CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 122	Date: June 4, 2010
	Change Request 6953

SUBJECT: Dermal Injections for Treatment of Facial Lipodystrophy Syndrome (LDS)

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after March 23, 2010, dermal injections for facial LDS are only reasonable and necessary using dermal fillers approved by the Food and Drug Administration for this purpose, and then only in HIV-infected beneficiaries who manifest depression secondary to the physical stigma of HIV treatment.

This revision [to the Medicare National Coverage Determinations Manual] is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries,[contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions], quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: MARCH 23, 2010
IMPLEMENTATION DATE: JULY 6, 2010

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/250.5/Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) – Effective March 23, 2010

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. if the contractor considers anything provided, as described above, to be

outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment – Business Requirements

Pub. 100-03	Transmittal: 122	Date: June 4, 2010	Change Request: 6953

SUBJECT: Dermal Injections for Treatment of Facial Lipodystrophy Syndrome (LDS)

EFFECTIVE DATE: MARCH 23, 2010
IMPLEMENTATION DATE: JULY 6, 2010

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) received a request for national coverage of treatments for facial lipodystrophy syndrome (LDS) for human immunodeficiency virus (HIV)-infected Medicare beneficiaries. Facial LDS 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 highly active antiretroviral therapy. Due to their appearance and stigma of the condition, patients with facial LDS may become depressed, socially isolated, and in some cases may stop their HIV treatments in an attempt to halt or reverse this complication.

B. Policy: Effective for claims with dates of service on and after March 23, 2010, dermal injections for facial LDS are only reasonable and necessary using dermal fillers approved by the Food and Drug Administration for this purpose, and then only in HIV-infected beneficiaries who manifest depression secondary to the physical stigma of HIV treatment.

NOTE: See Pub. 100-04, business requirements for specific payment and coding instructions.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6953.1	Effective for claims with dates of service on and after March 23, 2010, contractors shall allow payment for dermal injections for facial LDS using dermal fillers approved by the FDA for this purpose, and then only in HIV-infected Medicare beneficiaries who manifest depression secondary to the physical stigma of HIV treatment. See Pub. 100-03, NCD, chapter 1, section 250.5, for specific coverage criteria. See Pub. 100-04, CPM, business requirements and Pub. 100-04, CPM, chapter 32, section 260, for specific claims payment/coding instructions.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6953.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with local information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): JoAnna Baldwin, coverage, 410-786-7205, joanna.baldwin@cms.hhs.gov, Pat Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov; Michelle Atkinson, coverage, 410-786-2881, michelle.atkinson@cms.hhs.gov; Joe Bryson, institutional claims processing, 410-786-2986, joseph.bryson@cms.hhs.gov, Tom Dorsey, practitioner claims processing, 410-786-7434, Thomas.dorsey@cms.hhs.gov.

Post-Implementation Contact(s): Appropriate CMS RO or A/B MAC project officer

VI. FUNDING

A. For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. *For Medicare Administrative Contractors (MACs)*:
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)

Coverage Determinations

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(Rev.122, 06-04-10)

250.5 - Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) - Effective March 23, 2010

(Rev.122, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)

A. General

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.

B. Nationally Covered Indications

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.

C. Nationally 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.*

D. Other

N/A

(This NCD last reviewed March 2010.)