Subject: Facial Lipodystrophy Treatments (i.e. Sculptra, Radiesse)

Policy Number: NMP193

Effective Date*: December 2004

Updated: May 2016

This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

For Medicaid Plans: Please refer to the appropriate State’s Medicaid manual(s), publication(s), citation(s), and documented guidance for coverage criteria and benefit guidelines prior to applying Health Net Medical Policies

The Centers for Medicare & Medicaid Services (CMS)
For Medicare Advantage members please refer to the following for coverage guidelines first:

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**Current Policy Statement**

Health Net, Inc. considers FDA approved fillers for HIV-associated lipoatrophy (i.e., Sculptra, Radiesse) medically necessary in HIV-infected individuals with facial lipodystrophy caused by the antiretroviral HIV treatment.

**Note:**

Treatment for facial lipodystrophy is considered reconstructive surgery and therefore covered under the California Health and Safety Code 1367.63 and California Insurance Code 10123.88 which requires health care service plans and health insurance plans, respectively, to cover reconstructive surgery.
Facial Lipodystrophy Treatments (i.e. Sculptra and Radiesse)  May 16

Abbreviations
HIV  Human immunodeficiency virus
FSTV  Facial soft tissue volume
PLA  Poly-L-lactic acid
HAART  Highly active antiretroviral therapy
FLA  Facial lipoatrophy
LDS  Lipodystrophy syndrome
RCT  Randomized controlled trial
FSTV  Facial soft tissue volume
QoL  Quality of Life

Codes Related To This Policy
NOTE:
The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures have been replaced by ICD-10 code sets.

ICD-9 Codes
272.6  Lipodystrophy

ICD-10 Codes
E88.1  Lipodystrophy, not elsewhere classified

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 10.00cc
11954  Subcutaneous injection of filling material OVER 10.00cc

HCPCS Codes
C9800  Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies
G0429  Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)
Q2026  Injection, Radiesse, 0.1 ml
Q2027  Injection, Sculptra, 0.1 ml (Code deleted in 2014)
Q2028  Injection, Sculptra, 0.5 ml

Scientific Rationale – Update May 2015
Duracinsky et al (2014) sought to establish, in real life conditions and in a large sample, the safety of PLLA (New Fill, Valeant US, Sinclair Pharma Paris, France) to correct facial lipoatrophy among HIV-positive patients. A longitudinal study was conducted between 2005 and 2008 in France. Data from 4,112 treatment courses (n=4,112 patients) and 15,665 injections sessions (1 to 5 injection sessions per treatment course) were gathered by 200 physicians trained in the use of PLLA. The average age of patients (88.3% males) treated for lipoatrophy was 47.1±8.1
years (Mean±SD); 91.2% of patients had been receiving ARV treatment for 10.9
(±4.2) years; CD4 T-cell count was 535±266 cells/mm3. The duration of facial
lipoatrophy was 5±2.8 years and the severity was such that 47.3% of patients
required five injection sessions of PLLA and 81.9% of the sessions required two vials
of the preparation. The final visit, scheduled two months after the last injection
session, was attended by 66.0% of patients (n=2,713). 48 treatment courses
(2.8%) were discontinued due to adverse events (AEs). The overall incidence of AEs
per course was 18.8%. Immediate AEs, bleeding (3.4%), bruising (2.3%), pain
(2.0%), redness at injection site (1.6%), and swelling of the face (0.7%), occurred
in 15.4% of courses and 7.0% of sessions (usually during the first session). Non-
immediate AEs, mainly nodules (5.7%), inflammation (0.7%), granuloma (0.3%),
Discoloration (0.2%), and skin hypertrophy (0.1%), occurred in 6.7% of courses.
Non-immediate AEs occurred within a time ranging from 21 days (inflammation) to
101 days (granuloma) and all but three of the 13 cases of granuloma resolved.
Product efficacy was rated satisfactory by 95% of the patients and physicians. The
authors concluded this study demonstrated, in real-life conditions and on a large
sample, that PLLA injections were feasible, efficient, and safe when performed by
trained physicians.

Scientific Rationale – Update May 2013
Duracinsky et al (2013) sought to describe change in quality of life (QoL) of HIV
patients treated with NEW-FILL (Sculptra is marketed as New-Fill in Europe) in the
management of facial lipoatrophy; efficacy of NEW-FILL using facial photographs and
a patient-reported "Overall Treatment Effect" (OTE) scale; and safety of NEW-FILL.
Doctors from 13 treatment centers recruited 230 HIV patients to receive up to 5
sessions of NEW-FILL injections. Patients self-reported QoL with the ABCD
questionnaire before the first set of injections, at 2 months and at 12 to 18 months
after the last session of injections. Efficacy was evaluated at each interval through
photographs and OTE scale. Safety was evaluated via Case Report Form (CRF) data.
64.4% of patients reported QoL improvements of >10% at 2 months, and 58.8% at
12-18 months. Lipoatrophy grades improved at each visit ("no lipoatrophy" or
"limited lipoatrophy": 20.3% at inclusion, 77.4% at 2 months, 58.4% at 12-18
months). Average OTE scores of 5.3 and 5.0 at 2 and 12-18 months indicated
"moderate improvement". Minimum Important Difference (MID) in QoL score was 7.1
points at 2 months; 7.4 points at 12-18 months. For 911 injection sessions
performed, 3.4% resulted in "immediate" adverse events, 7% in "non-immediate"
events, and 1.7% in "other" events. Investigators concluded improvements to
quality of life and diminished lipoatrophy visibility were observed in the months
immediately following NEW-FILL treatment and were maintained 12-18 months post-
treatment. Most adverse events were mild and transient. ABCD MID thresholds
provide clinicians with means to assess the impact of lipoatrophy therapies on QoL.

Shuck et al (2013) sought to identify the most clinically durable and efficient way of
addressing facial lipoatrophy, reviewing all available evidence for the use of
injectable dermal fillers and autologous fat transfers as treatment modalities,
focusing on safety, outcomes, and long-term durability. A systematic review of the
Cochrane and MEDLINE databases for autologous fat transfer and injectable dermal
fillers for the treatment of human immunodeficiency virus-associated lipodystrophy
was performed. Based on U.S. Food and Drug Administration approval in human
immunodeficiency virus lipoatrophy, studies were limited to the use of hyaluronic
acid and/or poly-L-lactic acid. Facial volume, subjective patient satisfaction,
standardized outcome scales, reinjection rates, and complications were recorded.
Nineteen studies were included representing 724 patients, with 549 patients in the hyaluronic acid/poly-L-lactic acid cohort and 175 in the autologous fat transfer cohort. Improvements in facial volume and durability of treatment were similar between dermal fillers and fat transfer, as measured by both objective means and subjective patient outcomes. However, poly-L-lactic acid was reinjected at a rate three times that of autologous fat, and was associated with a relatively high rate of subcutaneous papule formation at 22 percent (range, 3 to 44 percent). The reviewers concluded dermal fillers and autologous fat transfer are effective treatment modalities for human immunodeficiency virus-associated facial lipoatrophy, with high rates of facial volume restoration and patient satisfaction. Autologous fat transfer may offer similar to superior long-term durability but with less of a financial burden compared with injectable fillers.

Scientific Rationale – Update May 2010
Lipodystrophy syndrome (LDS) is a common adverse effect of HIV treatment with highly active antiretroviral therapy (HAART). The LDS characteristically causes loss of facial fat from the cheeks giving the face a hollow appearance with thinning of the overlying skin. As the condition progresses, underlying musculature may appear more prominent with the overall impression of premature aging or illness. The fat lost from the face may redistribute to other parts of the body such as abdomen, neck and breasts. Atrophy of the arms and legs may also occur. Patients have reported feeling stigmatized by these changes, particularly if their HIV status has not been disclosed previously, and believe their relationships with others are adversely affected. LDS may contribute to psychological conditions, such as depression or adversely impact a patient’s adherence to antiretroviral regimens, thus jeopardizing his or her health. In addition, the metabolic derangements associated with lipodystrophy may predispose patients to accelerated atherosclerosis and diabetes mellitus. Therapeutic interventions to address HIV-associated lipodystrophy have the potential to favorably affect metabolic parameters and ultimately reduce the risk of atherosclerosis and diabetes.

Therapeutic approaches to lipoatrophy include medical management and surgical interventions. One option is to switch from a thymidine analogue NRTI (ie, stavudine or zidovudine) to an alternative agent, such as abacavir or tenofovir to reverse, or slow progression, of lipoatrophy. However, Abacavir use may be associated with increased risk of myocardial infarction, especially in patients with multiple cardiovascular risk factors. Another option includes switching to a protease inhibitor-containing, nucleoside-sparing regimen, however, this may be accompanied by a significant increase in triglycerides and total cholesterol.

Surgical options include treatment with various injectable fillers. Permanent fillers are synthetic materials that are designed to permanently fill in the space vacated by loss of facial fat. Permanent fillers, none of which are approved by the FDA for dermal augmentation, include purified silicone oil, polymethylmethacrylate, polyalkylamide, and polytetrafluoroethylene. Two temporary fillers, reinjected at regular intervals, that are FDA approved specifically for HIV-associated lipoatrophy, include Poly-L-lactic acid (PLLA or Sculptra) and Calcium hydroxylapatite (Radiesse). A typical treatment course of PLLA is three to six injections separated by two or more weeks. Local adverse effects lasting several days, including bruising and edema, are common. Up to half of patients develop subcutaneous papules at the injection site a median of seven months after the initial injection, and one quarter to one half of these papules resolve spontaneously. Local adverse effects to Radiesse are generally mild and short-lived and included ecchymosis, edema, erythema, pain, and pruritus.
It is proposed that the use of dermal injections improves the patient’s facial appearance and thus improves health related outcomes such as depression and adherence to antiretroviral regimens. According to the Centers of Medicare and Medicaid Services (CMS), when the treatment of HIV with highly active antiretroviral therapy (HAART) leads to facial lipoatrophy (FLA), it is the facial appearance caused by FLA that contributes to depression and related adverse psychological issues. In July 2009, CMS opened a national coverage analysis for the use of dermal injections for the treatment of facial facial lipodystrophy syndrome (LDS) in HIV infected persons. CMS focused its review on literature that reported psychological outcomes and outcomes related to medication adherence. They noted that while facial measurements and subjective measures of appearance are often reported, they do not necessarily correlate with psychological issues or medication adherence.

Medicare’s review included publications that report other health related outcomes and not solely intermediate measures. After examining the available medical evidence, CMS issued a decision stating that dermal injections for facial lipodystrophy syndrome (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 facial LDS caused by antiretroviral HIV treatment is a significant contributor to their depression. All other indications are noncovered.

Sturm et al (2009) assessed the safety and efficacy of injectable semi-permanent and permanent dermal fillers, compared to other facial augmentation techniques, for the management of facial lipoatrophy as a result of highly active antiretroviral therapy (HAART) for HIV infection through a systematic review of the literature. One randomized controlled trial (RCT), one pseudo-RCT, two nonrandomized comparative studies, and seven case series were included for review. Injections with permanent and semi-permanent dermal fillers improved subjective ratings of appearance and resulted in high patient satisfaction. Although short-term safety appeared favorable, of the seven studies that reported lumps, three studies reported these events in more than 40% of patients. Long-term safety data is lacking. The reviewers concluded that evidence suggests that permanent and semi-permanent dermal fillers achieve their objective, which is to decrease the visible effects of HIV-associated facial lipoatrophy, with high patient satisfaction. They note, safety appears favorable in the short term, but further studies are required to determine long-term outcomes.

Mest et al (2009) evaluated the long-term safety, duration of effect, and satisfaction with serial injections of injectable poly-l-lactic acid (PLA) for HIV-associated facial lipoatrophy in a single-site, open-label, retreatment study of 65 HIV-positive patients. Individuals were treated with injectable PLA every 5 weeks (until optimal recorrection). Presenting degree of lipoatrophy based on the James scale (1=mild, 4=severe) was reviewed. Skin thickness was measured at fixed points with calipers. Patients completed a post-retreatment satisfaction questionnaire. The investigators reported nearly 10% of patients had persistent correction >36 months, based on patient report. Approximately 50% required three or fewer retreatments to maintain satisfactory correction (determined by patient and physician). Milder lipoatrophy on initial presentation required fewer retreatments and had more sustained correction. Time to first retreatment varied according to James scale score: 1 (21.4 months) and 4 (13.0 months). The mean patient satisfaction score was 4.9 (1=dissatisfied, 5=very satisfied) at study end. No serious adverse events were reported. The authors concluded injectable PLA is a safe and effective long-term treatment option for HIV-associated lipoatrophy.

Facial Lipodystrophy Treatments (i.e. Sculptra and Radiesse) May 16 6
Carey et al (2009) reported Poly-l-lactic acid (PLA) injections modestly increase objectively assessed facial thickness but not facial soft tissue volume (FSTV) over 24 weeks. HIV-infected lipoatrophic adults were randomized to four open-label PLA treatments administered every 2 weeks from week 0 (immediate group, n=50) or from week 24 (deferred group, n=50). Endpoints included FSTV assessed by computed tomography, facial lipoatrophy severity, quality of life (QoL) and safety. Analyses were by intention to treat. The investigators reported between weeks 24 and 48, soft tissue thickness increased modestly in injection planes, at the maxillary [mean 0.9 mm; 95% confidence interval (CI) 0.3-1.5 mm; P=0.007] and base of nasal septum levels (mean 0.4 mm; 95% CI 0.1-0.8; P=0.021), but not in untreated areas (P=0.79 and P=0.24). PLA durability assessed at week 48 in immediate group participants showed a mean change in FSTV of 14 cm(3) (95% CI-1 to 29 cm(3); P=0.060) and increased tissue depth at the maxillary (P<0.0001), base of nasal septum (P<0.0001) and mandibular (P=0.0035) levels. At week 48, clinicians and patients subjectively assessed facial lipoatrophy severity as reduced in immediate participants (83 and 91%, respectively), and the Mental Health scale score of the Short Form-36 Health Survey improved significantly in immediate participants relative to deferred participants. Subcutaneous injection-site nodule incidence at 48 weeks was 10%. The investigators concluded PLA treatment benefits were durable, with objectively assessed modest increases in facial volume and tissue thickness sustained over 48 weeks in injection planes but not in other facial areas. Improvements in some QoL domains were maintained.

Ong et al (2009) reported on one hundred consecutive patients who had a course of Polylactic acid (PLA) facial implants. All patients were assessed clinically and had photographs, facial surface laser scans and completed psychological questionnaires throughout the course of treatment. After a mean of 4.85 treatments per patient, there were improvements in all measures. The mean clinical scores improved from a moderate-severe grade to none-mild grade after treatment. Three-dimensional (3D) laser surface scans showed a volume increase of 2.81 cc over the treated area of the cheek. There were significant improvements in all of the psychological measures. The investigators reported this study shows clear objective evidence of the psychological and physical benefit of PLA implants in HIV-associated facial lipodystrophy.

Levy et al (2008) evaluated the long-term efficacy and safety of PLA during 3 years of follow-up in a prospective cohort study. Primary outcome measures were facial lipoatrophy score, complications, and patient satisfaction. In all, 65 patients were initially treated with PLA; 27 patients were HIV positive and 38 were HIV negative (lipoatrophy of aging). Of those patients, 12 were lost to follow-up between years 2 and 3. Both HIV-positive and HIV-negative patients demonstrated statistically significant improvement in facial lipoatrophy score at the end of 3 years; HIV-positive patients had a net improvement of 2.50 points and HIV-negative patients had a net improvement of 1.11 points on the Facial Lipoatrophy Grading Scale. Subgroup analyses revealed no statistically significant difference in facial lipoatrophy score between years 2 and 3 among patients who did not receive treatment during the third year. Complications were rare and included subcutaneous papule formation, which improved spontaneously and partially responded to subcision in one patient. The author concluded that PLA provides volumetric correction of HIV lipoatrophy and lipoatrophy of aging, with long lasting results and correction can be maintained for up to 3 years with additional treatment sessions. In a subset of patients, correction is maintained for at least 1 year after their last treatment session. They also noted patient satisfaction with PLA is high.
Rajagopalan et al (2008) evaluated the impact of lipoatrophy on the health-related quality of life (HRQL) in HIV-infected individuals receiving anti-retroviral treatment (ART). Data from a Consumer Health Sciences Survey collected between November 2003 and January 2006 was utilized and evaluated using analysis of variance with item scores and mental component summary (MCS) and physical component summary (PCS) scores from the Medical Outcomes Trust questionnaire, SF-8 as dependent variables and lipoatrophy as the independent variable controlling for baseline age, sex and ethnicity. Clinical meaningfulness (mean difference divided by population standard deviation, delta/σ) of differences between the groups with and without lipoatrophy was also evaluated. A cohort of 1124 subjects with at least six months of ART was selected based on the availability of data on whether or not lipoatrophy was present. Subjects were primarily male (80%), between the ages of 30 and 60 years (90%), Hispanic (37%) and about 25% each of African American and White. Overall, prevalence of lipoatrophy in this cohort of HIV patients was 18.9%. Statistically significant differences in quality of life (as measured by SF-8 individual item scores and MCS and PCS scores) were observed between the two groups. The differences between the groups in item and summary scores were clinically meaningful in the small to near medium range. The author concluded HIV-infected patients already experience a considerable deficiency in HRQL compared to general population; this study demonstrates that lipoatrophy further enhances that negative impact on HRQL.

In an observational cross-sectional study of 250 patients, Crane et al (2008) sought to determine the association between body morphology abnormalities and depression, examining lipoatrophy and lipohypertrophy separately. Patients completed an assessment including measures of depression and body morphology. Linear regression analysis was used to examine the association between lipoatrophy or lipohypertrophy and depression. Analysis of variance was used to examine the relationship between mean depression scores and lipoatrophy and lipohypertrophy in 10 body regions. Of 250 patients, 76 had lipoatrophy and 128 had lipohypertrophy. Mean depression scores were highest among patients with moderate-to-severe lipoatrophy (16.4), intermediate among those with moderate-to-severe lipohypertrophy (11.7), mild lipohypertrophy (9.9) and mild lipoatrophy (8.5), and lowest among those without body morphology abnormalities (7.7). After adjustment, mean depression scores for subjects reporting moderate-to-severe lipoatrophy were 9.2 points higher, scores for subjects with moderate-to-severe lipohypertrophy were 4.8 points higher, and scores for subjects with mild lipohypertrophy were 2.8 points higher than those for patients without body morphology abnormalities. Facial lipoatrophy was the body region associated with the most severe depression scores (15.5 vs. 8.9 for controls; P=0.03).

Only small studies of PLLA have been performed to date with limited follow-up. There is a paucity of data for women, minorities and the elderly making it difficult to determine the value or possible harms of these treatments for those populations. Most of the published studies are small, lack control groups and only report short term results. Long term safety and efficacy results are lacking. In addition, most studies rely on patient self-assessment of the severity of symptoms to determine both the need for treatment of facial atrophy and the success of treatment.

A clinical trial evaluating the safety, tolerability and extent and duration of improvement in HIV-1 infected subjects with antiretroviral induced facial lipoatrophy, randomised in a 1:1 ratio to receive immediate or deferred deep subcutaneous injections of poly-L-lactic acid (PLA) was terminated due to no change in primary
endpoint at week 48. Subjects in the study received 4 treatments of PLA approximately every 2nd week, either at trial entry or following a delay period of 24 weeks.

**Scientific Rationale – Update July 2009**

In March of 2009, a clinical trial called the Biopsy Study for Sculptra was initiated with the purpose of evaluating evaluate new collagen (the elastic fibers that provide skin with its strength and resilience) formation in the skin following injections of Sculptra (Poly-L-Lactic Acid or PLLA). The secondary objectives of the study are to better understand the human skin responses to Sculptra and to assess the safety of Sculptra injections. It is considered an interventional, non randomized open label, uncontrolled study in which 14 healthy volunteers receive injections with Sculptra and the shin is biopsied at 3, 6 and 12 months to determine the level of the type of collagen that is produced and the degree of inflammation. The estimated study completion date is July 2010.

**Scientific Rationale – Update 2008**

Individuals with lipoatrophy have loss of subcutaneous fat, most noticeably in the limbs, face, and/or buttocks areas. Individuals with human immunodeficiency virus (HIV)-associated lipodystrophy often have low self-esteem as a result of the physical changes in their appearance, especially if they develop facial lipoatrophy. Sculptra is an injectable poly-L-lactic acid implant FDA approved for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in individuals with HIV. Cosmetic remodeling with Sculptra works by temporarily adding volume to facial tissue and restoring a smoother, fuller appearance to the face.

Kavouni et al (2008) analyzed the poly-L-lactic acid treatment protocols of 441 patients with HIV-associated facial lipoatrophy. Product dilution, product volume per session, number of sessions, time between sessions, facial areas treated, plane of injection and incidence of injection-site nodules were recorded. Assessments included the Hospital Anxiety and Depression Scale and the Appearance Satisfaction Questionnaire. During the learning curve 30 patients were treated every 2 weeks for a minimum of three sessions. A 3-ml dilution was used and a total of 5 ml was injected in the deep dermis of the buccal areas. The incidence of nodule formation was 31% and 52% of patients did not achieve resolution of their facial disfigurement. A total of 411 patients were treated every 4 weeks for a minimum of four sessions. A minimum 5-ml dilution was used and a minimum total of 10-ml was injected subcutaneously in the temporal, infraorbital and buccal areas. The incidence of nodule formation was 2.9% and 10% of patients did not achieve resolution of their facial disfigurement. Patient anxiety and depression scores and appearance satisfaction scores improved significantly with treatment.

Carey et al (2007) reports that facial lipoatrophy can stigmatize and can reduce quality of life, self-esteem, and antiretroviral adherence. They investigated HIV-positive adults with moderate/severe facial lipoatrophy randomized to 4 open-label poly-L-lactic acid treatments administered every 2 weeks from week 0 (immediate group, n = 51) or after week 24 (deferred group, n = 50). The primary endpoint was mean change in facial soft tissue volume (FSTV), as assessed by spiral computed tomography. Analyses were by intention to treat. The investigator reported at week 24, poly-L-lactic acid did not increase FSTV, although tissue thickness in injection planes increased modestly, an improvement observed by patients. The immediate group had a greater mean change in soft tissue depth at the maxilla and base of the nasal septum levels. Poly-L-lactic acid did not have an impact on peripheral fat mass,
viral load, or antiretroviral adherence. Patient and physician subjectively assessed facial lipoatrophy severity, 2 of 8 Short Form-36 Health Survey and 2 of 5 Multidimensional Body-Self Relations Questionnaire-Appearance Scales, scores improved significantly. The median duration of treatment-related adverse events was 2 (interquartile range: 1 to 3) days

Recently, the use of poly-L-lactic acid (PLA) treatment has been investigated for lipoatrophy of aging. Hanke et al (2007) investigated sixty-five patients treated with PLA; 27 were HIV positive and 38 were HIV negative. The HIV patients had more severe facial lipoatrophy at presentation and improved more given their level of severity. The HIV positive patients required more treatment sessions and more PLA to reach full correction than the non-HIV patients. Ninety-four percent of all patients had no complications and the effects of PLA were similar in both groups. All complications were temporary and resolved over time. Patient satisfaction metrics indicated that all patients were "very satisfied" with their treatment. The HIV lipoatrophy patients indicated marked quality of life improvement.

Salles et al (2008) evaluated the effect of PLA implant injection for the treatment of sunken nasolabial folds. Ten women with a median age of 54 years were injected with polylactic acid hydrogel (Newfill) in the nasolabial fold area for aesthetic reasons. All the patients underwent one injection per month for 3 months. Evaluation of the results based on clinical examination and photography was performed at each session, at 6 months, and then 36 months after the third session. Injectable PLA was able to correct nasolabial folds successfully with a more lasting result than absorbable fillers commonly used in clinical practice, such as hyaluronic acid and collagen.

**Scientific Rationale**

Lipodystrophy is an undefined syndrome typically associated with HIV positive patients that involves the thinning of the fatty tissue (lipoatrophy) of the face, temples, buttocks, as well as the redistribution of fat to the upper back region (often called a buffalo hump). Lipoatrophy is a common condition among individuals with human immunodeficiency virus (HIV). A sinking of the cheeks, eyes and temples can occur due to the loss of fat tissue under the skin. Current estimates suggest that approximately 30-40% of people taking highly active antiretroviral therapy (HAART) will develop some form of facial wasting, a component of the lipodystrophy syndrome, and that facial fat loss tends to occur quite rapidly, often within three months. How to prevent or reverse facial wasting is not known at present. Consequently, there has been a move towards the use of reconstructive or surgical procedures intended to fill-out sunken cheeks in people with facial wasting.

There are several experimental procedures being used to reduce the visible consequences of facial fat loss. These include: polylactic acid or New Fill; PMMA; Evolution or polyvinyl/polyacramide gel, and fat transfer injections and silicone oil.

Silicone is oil derived from the mineral silicon. It can be used for filling in plastic surgery, and has acquired a poor reputation as a result of misuse over the past twenty years from injecting larger volumes of silicone as well as using impure products rather than medical grade silicone oil. Academic cosmetic surgeons in the USA are planning studies of a product called SilSkin for treatment of facial lipoatrophy. In order to achieve optimum results silicone must be injected in tiny quantities using hundreds of micro-injections.
Facial injections of silicone oil induce an inflammatory response that triggers production of collagen. The 1000 centistoke silicone oil preparation used in the study is less viscous (thick) than other silicone oils and can be injected with a specialized needle. Regardless of the amount given, silicone doesn’t break down and stays unchanged in the body. The immune response to the foreign substance produces layers of collagen that surround the silicone. Eventually, permanent facial augmentation is achieved as collagen stimulates formation of new facial tissue due to the new tissue produced by the material.

An injectable form of poly-L-lactic acid, a biodegradable and biocompatible synthetic polymer from the alpha-hydroxy-acid family, is now available for use as a facial implant device (e.g., Sculptra, New-Fill). This device will not correct the underlying cause of the facial fat loss, but will help improve the appearance by increasing skin thickness in the treated area. Polylactic acid differs from silicon and collagen implants in that it isn’t immunologically active, thus avoiding any prospect of allergic or inflammatory response. In addition, unlike silicon implants, it is broken down and absorbed by the body. The poly-L-lactic acid implant is injected into areas of facial fat loss. It works by temporarily adding volume to facial tissue and restoring a smoother, fuller appearance to the face. The initial treatment series may consist of four to five injection sessions conducted at approximately two-week intervals. Repeat treatments are needed to maintain the effect. The effect lasts from several months to a year or more. The number of injection sessions and the quantity of injected product depends upon the severity of the lipoatrophy.

In August 2004, the Food and Drug Administration approved Sculptra, an injectable filler to correct facial fat loss in people with human immunodeficiency virus (HIV). The FDA expedited review of the product because of its importance in treating people living with AIDS. Sculptra is an injectable form of poly-L-lactic acid, a biodegradable, biocompatible synthetic polymer from the alpha-hydroxy-acid family that has been widely used for many years in dissolvable stitches, bone screws and facial implants.

FDA approval of Sculptra was based on from four studies, totaling 277 HIV-positive patients with severe facial lipoatrophy. The patients, who were all being treated with antiretroviral drugs, were primarily white males, mostly ages 41 to 45. Patients were given three to six injections of Sculptra at two-week intervals and were followed for two years. Skin thickness measurements and serial photographs from clinical studies were assessed, as well as submitted by the manufacturer, Dermik Laboratories, of Berwyn, Pa. Analysis indicated that the product significantly improved facial appearance, and was safe for restoration and/or correction of shape and contour deficiencies resulting from facial fat loss in patients with HIV/AIDS. Sculptra was shown to produce significant increases in dermal thickness (up to 2 to 3 times baseline values), adding volume to facial tissue and restoring shape to areas of the face with fat loss.

After an initial treatment series, repeat treatments may be needed to maintain the correction. Most adverse events were related to the injection itself and included nodules, redness, swelling and bruising in the injection area. The studies also demonstrated significant improvement in quality of life, and measures of anxiety and depression, conditions that can be associated with lipoatrophy. As a condition of approval, Dermik has agreed to conduct an open-label registry study of 100 patients for five years to evaluate Sculptra’s long-term safety. The study will include at least 30 females and 30 people with dark skin types.
Polyvinyl/polyacrylamide gel which goes by the brand name of *Evolution* is has been tried as a treated for facial wasting in HIV-positive patients. An observational study of Evolution injections in 35 people with facial wasting associated with long-term antiretroviral therapy found that 33 reported the results to be good or excellent one year after the intervention. Two-thirds required two injections of Evolution. The only reported side effect was transient, local swelling in two individuals (Del Pinto 2001).

**Review History**

December 14, 2004  Medical Advisory Council, initial approval
July 2006  Update – no revisions
August 2007  Update – no revisions
August 2008  Update – no revisions. CA reconstructive surgery law added to Disclaimer
July 2009  Update – Revised policy name to include “Sculptra”
May 2010  Update - Medicare considers FDA approved dermal fillers (i.e., Radiesse, Sculptra) for facial lipodystrophy syndrome (LDS) in HIV infected beneficiaries when facial LDS caused by antiretroviral HIV treatment is a significant contributor to their depression. No change to the policy for commercial members. Updated title to include Radiesse.

May 2011  Update. Added Medicare Table with link to NCD, LCD and National Benefit Category Analysis. Codes Updated. No revisions.
May 2012  Update – no revision
May 2013  Update - revised policy to consider FDA approved fillers for HIV-associated lipoatrophy (i.e., Sculptra, Radiesse) medically necessary in HIV-infected individuals with facial lipodystrophy caused by the antiretroviral HIV treatment.
May 2014  Update - no revision. Codes updated.
November 2014  Added CPT codes
May 2016  Update – no revision. Codes updated.

**References – Update May 2016**


**References – Update May 2015**

References – Update May 2014


2. Wanke CA. Epidemiology, clinical manifestations, and diagnosis of HIV-associated lipodystrophy. UpToDate. September 3, 2013

References – Update May 2013


References – Update May 2012


References – Update May 2011


References – Update May 2010


References – Update July 2009
   Accessed July 7, 2009

References – Update August 2008


References – Update August 2007


References
15. Christeff N et al. Lipodystrophy defined by a clinical score in HIV-infected men on highly active antiretroviral therapy: correlation between dyslipidaemia and steroid hormone alterations. AIDS 13(16):2251-2260, 1999

Important Notice

General Purpose.
Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary.
necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member’s contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net’s National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member’s benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to dictate to providers how to practice medicine.

**Policy Effective Date and Defined Terms.**
The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

**Policy Amendment without Notice.**
Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

**No Medical Advice.**
The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

**No Authorization or Guarantee of Coverage.**
The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

**Policy Limitation: Member’s Contract Controls Coverage Determinations.**
Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member’s contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member’s contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member’s contract shall govern. The Policies do not replace or amend the Member’s contract.

**Policy Limitation: Legal and Regulatory Mandates and Requirements**
The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

**Reconstructive Surgery**
CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. “Reconstructive surgery” means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

1. To improve function or
2. To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.
Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

**Reconstructive Surgery after Mastectomy**
California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy. Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

**Policy Limitations: Medicare and Medicaid**
Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.