

Injectable Dermal Fillers and Bulking Agents

Policy Number: OUTPATIENT 053.2
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[Instructions for Use](#)

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Related Policy
<ul style="list-style-type: none"> Cosmetic and Reconstructive Procedures

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 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 protocol titled [Medical Records Documentation Used for Reviews](#).

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 may apply.

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)

HCPCS Code	Description
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 patients with human immunodeficiency virus (HIV) infection who are treated with highly active antiretroviral therapy (HAART) develop significant facial lipoatrophy. This feature carries a negative social stigma and imparts such a poor body image that many individuals develop severe body dysmorphic disorder which may result in non-compliance with HAART, discontinue visits to the infectious disease clinics and stop taking other medications. Injectable fillers have been approved by the FDA to treat this facial lipoatrophy in HIV patients and include poly-L-lactic acid (Sculptra), calcium hydroxylapatite microspheres and carboxymethylcellulose (Radiesse). (Guzman and Al About, 2018)

Vocal cord insufficiency (also known as vocal cord dysfunction, paradoxical vocal fold movement, 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 including 147 patients with HIV-induced lipoatrophy treated with Sculptra (poly-L-lactic acid), Radiesse (calcium hydroxylapatite), 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 percent of the cases. Patient self-evaluation showed a general improvement after the use of facial fillers. Patients reported being satisfied with the treatment and with the reduced impact of lipodystrophy on their quality of life. Despite the nonsignificant differences observed in the number of sessions and volume, autologous fat showed significantly lower costs than all synthetic fillers ($p < 0.05$). 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 the quality of life of patients. Permanent fillers and autologous fat achieve the most consistent results over time.

Kraus et al. (2016) reported that the QOL outcomes associated with treatment of HIV facial lipoatrophy (FLA) with poly-L-lactic acid and similar agents appears to improve QOL as assessed by various QOL instruments. Additional studies are required to identify a unifying QOL instrument to effectively assess longitudinal QOL outcomes and to compare treatment modalities. Ho and Jagdeo (2016) found similar QOL results in 19 patients that completed a 12-month follow-up. The authors recommend use of the Facial Appearance Inventory (FAI) and FACE-Q in future studies for HA filler treatment of HIV FLA.

Jagdeo et al. (2015) conducted a systematic review of filler agents for aesthetic treatment of HIV facial lipoatrophy (FLA). A search, using predetermined criteria, was conducted in Medline. A total of 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 (PLLA; Sculptra) and 6 evaluated calcium hydroxylapatite (CaHA; Radiesse). Based on three randomized controlled trials with 2 follow-up studies, 20 observational studies and 4 case reports, PLLA for the treatment of HIV FLA was assigned a B-level recommendation. Six studies evaluated the efficacy and safety of CaHA for treatment of HIV FLA and of those, two showed that CaHA improvement of FLA severity was maintained for 12 months. Based on 6 observational studies, CaHA was assigned a C-level recommendation. The authors concluded that current literature suggests that filler agents for treatment of HIV FLA are an effective and generally safe option for aesthetic improvement and help improve patients' quality of life.

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 patients who underwent injection for glottal insufficiency. The change in Voice Handicap Index (VHI)-10 scores between pre injection scores and best post injection scores as well as between the pre injection and the most recent VHI-10 scores were used as primary outcome measures to determine the persistence of benefit or the time to loss of benefit. Ninety patients who underwent 108 vocal fold injections with CaHA were evaluated for inclusion. Twenty patients with 22 injections met the criteria for inclusion. Fourteen of 22 (64%) subjects showed 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 calcium hydroxylapatite (CaHA) vocal fold injection for patients with glottal insufficiency in a multicenter, open-label, prospective clinical study (n = 63). Voice-related outcome measures were collected for pre-injection, 1, 3, 6, and 12 months. Utilizing 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 one-year results in this cohort of patients 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 (NICE) provided guidance in 2005 on collagen injection for vocal cord augmentation. NICE concluded that the current evidence suggests collagen injection is efficacious for short-term symptom relief and there were no major safety concerns, and that 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 made 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. AAO-HNS recommended 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.

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, or 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 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 anatomic 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 lipodatrophy, or fat loss, in people with human immunodeficiency virus (HIV). For additional information, refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050052b.pdf. (Accessed June 12, 2024)

On August 3, 2004, the FDA approved Sculptra, an injectable filler to correct facial fat loss in people with HIV (FDA, 2004). 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: https://www.accessdata.fda.gov/cdrh_docs/pdf3/p030050b.pdf. (Accessed June 12, 2024)

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 12, 2024)

References

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2024T0650B]

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Policy History/Revision Information

Date	Summary of Changes
12/01/2024	<p>Title Change</p> <ul style="list-style-type: none">Previously titled <i>Injectables for Reconstructive Procedures</i> <p>Coverage Rationale</p> <p>Dermal Filler Injections</p> <ul style="list-style-type: none">Revised language to indicate:<ul style="list-style-type: none">Radiesse and Sculptra are considered:<ul style="list-style-type: none">Reconstructive and medically necessary for the treatment of facial defects due to facial lipoatrophy in individuals living with human immunodeficiency virus (HIV) infectionCosmetic and not medically necessary for all other indications

Date	Summary of Changes
	<ul style="list-style-type: none"> ○ The use of all other dermal filler products is considered cosmetic and not medically necessary <p><i>Injectable Bulking Agents</i></p> <ul style="list-style-type: none"> ● Replaced language indicating “injectable bulking agents (<i>e.g., Prolaryn, Prolaryn Plus</i>®) are proven, medically necessary, and <i>reconstructive</i> for treatment of vocal fold insufficiency/dysfunction when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions” with “injectable bulking agents are proven and medically necessary for the treatment of vocal fold insufficiency/dysfunction when used according to U.S. FDA labeled indications, contraindications, warnings, and precautions” <p>Medical Records Documentation Used for Reviews (previously titled <i>Documentation Requirements</i>)</p> <ul style="list-style-type: none"> ● Replaced list of <i>Required Clinical Information</i> with instruction to refer to the protocol titled Medical Records Documentation Used for Reviews <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>Clinical Evidence, FDA, and References</i> sections to reflect the most current information ● Archived previous policy version OUTPATIENT 053.1

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical 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.