



Easy Choice Health Plan

Harmony Health Plan of Illinois

Missouri Care

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

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

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

Policy Number: HS-134

Original Effective Date: 10/1/2009,

Revised Date(s): 10/29/2010; 9/15/2011;
10/4/2012; 10/3/2013; 10/2/2014; 8/6/2015;
6/1/2017; 5/3/2018

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 (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). 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 CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

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. ^{1,2,3}

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). ^{2,3,4}

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

Exclusions²

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

Contraindications⁶

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®

Coverage

Dermal filler injections (e.g., Sculptra™, Radiesse®) and autologous fat transfers for the treatment of facial lipodystrophy syndrome (FLS) in HIV-positive members and members with Acquired Immune Deficiency Syndrome (AIDS) **are 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).

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

Covered HCPCS Level II © Code

- 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))
Q2026 Injection, Radiesse, 0.1 ml
Q2028 Injection, Sculptra, 0.5 mg

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

Covered ICD-10-PCS Codes

- 3E013GC** Introduction of Other Therapeutic Substance into Subcutaneous Tissue, Percutaneous Approach

Covered 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

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

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7. Sivakumar T, Mechanic O, Fehmie DA, et al. Growth hormone axis treatments for HIV-associated lipodystrophy: a systematic review of placebo-controlled trials. HIV Med. 2011;12(8):453-62.
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MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
5/3/2018	<ul style="list-style-type: none"> • Approved by MPC. No changes.
6/1/2017	<ul style="list-style-type: none"> • Approved by MPC. Removed statement about non-covered benefit and added fat trasfers to covered benefits.
8/6/2015	<ul style="list-style-type: none"> • Approved by MPC. Clarified non covered indications; added criteria for Egrifta (tesamorelin).
10/2/2014, 10/3/2013	<ul style="list-style-type: none"> • Approved by MPC. No changes.
10/4/2012	<ul style="list-style-type: none"> • Approved by MPC. Added Hayes (2012) reference; inclusion of rhGH and GHRF type injections.
12/1/2011	<ul style="list-style-type: none"> • New template design approved by MPC.
9/15/2011	<ul style="list-style-type: none"> • Approved by MPC. • 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.