DERMAL INJECTIONS FOR THE TREATMENT OF
FACIAL LIPODYSTrophy SYNDROME (FLS)
HS-134

Easy Choice Health Plan, Inc.
Harmony Health Plan of Illinois, Inc.
Missouri Care, Inc.
‘Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.
WellCare Health Insurance of Illinois, Inc.
WellCare Health Plans of New Jersey, Inc.
WellCare Health Insurance of Arizona, Inc.
WellCare of Florida, Inc.
WellCare of Connecticut, Inc.
WellCare of Georgia, Inc.
WellCare of Kentucky, Inc.
WellCare of Louisiana, Inc.
WellCare of New York, Inc.
WellCare of South Carolina, Inc.
WellCare of Texas, Inc.
WellCare Prescription Insurance, Inc.
Windsor Health Plan
Windsor Rx Medicare Prescription Drug Plan

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.
DISCLAIMER

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. Note: The lines of business (LOB) are subject to change without notice; consult www.wellcare.com/Providers/CCGs for list of current LOBs.

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.¹²³

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.

Effective for claims with dates of service on and after March 23, 2010, dermal injections for LDS are only reasonable and necessary using dermal fillers approved by the Food and Drug Administration (FDA) for this purpose, and then only in HIV-infected beneficiaries when LDS caused by antiretroviral HIV treatment is a significant contributor to their depression. (CMS, 2010).²³⁴

Recombinant human growth hormone (rhGH) is used in the treatment of AIDS-associated wasting and lipodystrophy; tesamorelin, an analog of growth hormone–releasing factor (GHRF), is used for treatment of AIDS-associated lipodystrophy. The goal of these treatments is to increase lean body mass in patients with human immunodeficiency virus (HIV)-associated wasting and to reduce AIDS-related abnormal morphologic and metabolic changes in HIV patients with lipodystrophy.⁵

Based on the findings of 10 studies, GH axis treatments are effective in reducing VAT and increasing LBM in patients with HIV-associated lipodystrophy. However, clinicians must decide whether the attributed benefits are clinically significant, considering the costs and potential risks of GH axis treatments. A limitation of this study is the small number of studies available of each GH axis drug class.⁷ Treatment with tesamorelin reduces VAT and maintains the reduction for up to 52 wk, preserves abdominal sc adipose tissue, improves body image and lipids, and is overall well tolerated without clinically meaningful changes in glucose parameters.⁸ Tesamorelin is effective in improving visceral adiposity and body image in patients with HIV-associated lipodystrophy over 26-52 weeks of treatment. Potential limitations for its use include high cost and lack of long-term safety and adherence data. Tesamorelin provides a useful treatment option for management of patients with significant lipodystrophy related to HIV infection.⁹
POSITION STATEMENT

Applicable To:
- Medicaid – All Markets
- Medicare – All Markets

Dermal filler injections (e.g., Sculptra™, Radiesse®) for the treatment of facial lipodystrophy syndrome (FLS) in HIV-positive members and members with Acquired Immune Deficiency Syndrome (AIDS) is considered medically necessary. In addition, rhGH (Serostim®)* and growth hormone releasing factor (GHRF) (Egrifta / tesamorelin) injections are also considered medically necessary. All products must be approved by the Food and Drug Administration Members must meet the following criteria for dermal injections:

1. Have a diagnosis of HIV or AIDS; and
2. Have a diagnosis of facial lipodystrophy syndrome (FLS).

The injection of the dermal fillers poly-L-lactic acid (Sculptra™, Dermik Laboratories: sanofi-aventis, U.S. LLC., Bridgewater, NJ), and synthetic calcium hydroxyapatite, (Radiesse®, BioForm Medical, Inc., San Mateo, CA) is considered reconstructive and not a covered benefit when used to address a significant variation from normal related to the progression of the disease or treatment of the disease.

Non-Covered Indications

1. Dermal fillers that are not approved by the FDA for the treatment of LDS
2. Dermal fillers that are used for any indication other than LDS in HIV-infected individuals who manifest depression as a result of their antiretroviral HIV treatments

Contraindications

Egrifta (tesamorelin) is contraindicated for those who have or had:

- Cancer (including those currently receiving treatment);
- Diabetes;
- Kidney or liver problems;
- Head trauma or head irradiation;
- Disruption of hypothalamic-pituitary axis due to hypophysectomy;
- A pituitary gland tumor, pituitary gland surgery or other problems related to the pituitary gland (including hypopituitarism); OR,
- Any other medical condition

Egrifta (tesamorelin) should not be used by women who:

- Are or may be pregnant;
- Are breastfeeding or plan to breastfeed (it is unknown if the drug passes through breast milk)*;

NOTE: The Centers for Disease Control and Prevention (CDC) recommends that HIV-infected mothers not breastfeed to avoid the risk of passing HIV infection to your baby. Talk with your healthcare provider about the best way to feed your baby if you are taking EGRIFTA®

CODING

Covered CPT© Codes
11950 Subcutaneous injection or filling material 1 cc or less
11951 Subcutaneous injection or filling material 1.1 cc to 5.0 cc
11952 Subcutaneous injection of filling material 5.1 cc to 10.0 cc
11954 Subcutaneous injection of filling material over 10.0 cc
Covered HCPCS Level II © Code
C9800 Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sulphra dermal filler, including all items and supplies
G0429* Dermal Filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) as a result of highly active antiretroviral therapy
J2941 Injection, somatropin, 1mg (Use this code for Serostim)
J3490 Unclassified drugs (Use this code for Egrifta (tesamorelin))

Note: S-Codes are NON COVERED FOR MEDICARE. For Medicare, bill the appropriate CPT code listed above.

Covered ICD-9-CM Procedure Codes
83.98 Injection of locally-acting therapeutic substance into other soft tissue

Covered DRAFT ICD-10-PCS Codes
3E013GC Administration, Physiological Systems & Anatomical Regions, Introduction, Subcutaneous Tissue, Percutaneous

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

Covered DRAFT ICD-10-CM Diagnosis Codes
Both of the following diagnoses must be present to meet medical necessity, as per the criteria above:
B20 HIV
E88.1 Lipodystrophy


REFERENCES

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>8/6/2015</td>
<td>Approved by MPC. Clarified non covered indications; added criteria for Egrifta (tesamorelin).</td>
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<tr>
<td>10/2/2014</td>
<td>Approved by MPC. No changes.</td>
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<tr>
<td>12/1/2011</td>
<td>New template design approved by MPC.</td>
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<tr>
<td>9/15/2011</td>
<td>Approved by MPC.</td>
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<td>Added claims item by CMS stating dermal filters must be FDA-approved and only in HIV-infected individuals when LDS caused by antiretroviral HIV treatment is significant contributor to depression.</td>
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