KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Dermal Fillers for Facial Lipoatrophy

- Sculptra
- Radiesse

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (250.5)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Dermal filler injections are covered when **ALL** of the following criteria are met:

1) The member has **ALL** of the following:

   a) a diagnosis of human immunodeficiency virus (HIV), and

   b) a diagnosis of facial lipodystrophy/lipoatrophy, grades 3-4*, related to HIV or highly active antiretroviral therapy (HAART), and

AND

2) The dermal filler is approved by the Food and Drug Administration for Facial Lipodystrophy Syndrome (LDS), e.g. Sculptra® and Radiesse®.

Multiple sessions may be necessary to complete the therapy, depending upon the severity of the lipodystrophy. The following link provides examples of the Carruthers grading system*: www.facialwasting.org.

If the patient has:

1) Grade 3 lipodystrophy, up to 4 sessions may be required
2) Grade 4 lipodystrophy, up to 8 sessions may be required

*If additional treatments are desired, the treating provider will need to reevaluate the patient or repeat photos of the patient's face will be required to determine if further treatments are warranted.

Repeat treatment is typically necessary one to two years after the initial therapy, when the patient has regressed to Grade 2 or greater lipoatrophy.

CONTRAINDICATIONS

Coagulopathy, active infection (whether or not related to HIV disease), inadequate immune function as determined by HIV provider.

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If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

HIV-associated lipodystrophy has been reported in the literature starting in the late 1990s. This condition involves loss of subcutaneous fat or fat accumulations in particular regions of the body. It can include fat accumulation around the abdomen, dorsocervical area (buffalo hump) and breast hypertrophy. Regions affected by fat loss (lipoatrophy) include the limbs, buttocks and face, especially the nasolabial regions, the temples and the eye sockets. The condition is different from HIV wasting syndrome that is mainly due to loss of muscle mass. HIV-associated lipodystrophy is also associated with insulin resistance, hyperglycemia and low levels of high-density lipoprotein (HDL) (James et al., 2002).

Although the cause of HIV-associated lipodystrophy is not well understood, some investigators believe there is a link with HIV protease inhibitors (PI). The condition started being reported in the literature around the time that protease inhibitors were introduced and prescribed to HIV-infected patients. In addition, the prevalence of lipodystrophy is higher in HIV-infected patients who received PIs compared to PI-naïve patients (James et al., 2002). Lipoatrophy may be associated with the use of specific nucleosides such as stavudine and didanosine in treatment while lipoaccumulation may be associated with protease inhibitors, especially ritonavir (Dr. Wayne Dodge, personal communication).

The treatment of facial lipoatrophy is the subject of the current MTAC review. There is little published literature on this topic, but anecdotal information suggests that facial lipoatrophy negatively affects HIV-infected individuals' body image and self-esteem and can lead to social and sexual problems. The long-term natural history of lipoatrophy is also not well known. Lipoatrophy does not appear to resolve on its own, or after discontinuation of PIs and other medication (James et al., 2002; Huff, 2004).

Sculptra, an injectable form of poly-L-lactic acid (PLA) is the first FDA-approved treatment for HIV-associated facial lipoatrophy. PLA is a biocompatible, biodegradable substance that is synthetically derived from natural components. It was been used in surgical products such as dissolvable stitches and bone screws. PLA was approved in Europe in 1999 for cosmetic treatment of scars and wrinkles, under the brand name New-Fill. The FDA did not approve Sculptra for the treatment of wrinkles. FDA approval of Sculptra for facial lipoatrophy was based on unpublished data submitted by the manufacturer Dermik Laboratories. A condition of FDA approval was that Dermik agreed to conduct a registry study for five years to evaluate Sculptra's long-term safety (FDA press release; James et al., 2002). Potential limitations of injectable PLA for severe cases of facial lipoatrophy are that large quantities of material are needed to fill the defects and there may be high maintenance costs (Binder & Bloom, 2004).

Medical Technology Assessment Committee (MTAC)

Injectable Poly-L-Lactic Acid (PLA)

12/08/2004: MTAC REVIEW

Evidence Conclusion: There was one randomized controlled trial with 30 patients (Moyle, 2004) and this compared immediate treatment with PLA to delayed treatment after 12 weeks. The 12-week follow-up is the appropriate point in the study to compare treatment with no treatment. At 12 weeks, there were no significant differences between groups in depression or anxiety scores. A significantly greater proportion of patients in the immediate treatment group perceived "less thinness" in the face. The study was limited by the short follow-up period, small sample size with no statistical power analysis and lack of clear primary outcomes. The other empirical study reviewed was a case series with 50 patients (Valentin, 2003). Although there was no comparison group, advantages of the Valentin study were that there was objective measurement of changes in facial thickness and follow-up was longer, 96 weeks. There was a significant increase in total cutaneous thickness (TCT) of the face after a series of treatments with PLA and the increase in TCT persisted until the 96-week follow-up. There was a significant increase in the quality of life score compared to baseline at the 24- and 48 weeks follow-ups, but not at the 72- or 96-week follow-ups. No serious adverse effects were reported in either study. Safety and efficacy beyond 96 weeks is not known. The generalizability of Valentin study has been criticized because one dermatologist performed all of the injections; it is not known whether there would be similar results

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with other dermatologists. In summary, there is some evidence from an uncontrolled case series that treatment with Sculptra can reduce facial lipoatrophy for up to 96 weeks and has no serious adverse effects, when used by a trained dermatologist. There are no good data from controlled studies. The impact on quality of life is less clear. There are no published data on safety and efficacy of Sculptra beyond 96 weeks.

Articles: The search yielded 10 articles. Several were reviews or opinion pieces. Three empirical studies were identified. The ideal study would have the following characteristics: Randomized controlled trial, Comparison of Sculptra to alternative treatment, or placebo, Long-term follow-up, sufficiently large sample size, Important outcomes include whether treatment with Sculptra is effective at increasing facial fat and reduces any adverse psychosocial effects. In this case, there is no standard alternate treatment and no other FDA-approved new treatments for HIV-associated facial lipoatrophy. No placebo-controlled studies were identified. There was one randomized controlled trial that compared immediate treatment with PLA to delayed treatment. There was also a case series with 96 weeks' follow-up. Case series can provide important long-term safety data. The RCT and case series were critically appraised. Both used New-Fill, the European version of PLA. The third empirical study was a case report presenting data on 4 patients and was excluded from review. The following studies were critically appraised: Valantin M-A Aubron-Olivier C, Ghosn J et al. Polylactic acid implants (New-Fill) to correct facial lipoatrophy in HIV-infected patients: results of the open-label study VEGA. AIDS 2003; 17: 2471-2477. **See** Evidence Table. Moyle GJ, Lysakova L, Brown S et al. A randomized open-label study of immediate versus delayed polylactic acid injections for the cosmetic management of facial lipoatrophy in persons with HIV infection. *HIV Medicine* 2004; 5: 82-87. See Evidence Table.

The use of injectable poly-L-lactic acid (PLA) in the treatment of facial lipoatrophy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

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

CPT® or HCPC 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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
12/08/2004	12/08/2004, 07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 01/08/2013MDCRPC, 11/05/2013MPC, 09/02/2014MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC, 12/01/2020MPC, 12/07/2021MPC,12/06/2022MPC	05/04/2021

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
05/04/2021	MPC approved coverage criteria for non-Medicare members. Requires 60-day notice, effective date 10/01/2021.

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