Injectable Dermal Fillers and Bulking Agents

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➲ Instructions for Use

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Related Commercial/Individual Exchange Policy

- Cosmetic and Reconstructive Procedures

Community Plan Policy

- Injectable Dermal Fillers and Bulking Agents

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

Dermal Filler Injections

Radiesse® and Sculptra® are considered reconstructive and medically necessary for the treatment of facial defects due to facial lipoatrophy in individuals living with human immunodeficiency virus (HIV) infection.

Radiesse and Sculptra are considered cosmetic and not medically necessary for all other indications.

The use of all other dermal filler products is considered cosmetic and not medically necessary.

Injectable Bulking Agents

Injectable bulking agents are proven and medically necessary for the treatment of vocal fold insufficiency/ dysfunction when used according to U.S. Food and Drug Administration (FDA)–labeled indications, contraindications, warnings, and precautions.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

CPT Code	Description
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 (e.g., percutaneous, transoral), unilateral

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HCPCS Code	Description
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, 0.1ml
Q2028	Injection, Sculptra, 0.5 mg

Description of Services

It is estimated that approximately 50% of individuals living with HIV who are being treated with highly active antiretroviral therapy develop significant facial lipoatrophy. This carries a negative social stigma, and many individuals develop severe body dysmorphic disorder, which may result in nonadherence to highly active antiretroviral therapy, discontinuation of visits to the infectious disease clinics, and cessation of taking other medications. Two injectable fillers have been approved by the FDA to treat facial lipoatrophy in individuals living with HIV, and these are poly-L-lactic acid (Sculptra), calcium hydroxylapatite microspheres, and carboxymethylcellulose (Radiesse). (Guzman, 2022)

Vocal cord insufficiency (also known as vocal cord dysfunction, paradoxical vocal fold movement, or glottal insufficiency) is a condition in which one or both vocal cords do not open correctly. When the glottis does not close properly, vocal fatigue, poor voice quality or tone, and difficulty speaking, swallowing, or coughing may occur. Individuals with vocal fold insufficiency are at greater risk for larynx penetration, aspiration, and pneumonia (Rajaei, 2014). Treatment options include voice therapy, thyroplasty, or vocal fold injection. Vocal fold injection involves injecting a bulking agent into the affected fold to assist it in sufficiently aligning with the opposing fold. (Zhang, 2015)

Clinical Evidence

Human Immunodeficiency Virus Facial Lipoatrophy

Vallejo et al. (2018) conducted a clinical trial that included 147 participants with HIV-induced lipoatrophy who were treated with Sculptra (poly-L-lactic acid), Radiesse [calcium hydroxylapatite (CaHA)], Aquamid (polyacrylamide), or autologous fat. Objective and subjective changes were evaluated during a 24-month follow-up period. Number of sessions, total volume injected, and overall costs of treatment were also analyzed. Objective improvement in facial lipoatrophy, assessed by the surgeon in terms of changes from baseline using an established classification system, was reported in 53% of the participants. Self-evaluation showed a general improvement after treatment with facial fillers, and participants were satisfied with the treatment and the reduced impact of lipodystrophy on their quality of life. The authors concluded that surgical treatment of HIV-associated facial lipoatrophy using dermal fillers is a safe and effective procedure that improves the aesthetic appearance and quality of life.

Kraus et al. (2016) conducted a systematic review that evaluated treatment options for HIV-associated facial lipoatrophy, with a focus on quality-of-life outcomes. The primary outcome was change in quality of life, as measured by validated questionnaires. Overall, 58 articles were included, and 23 assessed quality of life using validated tools, including but not limited to the Medical Outcomes Study HIV Health Survey, 36-Item Short Form Survey, slightly modified Dermatology

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Quality of Life Survey, and Assessment of Body Change and Distress. Poly-L-lactic acid was the most frequently studied treatment, with observational and randomized trials showing significant improvements in quality-of-life scores across multiple domains, while CaHA, polyacrylamide gel, polyalkylimide gel, polymethylmethacrylate, silicone oil, hyaluronic acid, and autologous fat transfer also showed significant improvements. Limitations of this systematic review include the inability to directly compare quality-of-life outcomes due to different assessment scales used among the included studies, varied follow-up duration, varied types of injectables, small sample sizes, and study design. Furthermore, 19 of 23 studies used validated quality-of-life questionnaires, and two did not specify which one was used. Generalizability is further constrained because none of the available quality-of-life assessment tools specifically address facial lipoatrophy, despite the availability of several validated questionnaires in multiple languages.

Jagdeo et al. (2015) conducted a systematic review of filler agents for the treatment of HIV facial lipoatrophy. A search, using predetermined criteria, was conducted in MEDLINE. Overall, 321 articles were identified, and after screening, 76 original articles were deemed suitable for the review. Of those, 29 articles evaluated poly-L-lactic acid (Sculptra), and six evaluated CaHA (Radiesse). Based on three randomized controlled trials with two follow-up studies, 20 observational studies, and four case reports, poly-L-lactic acid for the treatment of HIV facial lipoatrophy was assigned a B-level recommendation. Six studies evaluated the efficacy and safety of CaHA for the treatment of HIV facial lipoatrophy, and of those, two showed that CaHA improvement of facial lipoatrophy severity was maintained for 12 months. Based on six observational studies, CaHA was assigned a C-level recommendation. The authors concluded that the current literature shows that filler agents for the treatment of HIV-related facial lipoatrophy are effective and generally safe and improve quality of life in individuals living with HIV-related facial lipoatrophy.

There are a number of studies that demonstrate that Sculptra and Radiesse are effective for the treatment of immunodeficiency virus–associated facial lipoatrophy. Studies show high rates of facial volume restoration, patient satisfaction, and improved quality of life, with results lasting up to 3 years before additional treatment is needed. (Ho and Jagdeo, 2016; Shuck et al., 2013; Moyle et al., 2006; Silvers et al., 2006; Lafaurie et al., 2005)

Vocal Fold Insufficiency

Carroll and Rosen (2011) evaluated the long-term effectiveness of CaHA as a vocal fold injectable by accessing data from a cohort of individuals who underwent injection for glottal insufficiency. The change in Voice Handicap Index-10 scores between pre injection scores and best post injection scores as well as between the pre injection and the most recent Voice Handicap Index-10 scores was used as a primary outcome measure to determine the persistence of benefit or the time to loss of benefit. Overall, 90 individuals who underwent 108 vocal fold injections with CaHA were evaluated for inclusion. In total, 20 individuals, with 22 injections, met the criteria for inclusion. In total, 14 of 22 individuals (64%) had loss of benefit of the CaHA material. The average length of benefit was 18.6 months, with a range of 8 to 36 months. Three complications were identified among the original cohort of 108 injections. The authors concluded that CaHA remains a safe and effective long-term vocal fold injectable, with an average length of benefit of 18.6 months.

Rosen et al. (2009) evaluated the long-term effectiveness of CaHA vocal fold injection in participants with glottal insufficiency in a multicenter, open-label, prospective clinical study (n = 63). Voice-related outcome measures were collected for pre-injection prior to injection and, 1, 3, 6, and 12 months. Using the Voice Handicap Index-10, visual analog scale (vocal effort), Consensus Assessment Perceptual Evaluation V (judgments of voice severity), and objective voice measures of glottal closure (maximum phonation time and S:Z ratio), paired t tests showed significant improvements after treatment. A 22% further treatment rate was found at the 12-month time point. The authors concluded that the 1-year results in this cohort of participants with glottal incompetence treated with CaHA vocal fold injection demonstrate that excellent clinical results were achieved.

The U.K.'s National Institute for Health and Care Excellence provided guidance in 2005 on collagen injection for vocal cord augmentation. The National Institute for Health and Care Excellence concluded that the current evidence suggests that collagen injection is efficacious for short-term symptom relief, there were no major safety concerns, and patients should be fully informed of the long-term efficacy and the alternative treatment options.

Clinical Practice Guidelines

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

In a 2013 clinical practice guideline on improving voice outcomes after thyroid surgery, the AAO-HNS makes a strong recommendation for identifying the recurrent laryngeal nerve(s) during thyroid surgery , and recommendations to examine and document voice and vocal fold mobility, both before and after surgery. The AAO-HNS recommends that if patients have voice change or abnormal vocal fold mobility after surgery, surgeons should provide counsel on options for rehabilitation. Vocal fold injection medialization is described as a temporary intervention that may reduce the need for later surgical reconstruction.

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In a 2018 practice guideline on dysphonia (hoarseness), the AAO-HNS states that 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, and glottic insufficiency. This surgery includes vocal fold injection medialization using bulking agents.

American Laryngological Association (ALA)

In a 2019 guideline on vocal fold injection augmentation, the ALA states that this procedure is indicated for 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. It is contraindicated for the individuals with the following:

- Unstable cardiopulmonary status
- Allergy to any injectable materials, including local anesthetic
- Poor exposure of the endolarynx due to a prolapsing arytenoid
- Severe supraglottic constriction, poorly defined anatomical landmarks of the neck

Relative contraindications:

- Individuals with a large posterior glottal gap or large interarytenoid defects that require laryngeal framework surgery
- Individuals being treated with anticoagulation medications

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

On December 22, 2006, the FDA approved Radiesse, an injectable (under the skin) implant, to restore or correct signs of facial lipidatrophy or fat loss in people with HIV. For additional information, refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050052b.pdf. (Accessed June 4, 2026)

On August 3, 2004, the FDA approved Sculptra, an injectable filler to correct facial fat loss in people with HIV Sculptra is an injectable form of poly-L-lactic acid, a biodegradable, biocompatible synthetic polymer from the alpha-hydroxy acid family. For additional information, refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf3/p030050b.pdf. (Accessed June 4, 2026)

The FDA has cleared a number of bulking agents for vocal cord medialization under the 510(k) pathway. Refer to the following website, and search using product code MIX: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 11, 2025)

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Policy History/Revision Information

Date	Summary of Changes
10/01/2026	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version 2026T0650F

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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