| CMS Manual System | Department of Health & Human Services (DHHS) |
|---|---|
| Pub 100-20 One-Time Notification | Centers for Medicare & Medicaid Services (CMS) |
| **Transmittal 1542** | **Date: September 4, 2015** |
| | **Change Request 9284** |

**NOTE: This Transmittal is no longer sensitive and is being re-communicated November 12, 2015. The Transmittal Number, Date of Transmittal and all other information remain the same. This instruction may now be posted on the Internet.**

**SUBJECT: Implementation of Biosimilar Claim Modifiers**

**I. SUMMARY OF CHANGES:** This Change Request (CR) instructs contractors to include an appropriate modifier that identifies the manufacturer of a specific product for biosimilar biological products assigned to a common HCPCS code.

**EFFECTIVE DATE: January 1, 2016**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: January 4, 2016**

***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:**
**One Time Notification**

# Attachment - One-Time Notification

| Pub. 100-20 | Transmittal: 1542 | Date: September 4, 2015 | Change Request: 9284 |
|---|---|---|---|

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**SUBJECT: Implementation of Biosimilar Claim Modifiers**

**EFFECTIVE DATE: January 1, 2016**
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**IMPLEMENTATION DATE: January 4, 2016**

## I. GENERAL INFORMATION

**A. Background:** This Change Request (CR) describes the requirements for the use of modifiers on claims containing biosimilar biological products.

**B. Policy:** In order to provide the Centers for Medicare & Medicaid Services (CMS) with more detailed tracking of claims payment and a better understanding of the use of biosimilars in Medicare Part B, claims for biosimilar biological products that are paid separately (that is, not paid as part of a bundle or package of services) and are assigned to a Healthcare Common Procedure Coding System (HCPCS) code will be required to include a modifier that identifies the manufacturer of the specific product. CMS will issue HCPCS codes and modifiers for biosimilar biological products and determine the associations between the two. Once CMS has assigned biosimilar modifiers to a HCPCS code that describes biosimilar biological products, and has disseminated the modifier assignments through the appropriate process, the use of a biosimilar modifier on a claim for the associated HCPCS code will become mandatory. Claims submitted for biosimilar biological products using HCPCS codes that are associated with modifiers and priced nationally by CMS will be returned unless the appropriate biosimilar modifier appears on the claim. Updates to the assignment of HCPCS codes and biosimilar modifiers will be done quarterly. If a HCPCS code and corresponding biosimilar modifier(s) do not appear on the quarterly update, then a modifier is not required to appear on claims for the code.

Currently the one established HCPCS code for a biosimilar drug is Q5101, “injection, filgrastim (G-CSF), biosimilar, 1 microgram."

Please note that the determination of the payment amount for biosimilars is not affected by this CR.

## 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 | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 9284.1 | Contractors shall be advised of new HCPCS codes for the biosimilar drugs and associated modifiers on a quarterly basis. | X | X | | | | | | | |
| 9284.2 | Contractors shall require an appropriate modifier be submitted for biosimilar drug claims. | X | X | | | | | | | IOCE |
| 9284.2.1 | Contractors shall require the following modifier when HCPCS code Q5101 is billed on the claim:<br>• ZA = Sandoz<br>**NOTE:** Modifier values will be updated once approved. | X | X | | | | | | | IOCE |
| 9284.3 | For professional claims, contractors shall return as unprocessable claim lines for biosimilar drugs submitted without one of the specified modifiers. Contractors shall use the following messages:<br>• Claims Adjustment Reason Code (CARC): 4 - "The procedure code is inconsistent with the modifier used or a required modifier is missing."<br>• Remittance Advice Remark Code (RARC): MA130 - "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."<br>• Group Code: CO (Contractual Obligation) | | X | | | | | | | |
| 9284.4 | The Integrated Outpatient Code Editor (IOCE) will create an edit to RTP claims if submitted without the corresponding modifiers for institutional claims. | | | | | | | | | IOCE |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| | None | | | | | |

## 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):** Dennis Savedge, 410-786-0140 or Dennis.Savedge@cms.hhs.gov , Yvonne Young, 410-786-1886 or Yvonne.Young@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**
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