Medical Coverage Policy

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Coverage Policy Number..... 0511

Injectable Fillers for Head and Neck Conditions

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses injection materials used for the treatment of vocal cord paralysis, velopharyngeal insufficiency, and facial lipodystrophy syndrome.

Coverage Policy

Coverage for injectable fillers varies across plans. Refer to the customer's benefit plan document for coverage details.

Vocal Cord Paralysis

Laryngeal injection of ANY of the following is considered medically necessary for the treatment of unilateral vocal cord paralysis:

- calcium hydroxylapatite (e.g., Radiesse™ Voice, Prolaryn™ Plus)
- autologous fat
- bulking agents specifically approved by the U.S. Food and Drug Administration (FDA) for the treatment of unilateral vocal cord paralysis

Velopharyngeal Insufficiency

Autologous fat injection is considered medically necessary for the treatment of velopharyngeal insufficiency when ALL the following criteria are met:

- History of hypernasal speech
- History of nasal regurgitation of food or liquid
- Naso-endoscopic evidence of a functional velopharyngeal insufficiency
- A speech evaluation, conducted by a speech-language pathologist, which documents the functional impairment that cannot be corrected by speech therapy alone.

Facial Lipodystrophy Syndrome

Injectable fillers approved by the Food and Drug Administration (FDA) (e.g., Sculptra or Radiesse) are considered medically necessary for the treatment of photographically documented facial lipodystrophy syndrome caused by antiretroviral therapy in HIV-infected persons.

Not Medically Necessary

Effective 9/15/2025

Injectable fillers including calcium hydroxylapatite, autologous fat*, collagen, hyaluronic acid and poly-L-lactic acid, are considered cosmetic and not medically necessary for ANY other indication.

***This coverage policy is not intended to address the use of injectable fillers for ANY other indication not addressed in this coverage policy. For coverage criteria specific to other conditions not listed in this policy, refer to the following policies:**

- **Breast Reconstruction Following Mastectomy or Lumpectomy**
- **Tissue Engineered Skin Substitutes**
- **Gender Dysphoria Treatment**
- **Scar Revision**

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Otolaryngology Disparities

Batool et al. (2023) conducted a systematic review of healthcare disparities in otolaryngology. Their findings indicate that peer-reviewed literature highlights disparities affecting various vulnerable populations, including racial and ethnic minorities, low-income individuals, and those living in rural areas. The authors found that individuals who identify as African American, Hispanic (Latinx), or belonging to other minority racial or ethnic groups are less likely to report voice problems compared to White individuals. Additionally, Hispanic (Latinix) individuals with voice disorders are more likely than their White counterparts to delay seeking care, often due to difficulties in reaching a medical office by telephone or experiencing long wait times at doctor's offices. Furthermore, the literature shows that men (36.1%) are less likely to report voice disorders compared to women (63.9%). When evaluated, women are less likely to be referred to an otolaryngologist for their voice disorder; however, they are more likely to receive treatment once seen.

Velopharyngeal Insufficiency
Cleft Palate
In the United States, cleft palate affects approximately 1 in 700 births, making it the second most common congenital malformation. Individuals with a diagnosis of cleft palate can experience many different health challenges, such as feeding and speech difficulties, dental abnormalities, hearing loss, and psychosocial problems (Peck et al., 2024).

A retrospective review by Peck et al (2024) (n=5927) found that health equity and disparities exist in patients with a cleft palate diagnosis. Compared to White individuals, Hispanics (Latinix) and Asian or Pacific Islander patients experienced delays in care. These delays in care have been associated with language barriers, medical mistrust, geographic location to cleft palate centers,

lack of resources, and public insurance usage. The authors suggest that these delays, particularly among different ethnic groups, can impact treatment for velopharyngeal insufficiency (VPI), which includes services like speech therapy, audiology, orthodontics, and surgery to correct VPI.

Head and Neck Cancers

The American Cancer Society (2025) estimates that in 2025, there will be approximately 59,660 new cases of cancer affecting the oral cavity (mouth) and pharynx (throat), with around 12,770 fatalities resulting from the disease. Men are three times more likely than women to be diagnosed with cancers of the oral cavity and pharynx. Furthermore, disparities exist in incidence rates, stages of diagnosis, access to timely cancer care, quality of care, and treatment outcomes among individuals from certain racial and ethnic backgrounds, socioeconomic groups, or geographic locations. For instance, Black patients with head and neck squamous cell carcinoma are 72% more likely to die from the disease compared to their White counterparts, and individuals with head and neck squamous cell carcinoma living in rural areas face an 11% higher mortality rate than those residing in urban areas (Marrero-Gonzalez and Graboyes, 2024). Due to these disparities in head and neck cancer treatment, the author suggests that such inequities could result in delays in care for conditions like vocal cord paralysis and velopharyngeal insufficiency.

Human Immunodeficiency Virus (HIV)

Human Immunodeficiency Virus (HIV) affects approximately 1.2 million people in the United States. In 2022, 49% of new HIV diagnoses in the U.S. occurred in the South. The prevalence of HIV is particularly notable in certain populations, including Black/African Americans, Hispanic/Latinx individuals, transgender people, the homeless, intravenous drug users, and older adults aged 55 and above. For those aged 25 to 34, the incidence of HIV infection is higher. Many individuals living with HIV do not receive adequate care regardless of highly effective treatment options due to barriers. Barriers preventing people with HIV from receiving effective care include HIV-related stigma, mental health challenges, and various structural and social determinants of health, such as poverty and distance from HIV care. The author suggests that barriers could prevent access for treatment of facial lipodystrophy syndrome (Daoud, et al., 2025).

General Background

Injectable fillers also referred to as injectable dermal or soft tissue fillers, are substances used to restore tissue volume loss caused by factors such as aging, lipoatrophy, injury or trauma. A wide variety of injectable fillers are available for clinical use, including products that break down over time (e.g., hyaluronic acid, collagen, calcium hydroxylapatite, and poly-L-lactic acid), products that remain indefinitely in tissue (e.g., polymethylmethacrylate microspheres, hydrogel polymers, and silicone), and autologous fat (Carruthers, et al., 2022).

Injectable soft tissue fillers play a role in the correction of defects that result from medical disorders, trauma, or surgery. A number of injectable fillers including autologous fat are used for medical purposes in non-facial areas such as nipple contouring, and improvement of chest wall defects after mastectomy and breast reconstruction (Carruthers, et al., 2022). Depending on the severity of defects or scarring, revision may aid in restoration of function, however treatment of scars is typically aimed at improving physical appearance, and as such be considered cosmetic. Treatments intended to improve personal appearance or that do not improve functional deficits are considered cosmetic in nature. The majority of injectable fillers can be divided into the following categories:

- Calcium hydroxylapatite microsphere (e.g., Radiesse, Prolaryn)
- Collagen (e.g., Cosmoderm, Evolence, Fibrel, Zyplast, Zyderm)
- Hyaluronic acid (e.g., Restylane, Perlane, Juvederm Ultra, Elevess, Prevelle Silk, Teosyal, Revanesse Ultra, Hylaform B Gel, Captique, Artefill, Beletero Balance)
- Poly-L-lactic acid (e.g., Sculptra)

Vocal Cord Paralysis

Laryngeal injections of select injectable fillers, also referred to as bulking agents, have been proven to be effective in treating glottis insufficiency or vocal cord dysfunction. Vocal cord (or fold) paresis or paralysis is a result of abnormal nerve input to the voice box muscles (i.e., laryngeal muscles). Vocal cord paresis/paralysis can occur at any age from a variety of causes (e.g., injury, trauma; tumors, viral infections) (Stachler, et al., 2018). The symptoms of vocal cord paralysis/paresis are voice changes, and airway and swallowing problems. Glottis insufficiency, which may be secondary to vocal cord paralysis, atrophy, or scarring, is a condition that leaves patients with phonatory compromise in both voice frequency and intensity. Proposed techniques for managing vocal cord paralysis include voice therapy, laryngeal framework surgery, reinnervation surgery, medialization thyroplasty, and injection laryngoplasty (Bruch and Kamani, 2021; Lorenz, et al., 2007; Kwon, et al., 2004). Laryngeal reinnervation has been performed with varying degrees of success. Medialization thyroplasty involves transcervical placement of an implant (e.g., silicone, Gore-Tex) through a surgically created window in the thyroid cartilage (Bruch and Kamani, 2021). Injectable agents proposed for treatment include autologous fat, calcium hydroxylapatite, hyaluronic acid, and collagen. Injection of these substances changes the position of the vocal folds, repositioning the laryngeal cartilage and bringing the vocal folds closer together. This procedure usually results in a stronger voice.

U.S. Food and Drug Administration (FDA): The Radiesse Laryngeal Implant (calcium hydroxylapatite) (BioForm Medical Inc.) obtained clearance from the FDA through the 510(k) approval process, as substantially equivalent to the predicate device on March 1, 2007. According to the FDA, the Radiesse Laryngeal Implant is indicated for vocal fold medialization and treatment of vocal fold insufficiency that can be improved by injection of a soft-tissue bulking agent. The Radiesse Laryngeal Implant is intended to augment the size of the displaced or deformed vocal fold so that it may meet the opposing vocal fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication for a Radiesse Laryngeal Implant (FDA, 2007). In February 2010, Merz Aesthetics Inc. acquired BioForm Medical Inc. Merz Aesthetics Inc. manufactures Radiesse Laryngeal Implant under the names Prolaryn Gel and Prolaryn Plus.

Multiple bulking agents have been approved by the U. S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of unilateral vocal cord paralysis. Manufacturers include Sofregen Medical (Medford, MA), Cytophil (East Troy, WI), Coapt Systems (Palo Alto, CA) and Bioform Medical (San Mateo, CA). According to the FDA, the product code dedicated to bulking agents for vocal cord medialization is MIX.

On March 25, 2005, Medicis Aesthetics Inc received PMA device approval for Restylane Injectable Gel for mid-to deep dermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. Allergan received PMA device approval for the Juvederm collection of dermal fillers for the correction of facial wrinkles and folds. Restylane and Juvaderm are not approved by the FDA for the treatment of vocal cord paralysis and therefore the use for this indication would be considered off-label and unproven.

Literature Review

Calcium Hydroxylapatite: Synthetic calcium hydroxylapatite (CaHA) (e.g., Radiesse™, Prolaryn) has biocompatibility properties that create no antigenic or inflammatory responses. CaHA is formed from calcium and phosphorus ions, which are natural to human teeth and bones (Rosen, 2004). The goal of the Radiesse injection is to augment a vocal fold to improve glottic closure, thereby improving phonation and voice quality. The principle component is synthetic CaHA, which is made up of small particles which are similar to naturally occurring CaHA. The semi-solid nature of Radiesse is due to the suspension of the CaHA particles in a gel carrier composed of water, glycerine, and a small amount of sodium carboxymethylcellulose. For cosmetic purposes, the CaHA is injected in the desired area and then gradually disappears over a period of three to four months. New collagen is formed as the substance is absorbed by the body.

Autologous Fat: Autologous fat injections have been used as an injection material since the later 1980s and early 1990s. The effectiveness, availability, biocompatibility, and low rate of complications of the autologous fat have contributed to its widespread use. Fat offers similar viscoelastic properties to those of the vocal cord tissue. The disadvantage of fat injection is the unpredictable rate and degree of resorption, which limits the predictability of long-term outcomes, and repeat injections are often required (Courey, 2004; Kwon, et al., 2004). Although there is a lack of long-term comparative outcome studies of fat injections as an implant material for vocal cord medialization and augmentation, there is sufficient evidence in the published, peer-reviewed medical literature that in carefully selected patients, fat injections may be beneficial for short-term treatment for unilateral laryngeal nerve paralysis (Fang, et al., 2010; Umeno, et al., 2005; Laccourreye, et al., 2003; McCulloch, et al., 2002; Laccourreye, et al., 1999).

Hyaluronic Acid: Hyaluronic acid is a protective, lubricating and binding gel substance that is produced naturally by the body (e.g., Restylane, Juvederm). Hyaluronic acid is hydrophilic or attracted to water. Injection of the substance results in a smooth surface at the affected area. Restylane injectable gel is a transparent hyaluronic acid gel that is typically injected into facial tissue to smooth wrinkles and folds, especially around the nose and mouth (nasolabial folds). Juvederm is a colorless hyaluronic acid gel that is injected into areas of facial tissue where moderate to severe facial wrinkles and folds occur, especially around the nose and mouth. Due to a lack of well-designed studies with sufficient sample sizes in the published, peer-reviewed medical literature, hyaluronic acid is unproven for the treatment of vocal cord paralysis.

Collagen: A variety of collagen products have been used in research studies, for example biochemical cross-linked products and purified bovine collagen. A micronized form of Alloderm tissue, Cymetra® (LifeCell Corporation, Branchburg, NJ) has been studied for injection laryngoplasty. It is processed from human tissue obtained from tissue banks and is therefore, classified by the FDA as human tissue for transplantation. The classification is not specific to use of Cymetra in conjunction with laryngoplasty. The allograft tissue is processed into a particulate acellular dermal matrix, dried and placed in a syringe. It is to be used in transplantation for the repair or replacement of damaged or inadequate integumental tissues (e.g., correction of soft-tissue defects and depressed scars, replacement of integumental tissue lost through atrophy). Cymetra is proposed for the treatment of vocal fold scars and medialization of vocal folds following thyroplasty. Due to resorption, repeated injections may be indicated (Simpson, et al., 2008; Remacle and Lawson, 2007; Simpson, 2006).

Due to a lack of well-designed studies with sufficient sample sizes in the published, peer-reviewed medical literature, Cymetra is unproven for the treatment of vocal cord paralysis.

Professional Societies/Organizations

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) issued a clinical practice guideline on improving voice outcomes after thyroid surgery. The AAO-HNS 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. If a patient has voice change or abnormal vocal fold mobility post operatively, 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 (Chandrasekhar, et al., 2013).

In a 2018 practice guideline on dysphonia (hoarseness), the AAO-HNS stated 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 agent (Stachler, et al., 2018).

In 2019 the American Laryngological Association (ALA) published a guideline on vocal fold injection augmentation. The group stated the 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

Velopharyngeal Insufficiency

Velopharyngeal insufficiency (VPI) is characterized by an anatomic or structural defect that results in an incomplete closure between the soft palate and posterior pharyngeal wall. Symptoms of a functional VPI can include hypernasal speech, nasal air emission, compensatory articulations, nasal regurgitation and/or feeding problems, which can impact an individual's quality of life. VPI in pediatric population can be caused by congenital (e.g. cleft palate), iatrogenic, and muscular etiologies, but can be caused by secondary to numerous other causes in older patients (e.g. following oncologic surgical resection or cerebrovascular accident) (Bell, et al., 2021). The most common treatments for severe VPI are reconstructive palatoplasty, surgical pharyngoplasty techniques, and prosthetic devices; however, for mild to moderate VPI, a less invasive approach, such as a posterior pharyngeal wall augmentation could be warranted. Augmentation is considered a less invasive approach because it usually involves injection or insertion of an autologous or nonautologous material (Meier and Muntz, 2016). For mild to moderate VPI or very small holes in the velopharynx during phonation, the preferred method for posterior pharyngeal wall augmentation is fat grafting (Beh et al., 2024). The AFI is performed as an outpatient operation at the same time as a naso-endoscopy and confirmation of the injection site is confirmed by the surgeons (Beh et al., 2024).

Literature Review

Autologous Fat: The existing peer-reviewed literature on the use of autologous fat injection for treating velopharyngeal insufficiency (VPI) includes medical textbooks, systematic reviews of case series, prospective studies, retrospective studies, and a meta-analysis comparing alloplastic materials with autologous fat injections (n= 21-594). Although the evidence supporting the use of autologous fat for treating mild to moderate VPI is not extensive, the studies indicate that autologous fat injections can lead to improved outcomes in a carefully selected subset of patients (e.g., reduction of hypernasality, gap size reduction, improved quality of life). The authors concluded that autologous fat grafting is a minimally invasive, safe, and effective treatment for mild to moderate VPI. Surgeons have long utilized autologous fat in clinical practice to reduce velopharyngeal insufficiency (VPI). This approach is now gaining acceptance as a standard treatment for this condition.

Bell, et al (2021) evidence shows that patients treated with synthetic materials compared to autologous fat injections had better outcomes, such as a great improvement in velopharyngeal closure and resonance balance; however, studies reviewed within the meta-analysis included limitations of small population of patients treated with heterogeneous alloplastic materials(n=5-72).(Beh, et al., 2024; Kirschner, et al., 2024; Mirsky, et al., 2024; Panizza, et al., 2018; Nigh, et al., 2017; Meier and Muntz, 2016; Boneti et al., 2015; Mazzola, et al., 2015).

Professional Societies/Organizations
Professional societies/organizations such as the American Academy of Otolaryngology–Head and Neck Surgery do not give specific recommendations for autologous fat injections for the treatment of VPI such as a formal guideline or a position statement could not be found.

Facial Lipodystrophy Syndrome

Facial lipodystrophy syndrome (LDS) is characterized by a localized loss of fat from the face, resulting in excessively sunken cheeks. The condition may occur as a side effect of antiretroviral therapy used in the HIV infection treatment regimen. Facial LDS can be socially stigmatizing and may impact patients' adherence to highly active antiretroviral therapy (HAART), psychological health, and quality of life (QoL), including feelings of distress, depression, anxiety, social isolation, and career barriers. Although new HAART medications are associated with less severe facial LDS, the prevalence of HIV facial LDS among treated individuals exceeds 50%. Treatment of HIV facial LDS is linked to improvement in the QoL of patients in health perception, mental health, social function, and emotional status (Jagdeo, et al., 2015). The FDA has approved two dermal fillers, Sculptra® and Radiesse® that are indicated for facial lipoatrophy, a component of HIV LDS.

U.S. Food and Drug Administration (FDA): On August 3, 2004, the FDA granted PMA device approval for Sculptra® (Dermik Laboratories, Berwyn, PA). According to the FDA, Sculptra is intended for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus (FDA, 2004). Sculptra Aesthetic received FDA PMA approval on July 28, 2009. Sculptra Aesthetic is indicated for use in immune-competent individuals as a single regimen for correction of shallow to deep nasolabial fold contour deficiencies and other facial wrinkles in which deep dermal grid pattern (cross-hatch) injection technique is appropriate (FDA, 2009). Radiesse (Mertz North America, Inc) was granted PMA device approval on December 22, 2006. The device is indicated for subdermal implantation for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus (FDA, 2006).

Literature Review
Moyle et al. (2006) conducted a randomized, open-label, comparative, single-center study that evaluated the safety and efficacy of injected poly-L-lactic acid (PLLA) in the correction HIV-related facial lipoatrophy. Patients (n=30) were randomized to immediate (n=15) or delayed (n=15) PLLA treatment. Patients were included if they were HIV positive, had moderate to severe nasolabial fat

pad loss and no previous treatment for the correction of their HIV associated lipoatrophy. At week 12, immediate treatment patients had significantly better visual analogue scores ($p<0.001$) and lower anxiety scores ($p=0.056$) than delayed-treatment patients. The results persisted until week 24. The study was extended from 24 weeks to 18 months and included a recall visit at 18 months. Twenty-seven patients returned for the recall visit, a minimum of 18 months post final study treatment. Fourteen of these patients were excluded from the recall visit because of additional treatment with PLLA. Improvements in VAS scores for facial appearance were sustained from baseline to the recall visit in both randomization groups ($p<0.05$ and $p<0.001$). The delayed PLLA treatment group also experienced significant improvements in depressive symptoms ($p<0.05$). One case of injection-site induration and nine cases of injection-site nodules were noted at the recall visit, none of which was described as serious or severe. The authors concluded that physical and psychological benefits of PLLA are sustained over 18 months.

Silvers at al. (2006) reported the results of a prospective open-label, multi-center study that evaluated the safety and effectiveness of Radiesse for the treatment of facial lipoatrophy in patients with human immunodeficiency virus (HIV). Patients (n=100) received an initial treatment and six months later, all patients were assessed for the need for a touch up injection. Effectiveness was assessed at three, six and 12 months from initial treatment by means of a Global Aesthetic Improvement Scale (GAIS) rating, cheek skin thickness measurements, and patient satisfaction assessment. Safety was assessed by the recording of adverse events through 12 months. All 100 patients were determined to be improved or better at three months. One hundred percent of assessable patients were rated as improved or better on the GAIS scale at every time point through 12 months; 91% were improved or better at 18 months. Patient satisfaction ranged from 97%–100% at every evaluation through 12 months. In addition, skin thickness measurements at 12 months remained statistically better than those at baseline. Adverse events reported through 12 months were generally mild (ecchymosis, edema, erythema, pain, and pruritus), and short in duration. Mean cheek thickness doubled in six months and was maintained over 12 months.

Several prospective non-randomized trials and systematic reviews have demonstrated Sculptra and Radiesse are effective treatment modalities for human immunodeficiency virus associated facial lipoatrophy, with high rates of facial volume restoration, patient satisfaction and improved quality of life. Results appear to be long lasting and correction can be maintained for up to three years with additional treatment sessions (Vallejo, et al, 2018; Ho & Jagdeo, 2016; Kraus, et al., 2016; Jagdeo, et al., 2015; Shuck, et al., 2013; Levy, et al., 2008; Lafaurie, et al., 2005).

Not Medically Necessary

The use of injectable dermal fillers has aesthetic applications such as providing volume for wrinkles around the eyes, cheeks, lips, and neck, thereby improving appearance. When performed solely for the purpose of altering appearance or self-esteem or to treat psychological symptomatology or psychosocial complaints related to one's appearance, injectable dermal fillers are considered cosmetic and not medically necessary. Examples of indications for which injectable fillers are considered cosmetic include but are not limited to the following:

- body contouring and sculpting
- rhytids (i.e., wrinkles)
- scarring (e.g., due to acne vulgaris)
- tissue volume loss (e.g., due to aging)

Poly-L-lactic acid (PLLA): PLLA (e.g., Sculptra) is a biocompatible polymer that contains microspheres in a powdered form. PLLA is mixed with water or lidocaine prior to injection. Like CaHA, the mechanism of action of PLLA is thought to involve a stimulation of new collagen production while the implant breaks down to lactic acid and is reabsorbed by the body. The average duration of the effect is 12 to 24 months. Indications for PLLA are primarily cosmetic.

Although PLLA is used in a number of surgical procedures, the substance has not been approved by the FDA for vocal cord dysfunction. As such use for this indication would be considered off-label and unproven.

U.S. Food and Drug Administration (FDA): The FDA has approved numerous injectable dermal fillers and volume-producing agents for treatment localized to the face in order to create a smoother appearance. "The Summary of Safety and Effectiveness Data as well as health care provider and patient labeling for each approved dermal filler may be found by searching the 510(k) premarket notification database for product code "LMH" (dermal fillers for the face) and "PKY" (dermal fillers for the hand)" (FDA, 2020).

Professional Societies/Organizations
Professional societies/organizations such as the American Society of Plastic Surgeons (ASPS) and the American Academy of Dermatology (AAD) provide information regarding treatments aimed at improving appearance. Specific recommendations for dermal fillers such as a formal guideline or a position statement could not be found.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (250.5)	7/6/2010
LCD	Wisconsin Physicians Service Insurance Corporation	Cosmetic and Reconstructive Surgery (L39051)	10/13/2024
LCD	CGS Administrators, LLC.	Cosmetic and Reconstructive Surgery (L39506)	5/28/2023
LCD	Palmetto GBA	Cosmetic and Reconstructive Surgery (L33428)	7/29/2021

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Vocal Cord Paralysis

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
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
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) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral

HCPCS Codes	Description
C1878	Material for vocal cord medialization, synthetic (implantable)
J3590	Unclassified biologics
L8607	Injectable bulking agent for vocal cord medialization, 0.1 ml, includes shipping and necessary supplies
Q2026	Injection, Radiesse, 0.1 ml

Velopharyngeal Insufficiency

CPT®* Codes	Description
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
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

Facial Lipodystrophy Syndrome

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
G0429	Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)
Q2026	Injection, Radiesse, 0.1 ml
Q2028	Injection, Sculptra, 0.5 mg

Considered Not Medically Necessary:

CPT®* Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); 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	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof

References

1. American Academy of Dermatology (AAD). Fillers: Overview. © 2025. Accessed on April 2, 2025. Available at URL address: https://www.aad.org/public/diseases/cosmetic-treatments/fillers

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	• No changes to coverage	05/15/2024
Annual Review	▪ Title change	9/15/2025

	▪ Removed policy statement for laryngeal injection of hyaluronic acid with or without lidocaine (e.g. Restylane) ▪ Added policy statement for velopharyngeal insufficiency	