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Northwest Region Utilization Review

UR 57: Facial Dermal Fillers Policy and Medical Necessity Criteria

Departments: Plastic Surgery	Number: UR 57
Section: KPNW Region	Effective: 08/10
Applies to: KPNW Region	Last Reviewed: 6/23
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Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

The purpose of these criteria is to provide coverage of limited facial enhancement to patients with HIV-associated lipodystrophy to alleviate the stigma associated with this condition. Due to their appearance, patients with facial lipodystrophy syndrome (LDS) may become depressed, socially isolated, and in some cases, may stop their HIV treatments to halt or reverse this complication.

Many systemic illnesses cause bodily shape changes. Any weight loss from illness, chemotherapy, or voluntary weight loss will lead to some facial skin sagging. Kaiser Permanente does not cover the correction of these conditions. The specialist administering the injections will use his/her best judgment in determining the difference between HIV lipodystrophy and natural, age-appropriate atrophy and aging. Kaiser Permanente coverage extends to improving the gaunt look of lipodystrophy. Coverage is not meant to be a yearly touch up. Frequency of treatment will be determined by the specialist administering the injections.

DEFINITIONS

Facial Lipodystrophy/lipoatrophy: a progressive, symmetrical loss of subcutaneous fat that results in a facial abnormality such as severely sunken cheeks. This fat loss can be a result of aging or weight loss or can arise as a complication of HIV and/or antiretroviral therapy (ART).

Filler: an injectable substance that fills in hollowed areas created by lipoatrophy.

CRITERIA

Coverage Guidance: Facial dermal fillers may be excluded from coverage. Check CM for exclusions or limitations.

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

Kaiser Permanente Medical Policy for Medicare members	UR 57 does not apply. For Medicare lines of business, apply the criteria in the NCD.
For Medicaid Members	
OR Medicaid	UR 57 does not apply. Check Linefinder.
WA Medicaid	UR 57 does not apply.
For Commercial Members and Self-Funded Members	
OR Commercial	UR 57 applies
WA Commercial	UR 57 applies
Self-Funded Plans	UR 57 applies

Filler injections are covered when the following criteria are met:

1) The member has the following conditions:
   a) diagnosis of human immunodeficiency virus (HIV),

      AND

   b) diagnosis of facial lipodystrophy/lipoatrophy, grades 3-4, related to HIV or antiretroviral therapy (ART).

AND

2) The filler is FDA approved for the treatment of facial lipodystrophy/lipoatrophy or otherwise approved by the KPNW Plastic Surgery Department (e.g., autologous fat transplantation).

CONTRAINDICATIONS

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

OTHER CONSIDERATIONS

Multiple sessions may be necessary to complete the therapy depending upon the severity of the lipodystrophy. Grade 3 may take up to 4 sessions; and Grade 4 may take up to 8 sessions. The following link provides photographic examples of the Carruthers grading system (scale of 1- 4): www.facialwasting.org. If additional treatments are desired, the treating specialist will need to reevaluate the patient or repeat photos of the patient's face will be required to determine if further treatments are warranted. Re-treatment may be needed long term.

CLINICAL

Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations Manual, Chapter 1, part 250.5- Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS)- *Rev. 122, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)*

RATIONALE

BACKGROUND

UpToDate – "Injectable soft tissue fillers: Permanent agents":

- **Surgical approaches:** Plastic surgery is the main therapy for severe facial lipoatrophy; autologous fat transplantation or, more commonly, injections of biodegradable or nonbiodegradable gel fillers can be performed.
- **Fillers:** Plastic surgeons, dermatologists, and others with specific training have treated facial lipoatrophy with various injectable fillers (19,20). Fillers can be temporary or permanent. Overall, temporary fillers are preferred.
- **Autologous fat transplantation:** Autologous fat transplantation involves harvesting of a small intact lump of fatty tissue from the abdomen, cervicodorsal area, or elsewhere that can be processed into small fat "parcels" that are injected by syringe with local anesthesia (47). Use of autologous fat implantation may be less costly than gel fillers but is often limited by the lack of suitable donor sites in patients with extensive lipoatrophy (48).

EVIDENCE BASIS

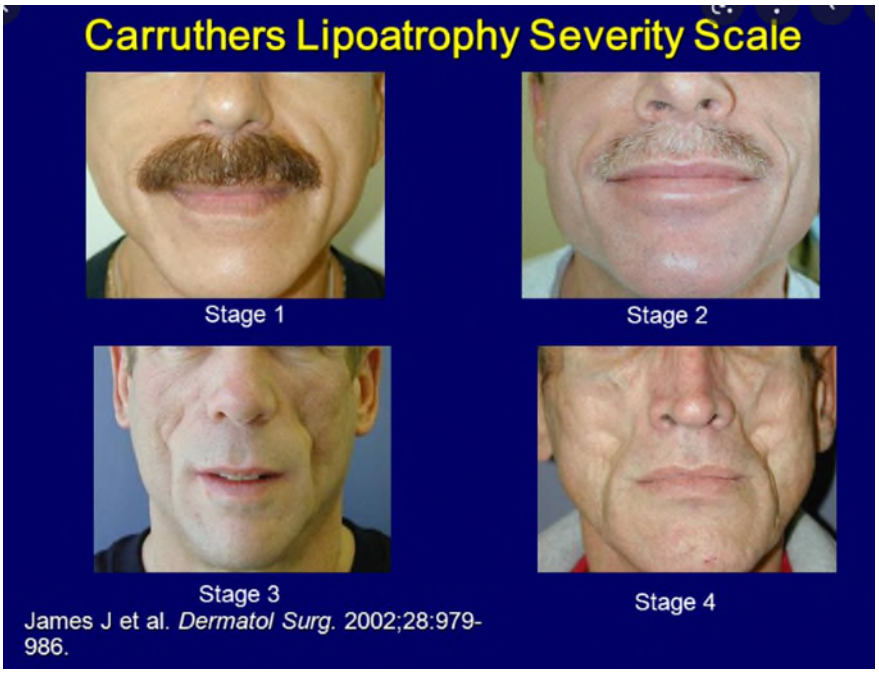
The Kaiser Permanente Interregional New Technologies Committee (INTC) reviewed the evidence on dermal injections for the treatment of facial lipodystrophy syndrome in 2010. A summary of their findings is provided below:

"There is sufficient evidence to determine that polylactic acid dermal filler injections are a medically appropriate treatment for select patients with HIV-associated facial lipoatrophy. The current evidence base consists of one RCT, several comparative studies and additional case series studies indicating improvements in skin thickness measurements and subjective ratings of lipoatrophy, including improved quality of life and patient satisfaction."[1]

The focus of the INTC assessment was on FDA approved dermal fillers (i.e., Sculptra, Radiesse and New-Fill) and did not describe evidence on autologous fat transplantation.

A 2013 systematic review of the durability, safety, and clinical outcomes from autologous fat grafting compared to hyaluronic acid and poly-L-lactic acid injectable fillers included 19 primary studies (12 on hyaluronic/PLLA filler, 7 on autologous fat), none of which made direct comparisons between treatment approaches. All included studies were relatively small in sample size (including fewer than 100 participants) and report a range of outcomes, thus, meta-analysis was not possible. Across studies, there were similar improvements in facial volume and durability of treatment between dermal fillers and fat transfer. However, patients treated with poly-L-lactic acid received more sets of injections than those treated with hyaluronic acid or fat transfer (3 or more sets of injections vs. up to 2 sets of injections, respectively). Studies of autologous fat transfer reported no serious adverse events or papule formation, whereas all reports of papule formation occurred in patients treated with poly-L-lactic acid.[2]

A 2018 prospective study (n=147) comparing Sculptra, Radiesse, Aquamid and autologous fat for treatment of HIV-induced lipoatrophy reports an improvement in self-perceived appearance and impact of lipodystrophy on quality of life in all treatment groups except the Radiesse group.[3]



REFERENCES

1. Kaiser Permanente Interregional New Technologies Committee (2010). Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome.
2. Shuck J, Iorio ML, Hung R, Davison SP. Autologous fat grafting and injectable dermal fillers for human immunodeficiency virus-associated facial lipodystrophy: a comparison of safety, efficacy, and long-term treatment outcomes. *Plast Reconstr Surg*. Mar 2013;131(3):499-506.
3. Vallejo A, Garcia-Ruano AA, Pinilla C, Castellano M, Deleyto E, Perez-Cano R. Comparing Efficacy and Costs of Four Facial Fillers in Human Immunodeficiency Virus-Associated Lipodystrophy: A Clinical Trial. *Plast Reconstr Surg*. Mar 2018;141(3):613-623.