MEDICAL POLICY

Medical Policy Title	**Injectable Fillers for Dermal and Laryngeal Conditions**
Policy Number	**7.01.119**
Current Effective Date	**September 18, 2025**
Next Review Date	**September 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

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

II. Laryngeal injection with calcium hydroxylapatite (e.g., Prolaryn and Radiesse Voice) or autologous fat is considered **medically appropriate** for vocal fold medialization and augmentation in the management of vocal cord paralysis/insufficiency.

III. Interarytenoid augmentation with calcium hydroxylapatite (e.g., Prolaryn and 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 as stated above is considered **not medically necessary** for any dermal or laryngeal indication.

RELATED POLICIES

Not Applicable

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 dermal layers, 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 medical purposes.

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) 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.

Injectable fillers are generally categorized into three main types:

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

Facial Lipodystrophy Syndrome

HIV-associated lipodystrophy is a complication of antiretroviral therapy (ART), characterized by abnormal redistribution of body fat (Guzman, 2022). It typically presents in two forms: fat accumulation (lipohypertrophy) or fat loss (lipoatrophy). Facial lipoatrophy is marked by the loss of buccal and temporal fat pads, resulting in sunken cheeks, hollowing around the eyes, and visible facial musculature. This condition can impact 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 (Reddy, 2020). 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 go deeper than the true vocal cords. Initial conservative treatment includes thickening of liquids, feeding adjustments and reflux mediation (van Stigt 2024). 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, thyroidectomy is the most prevalent.

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 nonsurgical procedure aims to treat unilateral vocal cord insufficiency by temporarily increasing the volume or bulk of the vocal fold to improve closure during phonation.

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 a 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 videofluoroscopic 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

Balouch et al (2023) conducted a retrospective study to measure the need for further medialization surgery and improvement in the glottic gap in 172 subjects that underwent type I thyroplasty (n=100) and autologous lipoinjection medialization (n=72). The majority of subjects (59.30%) had a unilateral vocal fold motion deficit (paresis or paralysis), and fewer had a bilateral deficit (40.70%), but the proportion did not differ significantly between thyroplasty and lipoinjection groups (59.00% versus 59.72% unilateral deficit, P=0.924). Need for further medicalization did not differ significantly between thyroplasty and lipoinjection groups (34.00% versus 32.39%, P=0.870). Postoperative implant migration or extrusion occurred significantly more often in subjects who underwent thyroplasty (22.00% versus 5.56%, P 0.003). Surgical explant of the migrated (n=20, 20.00%) or extruded (n=2, 2.00%) Gore-Tex or silastic implant was performed in 14.00% of thyroplasty subjects; however, explant of grafted fat was performed in just one (1.39%) lipoinjection subject (P=0.005). Subjects in the thyroplasty group were also significantly more likely to experience postoperative vocal fold hemorrhage (14.00% versus 2.78%, P=0.015). Voice handicap index (VHI-10) scores were available for 54 subjects, which did not differ significantly between thyroplasty and lipoinjection pre- or post-operatively. The authors conclude that both autologous lipoinjection medialization and type I thyroplasty provide effective medialization for patients with glottic insufficiency. Both techniques yield similar reoperation rates, and the benefit of surgery appears to last for at least 1 year for most patients.

Campagnolo et al (2023) conducted a systematic review of studies (n=13) analyzing the data of 472 patients who underwent fat injection laryngoplasty for treatment of glottic insufficiency. Included were patients over 18 years of age with gastrointestinal (GI) due to paralysis, atrophy, scarring, or sulcus of the vocal folds who underwent autologous fat injection into the vocal folds and who had their voice assessed before the procedure and at least 1 year later. Considerable heterogeneity across studies was found, including technique for harvest, processing the fat, site of injection, and acoustic analysis. In the studies that measured maximum phonation time (MPT) there was a significant improvement in a follow-up of at least 1 year after the injection. The patient's perception of vocal quality, measured by the Voice Handicap Index, also showed significant improvement in several studies after fat injection laryngoplasty. The authors concluded that the injection of autologous fat in the vocal folds is considered a viable technique, although there is no standard protocol for the method of fat extraction, preparing the fat for injection, and injecting the fat into the vocal folds. Further studies, using a standardized protocol and with long-term follow-up, are needed to define whether vocal fold fat injection can be deemed a long-term or, in some cases, permanent treatment for GI.

Safia et al (2024) conducted a comprehensive meta-analysis and meta-regression using data extracted from 82 studies up to February 2024. The studies primarily involved retrospective cohorts (42.5%), followed by prospective cohorts (32.5%) and case series (20%). The follow-up period varied, with most studies assessing outcomes at 12 months. Autologous fat (30.49%) was the most common injection material, followed by hyaluronic acid (26.83%), calcium hydroxyapatite (9.76%), and collagen (7.32%). The meta-analysis revealed significant improvements in maximum phonation time (MPT) and harmonics-to-noise ratio (HNR) post-injection. Materials such as polydimethylsiloxane (PDMS) and autologous fat significantly improved MPT and reduced the grade of dysphonia and roughness, respectively. Study limitations include variation in follow-up lengths and small sample

sizes for certain outcomes. Although the authors did not restrict study inclusion criteria, the reported 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 injection 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 an 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 (AAOHN) 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 AAOHN 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.

In 2019 the American Laryngological Association (ALA) published a 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 (Cymetra, Zyplast), hyaluronic acid (Restylane, Perlane, Juvederm), and carboxymethylcellulose (Prolaryn Gel).

In 2013, the National Institute for Health and Care Excellence (NICE) interventional procedures guidance states that the current evidence on the efficacy of deep dermal injection of non-absorbable gel polymer (NAGP) for HIV-related facial lipoatrophy is adequate.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates dermal fillers as 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 2025 Jul 18]

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 2025 Jul 18]

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 (NMN)	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951 (NMN)	; 1.1 to 5.0 cc
11952 (NMN)	; 5.1 to 10.0 cc
11954 (NMN)	; 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

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

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	

REFERENCES

Facial Lipodystrophy Syndrome

Bassichis B, et al. Injectable poly-L-lactic acid for human immunodeficiency virus-associated facial lipoatrophy: cumulative year 2 interim analysis of an open-label study (FACES). Dermatol Surg. 2012 Jul;38(7 Pt 2):1193-205.

Carruthers A, et al. Radiographic and computed tomographic studies of calcium hydroxylapatite for treatment of HIV-associated facial lipoatrophy and correction of nasolabial folds. Dermatol Surg. 2008 Jun;34 Suppl 1:S78-84.

Glesby MJ. Treatment of HIV-associated lipodystrophy [Internet]. In: UpToDate, Connor RF (Ed), Wolters Kluwer; 2025 Jun 25 [accessed 2025 Jul 10]. Available from: https://www.uptodate.com/contents/treatment-of-hiv-associated-lipodystrophy

Guida S, et al. A systematic review of Radiesse/calcium hydroxylapatite and carboxymethylcellulose: evidence and recommendations for treatment of the face. Int J Dermatol. 2024 Feb;63(2):150-160. Epub 2023 Oct 28.

Guzman N and Vijayan V. HIV-associated lipodystrophy. In StatPearls [Internet]. StatPearls Publishing. 2022 Nov 7 [accessed 2025 Jul 15]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK493183/

Jagdeo J, et al. A systematic review of filler agents for aesthetic treatment of HIV facial lipoatrophy (FLA). J Am Acad Dermatol. 2015 Dec;73(6):1040-54.e14.

National Institute for Health and Care Excellence (NICE) [Internet]. Deep dermal injection of non-absorbable gel polymer for HIV-related lipoatrophy. Interventional procedures guidance (IPG439). 2013 Jan 23 [accessed 2025 Jul 18]. Available from: https://www.nice.org.uk/guidance/ipg439/chapter/2-the-procedure

Silvers SL, et al. Prospective, open-label, 18-month trial of calcium hydroxylapatite (Radiesse) for facial soft-tissue augmentation in patients with human immunodeficiency virus-associated lipoatrophy: one-year durability. Plast Reconstr Surg. 2006 Sep;118(3 Suppl):34S-45S.

Tilhet L, et al. Current status and perspectives in the treatment of facial lipoatrophy in HIV-positive patients in 2024. Ann Chir Plast Esthet. 2025 May;70(3):192-205. Epub 2024 Dec 6.

Vallejo A, et al. Comparing efficacy and costs of four facial fillers in Human Immunodeficiency Virus-associated lipodystrophy: a clinical trial. Plast Reconstr Surg. 2018 Mar;141(3):613-623.

Laryngeal Cleft

Cole E, et al. Outcomes and swallowing evaluations after injection laryngoplasty for type I laryngeal cleft: Does age matter? Int J Pediatr Otorhinolaryngol. 2018 Dec;115:10-18.

Isaac A, et al. Injection augmentation and endoscopic repair of type 1 laryngeal clefts: development of a management algorithm. J Otolaryngol Head Neck Surg. 2020 Jul 14;49(1):49.

Jefferson ND, et al. Low inter-arytenoid height: a subclassification of type 1 laryngeal cleft diagnosis and management. Int J Pediatr Otorhinolaryngol. 2015 Jan;79(1):31-5. Epub 2014 Nov 4.

Mangat HS, et al. Injection augmentation of type I laryngeal clefts. Otolaryngol Head Neck Surg. 2012 May;146(5):764-8.

Mothersole KH, et al. Outcomes of injection laryngoplasty for deep interarytenoid groove. Int Arch Otorhinolaryngol. 2023 Oct 6;28(1):e101-e106.

Reddy P, et al. Presentation and management of type 1 laryngeal clefts: A systematic review and meta-analysis. Int J Pediatr Otorhinolaryngol. 2020 Nov;138:110370.

Stack TJ, et al. Interarytenoid injection outcomes in pediatric feeding disorders. Laryngoscope Investig Otolaryngol. 2023 Aug 16;8(5):1421-1427.

Timashpolsky A, et al. Management of type 1 laryngeal clefts: a systematic review and meta-analysis. Otolaryngol Head Neck Surg. 2021 Mar;164(3):489-500. Epub 2020 Aug 18.

van Stigt MJB, et al. International perspective of injection laryngoplasty for laryngeal cleft - A survey study. Int J Pediatr Otorhinolaryngol. 2024 Nov;186:112097.

Yeung JC, et al. International Pediatric Otolaryngology Group: Consensus guidelines on the diagnosis and management of type I laryngeal clefts. Int J Pediatr Otorhinolaryngol. 2017 Oct;101:51-56.

Vocal Cord Paralysis

American Laryngological Association [Internet]. Laryngology curriculum. Treatment, injection augmentation. 2019 Apr 15 [accessed 2025 Jul 10]. Available from: https://alahns.org/research-education/laryngology-curriculum/

Balouch B, et al. Long-term outcome of autologous lipoinjection medialization laryngoplasty versus type I thyroplasty. J Voice. 2023 Nov 6:S0892-1997(23)00321-1.

Campagnolo AM, et al. Vocal fold fat injection for glottic insufficiency: systematic review. J Voice. 2023 Dec 22:S0892-1997(23)00304-1.

Carsuzaa F, et al. Techniques of Injection Laryngoplasty Under Local Anaesthesia in Unilateral Vocal Fold Paralysis: A Systematic Review. Clin Otolaryngol. 2025 Jul;50(4):600-608.

Haddad R, et al. Lipoinjection for unilateral vocal fold paralysis treatment: a systematic review and meta-analysis. Laryngoscope. 2022 Aug;132(8):1630-1640.

Stachler RJ, et al. Clinical Practice Guideline: Hoarseness (Dysphonia) (Update). Otolaryngol Head Neck Surg. 2018 Mar;158(1_suppl):S1-S42. Erratum in: Otolaryngol Head Neck Surg. 2018 Aug;159(2):403.

Safia A, et al. Determinants of clinical response to injection laryngoplasty in unilateral vocal fold paralysis: a systematic review and meta-analysis. Int J Surg. 2024 Nov 1;110(11):7281-7310.

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 2025 Jul 10]

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	
Date	**Summary of Changes**
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