

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 13365</b>	<b>Date: August 14, 2025</b>
	<b>Change Request 14195</b>

**SUBJECT: National Fee Schedule for Vaccine Administration Quarterly Update - October 2025**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to provide updates to the Medicare Part B Preventive Vaccine Administration file.

**EFFECTIVE DATE: January 24, 2025; October 1, 2025**

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

**IMPLEMENTATION DATE: October 6, 2025**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
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: 13365	Date: August 14, 2025	Change Request: 14195
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**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to provide updates to the Medicare Part B Preventive Vaccine Administration file.

## **II. GENERAL INFORMATION**

**A. Background:** The “National Fee Schedule for Vaccine Administration (VAXA)” previously known as the Medicare Part B Vaccine Administration file will now serve as a comprehensive source for the administration rates of preventive vaccines, COVID-19, and monoclonal antibody products. This file will be updated with pricing data as needed in the future.

Under section 1861(s)(10) of the Act, Medicare Part B covers both the vaccine and its administration for the specified preventive vaccines—the influenza, pneumococcal, and Hepatitis B Virus (HBV) vaccines. Under sections 1833(a)(1)(B) and 1833(b)(1) of the Act, respectively, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccinations. Section 1861(s)(10)(A) of the Act, as amended by section 3713 of the Coronavirus 2019 (COVID-19) Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116– 136) includes the COVID–19 vaccine and its administration in the same subparagraph as the influenza and pneumococcal vaccines and their administration.

Medicare will continue to cover and pay COVID-19 monoclonal antibody products for post-exposure prophylaxis or treatment of COVID-19 under the Part B preventive vaccine benefit through the end of the calendar year in which the Secretary ends the current Emergency Use Authorization (EUA) declaration for COVID-19 drugs and biologicals.

Medicare will continue to cover and pay for monoclonal antibodies that are used for pre-exposure prophylaxis (PrEP) of COVID-19 under the Part B preventive vaccine benefit even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization and meet applicable coverage requirements.

Relevant HCPCS codes for COVID-19 monoclonal antibody products and their administration can be found on the Centers for Medicare & Medicaid Services (CMS) COVID-19 Vaccine Pricing website at <https://www.cms.gov/medicare/payment/part-b-drugs/vaccine-pricing>, under “COVID-19 Vaccines & Monoclonal Antibodies.”

**B. Policy:** AVTOZMA® (tocilizumab-anoh), a biosimilar to ACTEMRA® (tocilizumab), is approved for the treatment of rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and COVID-19.

CMS established HCPCS Level II code Q0237 to describe AVTOZMA® for post-exposure prophylaxis or treatment of COVID-19 and associated administrative codes. HCPCS Level II codes Q0237, M0237, and M0238 have the same effective date as the Food and Drug Administration (FDA) approval in order to align with the appropriate Medicare payment policies.

- Q0237 - “Injection, tocilizumab-anoh, for hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or Extracorporeal Membrane Oxygenation (ecmo) only, 1 mg”

Effective: January 24, 2025

- M0237 - “Intravenous infusion, tocilizumab-anoh, for hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, first dose”

Effective: January 24, 2025

- M0238 - “Intravenous infusion, tocilizumab-anoh, for hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, second dose”

Effective: January 24, 2025

In addition, effective October 1, 2025 CMS is establishing a “Not Otherwise Classified” (NOC) COVID-19 monoclonal antibody product HCPCS Level II code and associated administrative codes to be used to bill any newly FDA approved products that are not yet assigned to a unique HCPCS Level II code while the EUA declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) remains in effect.

- Q0235 - “Injection, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, not otherwise classified, 1 mg”

Effective: October 1, 2025

- M0235 - “Intravenous infusion, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, not otherwise classified, first dose”

Effective: October 1, 2025

- M0236 - “Intravenous infusion, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, not otherwise classified, second dose”

Effective: October 1, 2025

### III. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DM E  MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
14195.1	The CMS shall notify the contractors when the October 2025 National Fee Schedule for Vaccine Administration (VAXA) payment file and/or data in the cloud service is available for downloading, along with the file name, through an e-mail notification via the Parts A/B Functional Workgroup.									CMS, PCS
14195.1.1	The contractors shall retrieve, download, and install the October 2025 VAXA payment file from the CMS mainframe for testing and production through the CDC. The filename is as follows: <a href="#">MU00.@BF12390.VAX2025.VOCT</a> .  Note: Part A Contractors should retrieve the Mainframe file for comparison testing only. They should apply the October 2025 VAXA payment from the cloud	X								PCS

Number	Requirement	Responsibility								
		A/B MAC			DM E  MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	service for testing and production.									
14195.1.1	<p>The Part A Contractors shall retrieve the VAXA replacement data from the cloud service and implement it into their testing and production regions.</p> <p><b>Note:</b> The Fiscal Intermediary Shared System (FISS) system will compare the mainframe files with the Cloud Data.</p> <p><b>Note:</b> In the event of unexpected circumstances or issues, CMS will provide further instructions to the MACs and Data Centers (DCs) via email to load the Mainframe Files.</p>									Hybrid Cloud Data Center (HCD C)
14195.2	In the event that corrections are required, and a 2025 VAXA replacement payment file and/or data in the cloud service is issued, contractors shall be prepared to retrieve and apply the replacement Part B VAXA payment file(s) from the CMS mainframe and/or cloud service.	X								PCS
14195.2.1	<p>The Part A Contractors shall retrieve the VAXA replacement data from the cloud service and implement it into their testing and production regions.</p> <p><b>Note:</b> The FISS system will compare the mainframe files with the Cloud Data.</p> <p><b>Note:</b> In the event of unexpected circumstances or issues, CMS will provide further instructions to the MACs and DCs via email to load the</p>									Hybrid Cloud Data Center (HCD C), PCS

Number	Requirement	Responsibility								
		A/B MAC			DM E  MA C	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	Mainframe Files.									
14195.2.2	The CMS shall notify the contractors when the replacement file and/or data in the cloud service is available for retrieval, along with the file name, through an e-mail notification via the Part A/B Functional Workgroup.									CMS, PCS
14195.2.3	Contractors shall be ready to implement any replacement files no later than October 6, 2025, the implementation date of this CR, unless otherwise directed by CMS.	X								
14195.3	Contractors shall notify CMS of successful receipt of the VAXA and/or VAXA replacement file via e-mail to price_file_receipt@cms.hhs.gov, stating the name of the file received (e.g., CLAB, Average Sales Price, etc.), and the entity for which it was received (i.e., include states, workload numbers, quarter, and if Part A, Part B, or both).  <b>Note:</b> The business requirement is not applicable for data downloaded from the cloud service.	X								
14195.4	Contractors shall not apply beneficiary coinsurance or deductible for Part B Vaccine Administration HCPCS codes and Current Procedural Terminology (CPT) codes listed on the Monoclonal Antibody Product Administration Fee Schedule.	X								
14195.5	Contractors shall not search their history files but shall adjust any claims brought to their attention with the following codes: Q0237, M0237,	X								

Number	Requirement	Responsibility								
		A/B MAC			DM E	Shared-System Maintainers				Other
		A	B	HH H	MA C	FIS S	MC S	VM S	CW F	
	M0238.									

#### IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

**Impacted Contractors:** A/B MAC Part A

#### V. 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:
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**Section B: All other recommendations and supporting information:** N/A

#### VI. CONTACTS

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

#### VII. FUNDING

##### **Section A: For Medicare Administrative Contractors (MACs):**

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**ATTACHMENTS: 0**