

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3997	Date: March 7, 2018
	Change Request 10454

Transmittal 3966, dated February 2, 2018, is being rescinded and replaced by Transmittal 3997, dated, March 7, 2018, Year to add business requirement 10454.7. All other information remains the same.

SUBJECT: Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - April 2018 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.

Beginning on April 1, 2018, the following HCPCS codes will be established.

Q5103 Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg

Q5104 Injection, infliximab-abda, biosimilar, (renflexis), 10 mg

Q2041 Axicabtagene Ciloleucel, up to 200 million autologous Anti-CD19 CAR T Cells, including leukapheresis and dose preparation procedures, per infusion

Beginning on April 1, 2018, the following HCPCS code will be revised.

Q5101 Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram

Beginning on April 1, 2018, HCPCS code Q5102 and modifiers ZA, ZB, and ZC will be discontinued.

This Recurring Update Notification (RUN) applies to Chapter 17, Section 10 of the Claims Processing Manual.

EFFECTIVE DATE: April 1, 2018

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

IMPLEMENTATION DATE: April 2, 2018

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
N/A	N/A

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

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 3997	Date: March 7, 2018	Change Request: 10454
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SUBJECT: Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - April 2018 Update

EFFECTIVE DATE: April 1, 2018

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

IMPLEMENTATION DATE: April 2, 2018

I. GENERAL INFORMATION

A. Background: The HCPCS code set is updated on a quarterly basis. This instruction describes updates associated with the following: biosimilar biological product HCPCS codes, modifiers used with biosimilar biological products and an autologous cellular immunotherapy treatment.

The April 2018 HCPCS file includes three new HCPCS codes: Q5103 Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg; Q5104 Injection, infliximab-abda, biosimilar, (renflexis), 10 mg; and Q2041 Axicabtagene Ciloleucel, up to 200 million autologous Anti-CD19 CAR T Cells, Including leukapheresis and dose preparation procedures, per infusion. Also, the April 2018 HCPCS file includes a revision to the descriptor for HCPCS code Q5101, Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram which includes the trade name of the product. Please note that Q5102 Injection, infliximab, biosimilar, 10 mg will be discontinued effective March 31, 2018.

Also, beginning on April 1, 2018, providers and suppliers will no longer be required to report modifiers with HCPCS codes for biosimilars.

B. Policy: Medicare Part B policy changes for biosimilar biological products were discussed in the CY 2018 PFS final rule (www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1676-F.html). Effective January 1, 2018, newly approved biosimilar biological products with a common reference product will no longer be grouped into the same billing code. The rule also stated that instructions for new codes for biosimilars that are currently grouped into a common payment code and the use of modifiers would be issued. The business requirements in this document revise biosimilar biological product coding and payment for existing products as follows:

Effective for claims with dates of service on or after April 1, 2018, HCPCS code Q5102 (which describes both currently available versions of infliximab biosimilars) will be replaced with two codes, Q5103 and Q5104. The new biosimilar payment policy also makes the use of modifiers that describe the manufacturer of a biosimilar product unnecessary. However, please note that HCPCS code Q5102 and the requirement to use biosimilar modifiers remain in effect for dates of service prior to April 1, 2018.

In summary, effective for claims with dates of service on or after April 1, 2018, HCPCS code Q5101 will be revised, HCPCS codes Q5103 and Q5104 will be payable for Medicare, HCPCS code Q5102 will no longer be payable, and modifiers that describe the manufacturer of a biosimilar product (for example, ZA, ZB and ZC) will no longer be required on Medicare claims.

This CR also includes a new code, Q2041, an autologous cellular immunotherapy treatment.

HCPCS Code: Q5101

Short Description: Injection, zarxio

Long Description: Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram

HCPCS Code: Q5103

Short Description: Injection, inflectra

Long Description: Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg

TOS Code: 1,P

MPFSDB Status Indicator: E

HCPCS Code: Q5104

Short Description: Injection, renflexis

Long Description: Injection, infliximab-abda, biosimilar, (renflexis), 10 mg

TOS Code: 1,P

MPFSDB Status Indicator: E

Also, the following HCPCS code will be effective for claims with dates of service on or after April 1, 2018.

HCPCS Code: Q2041

Short Description: Axicabtagene ciloleucel car+

Long Description: Axicabtagene Ciloleucel, up to 200 million autologous Anti-CD19 CAR T Cells, Including leukapheresis and dose preparation procedures, per infusion

TOS Code: 1

MPFSDB Status Indicator: E

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility			
		A/B MAC	D M E	Shared- System Maintainers	Other

		A	B	H H H	M A C	F I S S	M C S	V M S	C W F	
10454.1	Contractors shall make user changes to accept Q5103, Q5104 and Q2041 as valid HCPCS codes for dates of service on or after April 1, 2018.		X	X	X				X	BCRC, IOCE
10454.2	Contractors shall use Type of Service (TOS) 1, P for Q5103 and Q5104, and TOS 1 for Q2041 for dates of service on or after April 1, 2018.		X		X				X	
10454.3	The Common Working File (CWF) shall use categories 60 and 17 for Q5103, Q5104 and Q2041 for dates of service on or after April 1, 2018.								X	
10454.4	Contractors shall discontinue code Q5102 for dates of service on or after April 1, 2018.	X	X	X	X				X	IOCE
10454.5	Contractors shall discontinue modifiers ZA, ZB, and ZC for dates of service on or after April 1, 2018.		X	X	X					IOCE
10454.6	Contractors shall revise the code descriptors for HCPCS code Q5101 as follows effective for dates of service on or after April 1, 2018: Long descriptor: Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram Short descriptor: Injection, zarxio	X	X		X				X	IOCE
10454.7	Contractor shall use the first 100 characters of the long descriptions of HCPCS codes Q5101, Q5103, Q5104 and Q2041 below to update and revise the MSN descriptors effective when the MSN is processed on or after 4/1/2018: Q5101 Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram Q5103 Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg Q5104 Injection, infliximab-abda, biosimilar, (renflexis), 10 mg Q2041 Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion							X		

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
10454.8	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): Felicia Eggleston, 410-786-9287 or felicia.eggleston@cms.hhs.gov, 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):

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ATTACHMENTS: 0