



**EFFECTIVE DATE:** 12|07|2010  
**POLICY LAST UPDATED:** 11|05|2019

## OVERVIEW

An injectable filler is a substance that can be injected under the skin. The filler raises the outlying skin and can improve the appearance of sunken areas of the face due to facial lipodystrophy syndrome.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Prior authorization is not required.

## POLICY STATEMENT

### BlueCHiP for Medicare

Radiesse® and Sculptra® are considered medically necessary for facial lipodystrophy syndrome (LDS) only in HIV-infected members when facial LDS caused by antiretroviral HIV treatment is a significant contributor to their depression.

### Commercial Products

Although approved by the U.S. Food and Drug Administration (FDA), Radiesse and Sculptra are not covered as these services are considered cosmetic and Blue Cross & Blue Shield of Rhode Island does not cover cosmetic services.

**Note:** Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations for benefits/coverage when services are not covered.

## BACKGROUND

Facial lipoatrophy is characterized by the loss of fat underneath the skin, and can result in sunken cheeks, hollow eyes, and indentations.

### Calcium Hydroxylapatite (Radiesse®)

Radiesse is a sterile, latex-free, non-pyrogenic, semi-solid, cohesive subdermal implant used to reduce the appearance of wrinkles and skin folds around the mouth and nose, as well as fill certain scars. The filler is biocompatible, non-toxic, and non-allergenic. Typical results last for six months or more.

Although not recommended around the lips because of its larger particle size, Radiesse is FDA approved for medical purposes and is used off-label for cosmetic treatment.

### **Injectable poly-L-lactic acid (Sculptra®)**

Sculptra is an FDA-approved biodegradable, biocompatible synthetic polymer injectable implant. The implant induces the synthesis and deposition of the body's own collagen, therefore improving the appearance of sunken areas of facial tissue restoring the shape and contour to pre-facial lipoatrophy. Typically the initial treatment lasts about one year.

### **BlueCHiP for Medicare**

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. Lipodystrophy is characterized by abnormal fat distribution in the body.

The LDS is often characterized by a loss of fat that results in a facial abnormality such as severely sunken cheeks. The patient's physical appearance may contribute to psychological conditions (e.g., depression) or adversely impact a patient's adherence to antiretroviral regimens (therefore jeopardizing their health) and both of these are important health-related outcomes of interest in this population. Therefore, improving a patient's physical appearance through the use of dermal injections could improve these health-related outcomes.

The following are considered non-covered indications:

- Dermal fillers that are not approved by the FDA for the treatment of LDS.
- 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.

### **CODING**

The following codes are covered for BlueCHiP for Medicare for the indications noted in the policy statement and not covered for Commercial Products:

**Q2026** Injection, Radiesse, 0.1 ml

**Q2028** Injection, Sculptra, 0.5 mg

### **RELATED POLICIES**

Not applicable

### **PUBLISHED**

Provider Update, January 2020

Provider Update, January 2019

Provider Update, February 2018

Provider Update, July 2016

Provider Update, November 2015

### **REFERENCES**

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (250.5)
2. BioForm Medical, Inc. Radiesse® Dermal Filler. Retrieved on 11/5/10 from: <http://www.radiesse-fl.com/>.
3. Comite SL, Liu JF, Balasubramanian S, Christian MA. Treatment of HIV-associated facial lipoatrophy with Radiance FN™ (Radiesse™). *Dermatology Online Journal*;10(2):2.
4. Fuller, Jon. *A 39-Year-Old Man With HIV-Associated Lipodystrophy*. *The Journal of the American Medical Association*;2008;300(9):1056-1066.

5. Morse CG, Kovacs JA. *Metabolic and Skeletal Complications of HIV Infection The Price of Success*. The Journal of the American Medical Association; August 16, 2006; 296(7):844-854.
6. Sanofi-aventis U.S. LLC. Sculptra Aesthetic. Retrieved on 11/5/10 from: <http://www.sculptraaesthetic.com/>.
7. Parkman HP, Miller MA, Trate D et al. Electrogastrography and gastric emptying scintigraphy are complementary for assessment of dyspepsia. *J Clin Gastroenterol* 1997; 24(4):214-9.
8. Brzana RJ, Koch KL, Bingaman S. Gastric myoelectrical activity in patients with gastric outlet obstruction and idiopathic gastroparesis. *Am J Gastroenterol* 1998; 93(10):1803-9.

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