefit appears to last at least 1 year for most patients.

Campagnolo et al (2023) conducted a systematic review of 13 studies (472 adult patients) who underwent autologous fat injection laryngoplasty for glottic insufficiency due to paralysis, atrophy, scarring, or sulcus, with voice assessed preoperatively and at least 1 year later. Considerable heterogeneity was found in fat harvest, processing, injection site, and acoustic analysis. Studies measuring maximum phonation time (MPT) showed significant improvement at ≥1 year, and Voice Handicap Index scores improved significantly in several studies. The authors concluded fat injection is a viable technique but that no standard protocol exists, and further standardized studies with long-term follow-up are needed to determine whether the effect is long-term or permanent.

Henriques et al (2023) conducted a systematic review and meta-analysis of 12 studies evaluating hyaluronic acid (HA) and CaHA injection laryngoplasty in adults with glottic incompetence. Improvements in maximum phonation time, Voice Handicap Index (VHI), and GRBAS measures were reported at 4 to 6 weeks and 6 months following treatment. Evidence certainty for the primary outcome was moderate at 1 month due to heterogeneity and high at 6 months. Limitations included small studies, small sample sizes, heterogeneity across outcomes, and limited direct comparative evidence between injectable materials. The authors concluded that both HA and CaHA were effective for glottic incompetence; however, evidence was insufficient to establish superiority of one injectable material over another, and additional comparative studies are needed.

Safia et al (2024) conducted a meta-analysis and meta-regression of 82 studies (through February 2024), predominantly retrospective cohorts (42.5%), prospective cohorts (32.5%), and case series (20%), with most outcomes assessed at 12 months. Injection materials included autologous fat (30.49%), hyaluronic acid (26.83%), calcium hydroxylapatite (9.76%), and collagen (7.32%). Significant post-injection improvements were found in MPT and harmonics-to-noise ratio; polydimethylsiloxane (PDMS) and autologous fat significantly improved MPT and reduced grade of dysphonia and roughness, respectively. Limitations include variable follow-up length and small sample sizes for certain outcomes. Findings are limited to the adult population.

PROFESSIONAL GUIDELINE(S)

Laryngeal Cleft – Type 1

The International Pediatric Otolaryngology Group developed consensus guidelines on the diagnosis and management of type 1 laryngeal clefts (Yeung 2017). Forty percent of members (8/20) will conduct a trial of filler augmentation, while 60% (12/20) would proceed to definitive repair.

- The benefits of interarytenoid filler injections include its reversibility, short procedure time, and evaluation of the potential effect of a definitive repair.
- The potential risks of injection include filler migration into the subglottis, untoward fibrotic scarring of the injected regions, and need for repeat procedure.
- Conservative management strategies include the control of concomitant laryngopharyngeal reflux as well as feeding therapy and thickening of the diet. All group members consider feeding therapy to be appropriate initial management, with a treatment range of 3- to 12-months.
- The choice of filler agent was largely surgeon dependent. Several options include calcium hydroxyapatite (20% of members), carboxymethylcellulose (13% of members), hyaluronic acid (13% of members), absorbable gelatin sponge (Gelfoam) (6% of members), and autologous fat (13% of members).

Vocal Cord Paralysis

In 2018 the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) issued an updated clinical practice guideline for hoarseness (dysphonia) (Stachler 2018). Those with more severe variants of dysphonia (e.g., unilateral vocal fold paralysis) have substantially worse quality of life and more productivity losses. The AAO-HNS recommends:

- Clinicians should advocate for surgery as a therapeutic option for patients with dysphonia with conditions amenable to surgical intervention, such as suspected malignancy, symptomatic benign vocal fold lesions that do not respond to conservative management, or glottic insufficiency (Grade B).
- Vocal fold medialization can be achieved with temporizing injection of bulking agents into the affected vocal fold (injection medialization) or external medialization with open surgery (laryngeal framework surgery). The use of polytetrafluoroethylene as a permanent injectable implant is not recommended due to its association with foreign body granulomas that can result in voice deterioration and airway compromise.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates dermal fillers as Class III medical devices. All dermal fillers require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Aug 6]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls [accessed 2026 Aug 6]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	; 1.1 to 5.0 cc
11952	; 5.1 to 10.0 cc
11954	; over 10.0 cc
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
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
31573	Laryngoscopy, flexible; with therapeutic injection(s) (e.g., chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral

Code	Description
31574	Laryngoscopy, flexible; with injection(s) for augmentation (e.g., percutaneous, transoral), unilateral

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HCPCS Codes

Code	Description
C1878	Material for vocal cord medialization, synthetic (implantable)
G0429	Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)
L8607	Injectable bulking agent for vocal cord medialization, 0.1 ml, includes shipping and necessary supplies
Q2026	Injection, Radiesse, 0.1 ml
Q2028	Injection, Sculptra, 0.5 mg
Q4112 (NMN)	Cymetra, injectable, 1 cc

ICD10 Codes

Code	Description
Multiple Codes	

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Vocal Cord Paralysis

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (NCD 250.5) [accessed 2026 Aug 6]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

09/18/25, 09/17/26	
Date	**Summary of Changes**
09/17/26	• Annual review, policy intent unchanged.
09/18/25	• New policy created for interarytenoid augmentation criteria and to include criteria from CMP #7.01.11 Cosmetic and Reconstructive Procedures.
09/18/25	• Original effective date