



Clinical Policy: Facial Lipodystrophy Treatments (i.e. Sculptra, Radiesse)

Reference Number: HNCA.CP.MP 193

Last Review Date: 05/19

[Coding Implications](#)

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See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Sculptra is an injectable poly-L-lactic acid implant approved by the FDA for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in individuals with HIV. Radiesse is also FDA approved for the correction of facial lipoatrophy. The principle durable component of Radiesse is synthetic calcium hydroxylapatite. Cosmetic remodeling with these fillers works by temporarily adding volume to facial tissue and restoring a smoother, fuller appearance to the face.

Policy/Criteria

- I. It is the policy of Health Net of California that FDA approved fillers for HIV-associated lipoatrophy are **medically necessary** for HIV-infected individuals with facial lipoatrophy caused by the antiretroviral HIV treatment.

Note:

Treatment for facial lipoatrophy is considered reconstructive surgery and therefore covered under the California Health and Safety Code 1367.63 and California Insurance Code 10123.88 which requires health care service plans and health insurance plans, respectively, to cover reconstructive surgery.

Background

The lipodystrophy syndrome (LDS) is a common adverse effect of human immunodeficiency virus (HIV) treatment with highly active antiretroviral therapy (HAART). Lipoatrophy involves the loss of subcutaneous fat in the face, arms, legs, abdomen, and/or buttocks. Facial lipoatrophy is characterized by loss of the buccal and/or temporal fat pads, leading to facial skeletonization with concave cheeks, prominent nasolabial folds, periorbital hollowing, and visible facial musculature. Atrophy of the buccal fat pads is of particular concern to patients since it gives the appearance of facial wasting and can have an impact on self-esteem; lipoatrophy may also contribute to stigma as it is recognized to be associated with HIV infection. In addition, both lipoatrophy and fat accumulation have been associated with abnormalities in lipid and glucose metabolism, even in the absence of frank obesity.

Therapeutic approaches to lipoatrophy include medical management and surgical interventions. The FDA has approved two temporary fillers for the treatment of HIV-associated lipoatrophy, i.e., Poly-L-lactic acid (PLLA or Sculptra) and Calcium hydroxylapatite (Radiesse). These fillers are reinjected at regular intervals. A typical treatment course of PLLA is three to six injections separated by two or more weeks. The peer review literature supports the use of



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PLLA and Radiesse for HIV-associated facial lipoatrophy. A randomized open-label study reported that at 24 weeks, PLA did not increase facial soft tissue volume (FSTV), although tissue thickness in injection planes increased modestly, an improvement observed by patients. PLLA was safe and well tolerated. Facial lipoatrophy severity and some quality-of-life domains improved. A randomized, open-label, comparative, single-center study of injected PLLA in patients with HIV-related facial lipoatrophy reported physical and psychological benefits of PLLA are sustained over at least 18 months. Delayed adverse events include mild nodularity at the treatment site. Another study with longer follow up concluded that PLLA provides volumetric correction of HIV lipoatrophy. The authors noted results appear to be long lasting and correction can be maintained for up to 3 years with additional treatment sessions. In a subset of patients, correction is maintained for at least 1 year after their last treatment session. Patient satisfaction with PLLA is high. An 18 month, prospective, open-label, multicenter clinical trial of calcium hydroxylapatite for soft-tissue augmentation of patients with facial lipoatrophy concluded that Radiesse is an appropriate and well-tolerated treatment for patients with facial lipoatrophy. The authors noted it demonstrates an excellent safety profile, causes immediate augmentation of the soft tissues, and appears to provide relatively long-lasting improvement in appearance, with very high patient satisfaction.

Coding Implications

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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

HCPCS Codes	Description
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies
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



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HCPCS Codes	Description
Q2027	Injection, Sculptra, 0.1 ml
Q2028	Injection, Sculptra, 0.5 mg

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
B20	Human immunodeficiency virus [HIV] disease
E88.1	Lipodystrophy, not elsewhere classified

Reviews, Revisions, and Approvals	Date	Approval Date
Initial policy	12/04	12/04
Update - Medicare considers FDA approved dermal fillers (i.e., Radiesse, Sculptra) for facial lipodystrophy syndrome (LDS) in HIV infected beneficiaries when facial LDS caused by antiretroviral HIV treatment is a significant contributor to their depression. No change to the policy for commercial members.	02/10	02/10
Revised policy to consider FDA approved fillers for HIV-associated lipoatrophy (i.e., Sculptra, Radiesse) medically necessary in HIV-infected individuals with facial lipodystrophy caused by the antiretroviral HIV treatment	02/13	02/13
Policy adopted from Health Net NMP193 Facial Lipodystrophy Treatments (i.e. Sculptra, Radiesse)	05/17	05/17
Update, added HIV ICD-10 code, no other changes	5/18	5/18
No changes	5/19	5/19

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18. CMS: National Coverage Determination (NCD) for Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (250.5)

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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