

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline

WellCare Prescription Insurance, Inc.



*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*



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Harmony Behavioral Health, Inc.

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WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (FLS)

Guideline Number: HS-134

Original Effective Date: 10/1/2009

Revision Date: n/a

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Dermal filler injections (Sculptra™, Radiesse®; see below) for the treatment of facial lipodystrophy syndrome (FLS) in HIV-positive members and members with Acquired Immune Deficiency Syndrome (AIDS) is considered medically necessary.

The injection of the dermal fillers poly-L-lactic acid (Sculptra™, Dermik Laboratories: sanofi-aventis, U.S. LLC., Bridgewater, NJ), and synthetic calcium hydroxylapatite, (Radiesse®, BioForm Medical, Inc., San Mateo, CA) is considered **reconstructive** when used to address a significant variation from normal related to the progression of the disease or treatment of the disease.

BACKGROUND

Some medical conditions may result in a condition called lipoatrophy, characterized by facial wasting of fat under the skin of the face and other parts of the body. Treatment of persons infected with the human immunodeficiency virus (HIV) or persons who have Acquired Immune Deficiency Syndrome (AIDS) may include highly active antiretroviral therapy (HAART). Drug reactions commonly associated with long-term use of HAART include metabolic complications such as, lipid abnormalities, e.g., hyperlipidemia, hyperglycemia, diabetes, lipodystrophy and heart disease. There is fat wasting in some areas and increased deposits of fat in other areas. Lipoatrophy occurs when there is a loss of subcutaneous tissue. Facial lipodystrophy syndrome (FLS) is often characterized by a loss of fat that results in a facial abnormality such as severely sunken cheeks. This fat loss can arise as a complication of HIV and/or HAART. Due to their appearance and stigma of the condition, patients with FLS may become depressed, socially isolated and in some cases may stop their HIV treatments in an attempt to halt or reverse the complication. There are no health problems related specifically to this condition.

Reconstructive treatments involving the injection of dermal fillers such as poly-L-lactic acid implant (Sculptra) or synthetic

calcium hydroxylapatite (Radiesse) are available. Poly-L-lactic acid is a biodegradable synthetic substance used in the manufacture of absorbable stitches and implantable medical devices. Sculptra is an injectable form of this material injected under the skin of a patient with lipoatrophy to restore a more normal facial or body contour. Radiesse, a semi-solid, cohesive implant whose principle component is a synthetic calcium hydroxylapatite suspended in a gel carrier, is also injected subdermally for restoration, or correction, or both for lipoatrophy in members with HIV.

CODING

Covered CPT Codes

- 11950** Subcutaneous injection or filling material 1cc or less
- 11951** Subcutaneous injection or filling material 1.1 cc to 5.0cc
- 11952** Subcutaneous injection of filling material 5.1 cc to 10.0cc
- 11954** Subcutaneous injection of filling material over 10.00cc

ICD-9-CM Procedure Codes

- 86.99** Other operations on skin and subcutaneous tissue, i.e. Injection of filler material

HCPCS Code

- S0196+** Injectable poly-L-lactic acid, restorative implant, (Sculptra) 1 ml, face (deep dermis, subcutaneous layers)
+Non-covered by Medicare – See HCPCS Level II Temporary National Codes Non-Medicare)

NOTE: There is no designated HCPCS code for synthetic calcium hydroxylapatite (Radiesse)

Covered ICD-9-CM Diagnosis Codes

Both of the following diagnoses must be present to meet medical necessity, as per the criteria above.

- 042** HIV
- 272.6** Lipodystrophy

***Current Procedural Terminology (CPT) 2009 American Medical Association: Chicago, IL.**

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS) NCA Tracking Sheet for Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (FLS) (CAG-00412N). Jul 16, 2009.
2. Lafaurie M, Dolivo M, Porcher R, et al. Treatment of facial lipoatrophy with intradermal injections of polylactic acid in HIV-infected patients. J Acquir Immune Defic Syndr. 2005; 38(4):393-398.
3. Alam M, Dover JS. Management of complications and sequelae with temporary injectable fillers. Plast Reconstr Surg. 2007; 120(6 Suppl):98S-105S.