CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1978	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.

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	32/Table of Contents
N	32/260/Dermal Injections for Treatment of Facial Lipodystrophy Syndrome (LDS)
N	32/260.1/Policy
N	32/260.2/Billing Instructions
N	32/260.2.1/Hospital Billing Instructions
N	32/260.2.2/Practitioner Billing Instructions
N	32/260.3/Claims Processing System Editing

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. 100-04	Transmittal: 1978	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. 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 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 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: Effective with the July 2010 Healthcare Common Procedure Coding System (HCPCS) update, the July Medicare Physician Fee Schedule (MPFS) and the July Integrated Outpatient Code Editor (IOCE), HCPCS codes Q2026, Q2027, and G0429, will be designated for dermal fillers Sculptra® and Radiesse®. The HCPCS codes are effective back to dates of service March 23, 2010. HCPCS Q2026 and Q2027 are contractor-priced under the July MPFS. HCPCS G0429 is payable under the July MPFS. However, because HCPCS Q2026, Q2027 and G0429 are not considered valid HCPCS until implementation of the July 2010 HCPCS update, providers will not be able to bill and receive payment for the HCPCS prior to July 6, 2010.

Also included in the July 2010 HCPCS update and in the July IOCE is a temporary HCPCS code, C9800, which was created to describe both the injection procedure and the dermal filler product. This code provides a payment mechanism to hospital outpatient perspective payment system (OPPS) and ambulatory surgery center (ASC) providers until average sales price (ASP) or wholesale acquisition cost (WAC) pricing information becomes available. When ASP or WAC pricing information becomes available, HCPCS code C9800 will be deleted and separate payment will be made under the OPPS and ASC payment systems for HCPCS G0429, Q2026, and Q2027.

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	Contractors shall allow payment using current	X		X							

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	
	payment methodologies for covered institutional non-OPPS outpatient claims for dermal injections for treatment of LDS that contain the following criteria: • A line with a HCPCS codes Q2026 or Q2027 with a Line Item Date of service (LIDOS) on or after March 23, 2010, • A line with HCPCS codes G0429 with a LIDOS on or after March 23, 2010, and • ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy). **NOTE:** An ICD-9-CM diagnosis code for a depression comorbidity may also be present, but is not mandatory, as will be determined by the individual contractor.										
6953.2	Until pricing information is made available to price HCPCS G0429, Q2026, and Q2027, contractors shall allow an ambulatory payment classification (APC) payment for covered OPPS claims for dermal injections for treatment of LDS that contain the following criteria: • A line with a HCPCS codes C9800 with a LIDOS on or after March 23, 2010, and • ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy). **NOTE:** An ICD-9-CM diagnosis code for a depression comorbidity may also be present, but is not mandatory, as will be determined by the individual contractor.	X		X							
6953.3	Even though OPPS hospitals are unable to bill/receive payment for HCPCS G0429, Q2026, and Q2027 until pricing information is made available, contractors shall allow an APC payment to be made (once payment indicators are updated appropriately in the HCPCS file and IOCE) for covered OPPS claims for dermal injections for treatment of LDS that contain the following criteria: • A line with HCPCS codes Q2026 or Q2027 with a LIDOS on or after March 23, 2010, • A line with HCPCS codes G0429 with a LIDOS on or after March 23, 2010, and	X		X							

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	
	• ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy). **NOTE:** An ICD-9-CM diagnosis code for a depression comorbidity may also be present, but is not mandatory, as will be determined by the individual contractor.										
6953.4	The IOCE shall line item deny (per OCE edit 68) lines billed with either C9800, G0429, Q2026, or Q2027, and has a LIDOS prior to March 23, 2010.										IOCE
6953.4.1	Contractors shall use existing messages already associated with edit 68 when denying.	X		X							
6953.5	Contractors shall allow payment for covered practitioner claims for dermal injections for treatment of LDS by the presence of all the following criteria: • Date of service (DOS) on or after March 23, 2010, • HCPCS codes Q2026 or Q2027, • HCPCS code G0429, and • ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystophy). **NOTE**: An ICD-9-CM diagnosis code for a depression comorbidity may also be present, but is not mandatory, as will be determined by the individual contractor.	X			X						
6953.6	Until pricing information is made available for HCPCS G0429, Q2026, and Q2027, contractors shall allow payment for covered ASC claims for dermal injections for treatment of LDS that contain the following criteria: • A line with a HCPCS codes C9800 with a LIDOS on or after March 23, 2010, and • ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy). **NOTE:** An ICD-9-CM diagnosis code for a depression comorbidity may also be present, but is not mandatory, as will be determined by the individual contractor.	X			X						
6953.7	Even though ASC hospitals are unable to bill/receive payment for HCPCS G0429, Q2026, and Q2027 until pricing information is made available, contractors	X			X						

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	
	shall allow for payment to be made (once payment indicators are updated appropriately in the HCPCS File) for covered ASC claims for dermal injections for treatment of LDS that contain the following criteria: • A line with a HCPCS codes Q2026 or Q2027 with a LIDOS on or after March 23, 2010, • A line with HCPCS codes G0429 with a LIDOS on or after March 23, 2010, and • ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy). **NOTE:** An ICD-9-CM diagnosis code for a depression comorbidity may also be present, but is not mandatory, as will be determined by the individual contractor.										
6953.8	Contractors shall deny ASC and practitioner LDS claims when the date of service is prior to March 23, 2010.	X			X						
6953.8.1	Contractors shall use the following messages when denying: Claim Adjustment Reason Code (CARC) 28 - Coverage not in effect at the time the service was provided. Remittance Advice Remark Code (RARC) N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD. Group Code - Contractual Obligation (CO) Medicare Summary Notice (MSN) 21.11 - This service was not covered by Medicare at the time you received it. Spanish Version: Este servicio no estaba cubierto por Medicare cuando usted lo recibió.	X			X						
6953.9	Contractors shall deny LDS claims containing valid	X		X	X						

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	
	LDS HCPCS codes (as listed above) for services on or after March 23, 2010 where both ICD-9-CM diagnosis codes 042 and 272.6 are not present.										
6953.9.1	Contractors shall use the following messages when denying LDS claims without both ICD-9-CM diagnosis codes 042 and 272.6: CARC 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD. RARC M64 - Missing/incomplete/invalid other diagnosis. Group Code - Contractual Obligation (CO) MSN 15.4 - The information provided does not support the need for this service or item. Spanish Version: La información proporcionada no confirma la necesidad para este servicio o artículo.	X		X	X						
6953.10	Contractors shall pay covered LDS inpatient claims (using current payment methodologies) that contain the following criteria: • Discharge date is on or after March 23, 2010; • ICD-9-CM procedure code 86.99; and • ICD-9-CM Diagnosis Codes 042 (HIV) and 272.6 (Lipodystrophy). **NOTE:** An ICD-9-CM diagnosis code for depression comorbidity may also be present, but is not mandatory, as will be determined by the individual contractor.	X		X							
6953.10.1	Contractors shall deny LDS claims when an ICD-9-CM procedure code is billed on a claim with a	X		X							

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	
	discharge date on or after March 23, 2010 but both ICD-9-CM diagnosis codes 042 and 272.6 are not present, using the same messages noted in BR 6953.9.1 above.										

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	
6953.11	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): A/B MAC project officer or regional office (http://www.cms.hhs.gov/RegionalOffices/01_Overview.asp)

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 Claims Processing Manual
Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev.1978, 06-04-10)

260 - Dermal Injections for Treatment of Facial Lipodystrophy Syndrome (LDS)
(Rev.1978, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)

260.1 – Policy
(Rev.1978, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)

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.
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 stigmata of HIV treatment.

260.2 –Billing Instructions
(Rev.1978, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)

260.2.1 – Hospital Billing Instructions
(Rev.1978, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)

For hospital <u>outpatient</u> claims, hospitals must bill covered dermal injections for treatment of facial LDS by having all the required elements on the claim:

- *A line with HCPCS codes Q2026 or Q2027 with a Line Item Date of service (LIDOS) on or after March 23, 2010,*

- *A line with HCPCS code G0429 with a LIDOS on or after March 23, 2010, and*

- *ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy).*

Note to outpatient prospective payment system (OPPS) hospitals or ambulatory surgical centers (ASCs): *For line item dates of service on or after March 23, 2010, and until HCPCS codes Q2026 and Q2027 are billable, facial LDS claims shall contain a temporary HCPCS code C9800, instead of HCPCS G0429 and HCPCS Q2026/Q2027, as shown above.*

For hospital inpatient claims, hospitals must bill covered dermal injections for treatment of facial LDS by having all the required elements on the claim:

- *Discharge date on or after March 23, 2010,*

- *ICD-9-CM procedure code 86.99 (other operations on skin and subcutaneous tissue, i.e., injection of filler material), and*

- *ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy).*

***Note on all hospital claims**: An ICD-9-CM diagnosis code for a depression comorbidity may also be required for coverage on an outpatient and/or inpatient basis as determined by the individual Medicare contractor's policy.*

260.2.2 – Practitioner Billing Instructions
(Rev.1978, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)

Practitioners must bill covered claims for dermal injections for treatment of facial LDS by having all the required elements on the claim:

- *A line with HCPCS codes Q2026 or Q2027 with a LIDOS on or after March 23, 2010,*

- *A line with HCPCS code G0429 with a LIDOS on or after March 23, 2010, and*

- *ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy).*

***NOTE**: An ICD-9-CM diagnosis code for a depression comorbidity may also be required for coverage based on the individual Medicare contractor's policy.*

260.3 – Claims Processing System Editing
(Rev.1978, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)

Billing for Services Prior to Medicare Coverage

Hospitals and practitioners billing for dermal injections for treatment of facial LDS prior to the coverage date of March 23, 2010, will receive the following messages upon their Medicare denial:

- *Claim Adjustment Reason Code (CARC) 28: Coverage not in effect at the time the service was provided.*

- *Remittance Advice Remark Code (RARC) N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.*

- *Group Code: Contractual Obligation (CO)*

***NOTE:** Outpatient hospitals and beneficiaries that received services in a hospital outpatient setting may receive different message as established by their particular Medicare contractor processing the claim.*

Medicare beneficiaries whose provider bills Medicare for dermal injections for treatment of facial LDS prior to the coverage date of March 23, 2010, will receive the following Medicare Summary Notice (MSN) message upon the Medicare denial:

21.11 - This service was not covered by Medicare at the time you received it. (Spanish Version: Este servicio no estaba cubierto por Medicare cuando usted lo recibió.)

Billing for Services Not Meeting Comorbidity Coverage Requirements

Hospitals and practitioners billing for dermal injections for treatment of facial LDS on patients that do not have a comorbidity of HIV and lipodystrophy (or even depression if deemed required by the Medicare contractor) will receive the following messages upon their Medicare denial:

- *CARC 50: These are non-covered services because this is not deemed a 'medical necessity' by the payer.*

***NOTE:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.*

- *Remittance Advice Remark Code (RARC) N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.*

- *RARC M64: Missing/incomplete/invalid other diagnosis.*

- *Group Code: Contractual Obligation (CO)*

Medicare beneficiaries who do not meet Medicare comorbidity requirements of HIV and lipodystrophy (or even depression if deemed required by the Medicare contractor) and whose provider bills Medicare for dermal injections for treatment of facial LDS will receive the following MSN message upon the Medicare denial:

15.4 - The information provided does not support the need for this service or item. (Spanish Version: La información proporcionada no confirma la necesidad para este servicio o artículo.)