Injectables for Reconstructive Procedures

Policy Number: CS371.A
Effective Date: April 1, 2024

➲ Instructions for Use

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Related Community Plan Policy

- Cosmetic and Reconstructive Procedures

Commercial Policy

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Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	None
Kentucky	None
Louisiana	Injectables for Reconstructive Procedures (for Louisiana Only)
Mississippi	Injectables for Reconstructive Procedures (for Mississippi Only)
Nebraska	Injectables for Reconstructive Procedures (for Nebraska Only)
New Jersey	Injectables for Reconstructive Procedures (for New Jersey Only)
New Mexico	Injectables for Reconstructive Procedures (for New Mexico Only)
North Carolina	None
Ohio	Injectables for Reconstructive Procedures (for Ohio Only)
Pennsylvania	Injectables for Reconstructive Procedures (for Pennsylvania Only)
Tennessee	Injectables for Reconstructive Procedures (for Tennessee Only)

Coverage Rationale

Dermal Filler Injections

Radiesse and Sculptra are proven, medically necessary, and reconstructive for treating facial defects due to facial lipoatrophy in persons with human immunodeficiency virus (HIV). The use of other dermal filler products is considered cosmetic.

Injectable Bulking Agents

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

Documentation Requirements

Benefit coverage for health services is determined by federal, state, or contractual requirements that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

Required Clinical Information
Dermal Filler Injections

Medical notes documenting the following, when applicable:
• History of medical conditions requiring treatment or surgical intervention which includes all the following:
  ○ To prove medical necessity, a well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment
• High-quality color photograph(s); all photographs must be labeled with:
  ○ Date taken
  ○ Applicable case number obtained at time of notification, or member's name and ID number on the photograph(s)
• Submission of color image(s) is required and can be submitted via the portal at uhcprovider.com/paan; faxes will not be accepted

*For code descriptions, refer to the Applicable Codes section.

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 federal, state, or contractual requirements 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.

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 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 Aboud, 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

In 2022, Dwyer at al. published the preliminary results from a single surgeon on the efficacy of a novel silk-hyaluronic acid vocal cord augmentation material.

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 (AAOHNS)

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. AAOHNS 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 AAOHNS 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 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 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 November 8, 2018, the FDA cleared the Silk Voice® (Sofregen Medical, Inc.) synthetic polymer for vocal fold medialization and vocal fold insufficiency. For additional information, refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180631.pdf. (Accessed May 22, 2023)

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 human immunodeficiency virus (HIV). For additional information, refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050052b.pdf. (Accessed March 28, 2023)

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 website: https://www.accessdata.fda.gov/cdrh_docs/pdf3/p030050b.pdf. (Accessed March 28, 2023)

On March 7, 2007, the FDA approved the Radiesse Laryngeal Implant, a sterile, non-pyrogenic injectable material consisting of calcium hydroxylapatite (CaHA) suspended in an aqueous formulation of USP grade pharmaceutical excipients consisting of sterile water, glycerin, and sodium carboxymethylcellulose, stabilized with a phosphate buffer. It is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue hulking agent. For additional information refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf7/K070090.pdf. (Accessed March 28, 2023)

Additionally, the FDA 510(k) documents refer to the Prolaryn products above using their original product names. Prolaryn Plus was originally cleared as the Radiesse Laryngeal Implant (Bioform Medical, Inc., Franksville, WI, USA), and Prolaryn Gel was originally cleared for marketing as the Laryngeal Augmentation Implant (Bioform, Inc.).

References

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Policy History/Revision Information

Date	Summary of Changes
07/01/2024	**Application** ***New Mexico*** • Added language to indicate this policy does not apply to the state of New Mexico; refer to the state-specific policy version
06/01/2024	**Application** ***Louisiana*** • Added reference link to state-specific policy version
04/01/2024	**Template Update** • Created service-specific policy version for content previously included in the Medical Policy titled *Omnibus Codes* **Coverage Rationale** ***Dermal Filler Injections*** • Added language to indicate the use of other dermal filler products [not listed as proven, medically necessary, and reconstructive in the policy] are considered cosmetic ***Injectable Bulking Agents*** • Replaced language indicating "Prolaryn and Prolaryn Plus® *(formerly the Radiesse Laryngeal Implant)* are proven and medically necessary and reconstructive for treatment of vocal fold insufficiency" with "*injectable bulking agents* (e.g., Prolaryn, Prolaryn Plus®) are proven, medically necessary, and reconstructive for treatment of vocal fold insufficiency/*dysfunction when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions*"

Date	Summary of Changes

	Documentation Requirements (new to policy)
	• Added language to indicate medical notes documenting the following (when applicable) are required:
	  ○ History of medical conditions requiring treatment or surgical intervention, including documentation of a well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment to prove medical necessity
	  ○ High-quality color photograph(s); all photographs must be labeled with:
	  ▪ Date taken
	  ▪ Applicable case number obtained at time of notification, or member's name and ID number on the photograph(s)
	  ○ Submission of color image(s) is required and can be submitted via the external portal at uhcprovider.com/paan; faxes will not be accepted
	Supporting Information
	• Added *Description of Services* and *FDA* section
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version CS087.AU

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. 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.

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