CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3292	**Date: July 10, 2015**
	Change Request 9167

Transmittal 3254, dated May 8, 2015, is being rescinded and replaced by Transmittal 3292, dated July 10, 2015, to modify business requirement 9167.5 and to clarify the use of Q9977.

SUBJECT: Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2015 Update

I. SUMMARY OF CHANGES: The HCPCS code set is updated on a quarterly basis. This instruction informs the contractors of updating specific drug/biological HCPCS codes. The attached Recurring Update Notification applies to Chapter23, Section 20.3.

Beginning in July 2015, claims for compounded drugs shall be submitted using the compounded drug, not otherwise classified (NOC) HCPCS code. This CR is also updating the Section 20.1.2 – Average Sales Price (ASP) Payment Methodology in Chapter 17 of the Claims Processing Manual 100-04.

EFFECTIVE DATE: July 1, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 2015

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	17/20.1.2/Average Sales Price (ASP) Payment Methodology

III. FUNDING:
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:

Recurring Update Notification
Manual Instruction

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 3292	Date: July 10, 2015	Change Request: 9167

Transmittal 3254, dated May 8, 2015, is being rescinded and replaced by Transmittal 3292, dated July 10, 2015, to modify business requirement 9167.5 and to clarify the use of Q9977.

SUBJECT: Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2015 Update

EFFECTIVE DATE: July 1, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 6, 2015

I. GENERAL INFORMATION

A. Background: The HCPCS code set is updated on a quarterly basis. This instruction describes the process for updating specific HCPCS codes.

The July 2015 HCPCS file includes a new HCPCS code for biosimilar filgrastim, Q5101," injection, filgrastim (G-CSF), biosimilar, 1 microgram." Contractors will have until July 1, 2015 to incorporate this code into their systems, but the code will be effective for dates of service after the FDA approval of the first biosimilar version of filgrastim March 6, 2015.

The July 2015 HCPCS file also includes a new HCPCS code to identify compounded drugs, Q9977, "compounded drug, not otherwise classified (NOC)." This CR updates Section 20.1.2 – Average Sales Price (ASP) Payment Methodology in Chapter 17 of the Claims Processing Manual 100-04 to address the use of a compounded drug NOC code on claims for compounded drugs.

In addition, the July 2015 HCPCS file includes new HCPCS codes Q9976, "injection, ferric pyrophosphate citrate solution, 0.1 mg of iron," and Q9978, "netupitant 300 mg and palonosetron 0.5 mg, oral."

B. Policy: Effective for claims with dates of service on or after March 6, 2015, HCPCS code Q5101 will be payable for Medicare:

HCPCS Code: Q5101

Short Description: Inj filgrastim g-csf biosim

Long Description: Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram

TOS Code: 1, P

MPFSDB Status Indicator: E

Effective for claims with dates of service on or after July 1, 2015, the following HCPCS codes will be payable for Medicare:

HCPCS Code: Q9976

Short Description: Inj Ferric Pyrophosphate Cit

Long Description: Injection, Ferric Pyrophosphate Citrate Solution, 0.1 mg of iron

TOS Code: 1,L

MPFSDB Status Indicator: E

HCPCS Code: Q9978

Short Description: Netupitant Palonosetron oral

Long Description: Netupitant 300 mg and Palonosetron 0.5 mg, oral

TOS Code: 1

MPFSDB Status Indicator: E

HCPCS Code: Q9977

Short Description: Compounded Drug NOC

Long Description: Compounded Drug, Not Otherwise Classified

TOS Code: 1, P

MPFSDB Status Indicator: E

Please note: The new compounded drug code, Q9977 Compounded Drug, Not Otherwise Classified, is not a replacement for existing codes. It is intended to distinguish compounded drugs (which may include biologicals) from other “not otherwise classified” codes such as J3490, J3590, J7799, J9999 and existing specific codes for compounded nebulized drugs. The implementation of Q9977 as a means of identifying compounded drug claims does not affect existing payment policy for compounded drugs as outlined in the Claims Processing Manual 100-04 Chapter 17 Section 20.1.2.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9167.1	Contractors shall make user changes to accept Q9976, Q9977, and Q9978 as valid HCPCS codes for dates of service on or after July 1, 2015, and code Q5101 for dates of service on or after March 6, 2015.	X	X	X	X	X			X	BCRC, IOCE
9167.2	Contractors shall use Type of Service (TOS) 1, P for Q9977 for dates of service on or after July 1, 2015, and for Q5101 for dates of service on or after March 6.		X		X				X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9167.3	Contractors shall use Type of Service (TOS) 1, L for Q9976 for dates of service on or after July 1, 2015.		X		X				X	
9167.4	Contractors shall use Type of Service (TOS) 1 for Q9978 for dates of service on or after July 1, 2015.		X		X				X	
9167.5	The Common Working File (CWF) shall use categories 60 and 17 for Q9976 and Q9978 and categories 60, 17 and 56 for Q9977 for dates of service on or after July 1, 2015. The CWF shall use categories 60 and 17 for Q5101 for dates of service on or after March 6, 2015.								X	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9167.6	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Prabath Malluwa-Wadu, 410-786-4620 or prabath.malluwa-wadu@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

20.1.2 – Average Sales Price (ASP) Payment Methodology

(Rev. 3292, Issued: 07-10-15, Effective: 07-01-15, Implementation: 07-06-15)

Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis. Per the MMA, beginning January 1, 2005, the vast majority of drugs and biologicals not priced on a cost or prospective payment basis will be priced based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the local contractor. *Beginning in July 2015, claims for compounded drugs shall be submitted using a compounded drug, not otherwise classified (NOC) HCPCS code.* Beginning in 2006, all ESRD drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS), will be priced based on the ASP methodology. The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. Contractors will be notified of the availability of this file via a Recurring Update Notification. Visit http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?redirect=/McrPartBDrugAvgSalesPrice for more information about the ASP payment methodology.

The absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. The local Medicare contractor processing the claim shall make these determinations.

Beginning January 1, 2005, in general, the payment allowance limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP. Beginning January 1, 2006, in general, the payment allowance limits for ESRD drugs when separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS, will be paid based on 106 percent of the ASP. CMS will update the payment allowance limits quarterly.

As announced in late 2006, CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by Section 1847A of the Social Security Act. As part of this effort, we have also reviewed how we have operationalized the terms “single source drug,” “multiple source drug,” and “biological product” in the context of payment under Section 1847A. For the purposes of identifying “single source drugs” and “biological products” subject to payment under Section 1847A, generally CMS (and its contractors) will utilize a multi-step process. We will consider:

- The FDA approval;
- Therapeutic equivalents as determined by the FDA; and
- The date of first sale in the United States.

For a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book) first sold in the United States after October 1, 2003, the payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may be operationalized through use of “not otherwise classified” HCPCS codes.