

<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 10836</b>	<b>Date: June 8, 2021</b>
	<b>Change Request 12244</b>

**Transmittal 10708, dated April 27, 2021, is being rescinded and replaced by Transmittal 10836, dated, June 8, 2021 to update the policy section with additional information. All other information remains the same.**

**SUBJECT: July 2021 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files**

**I. SUMMARY OF CHANGES:** The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply the contractors with the ASP and Not Otherwise Classified (NOC) drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the OPPI are incorporated into the Outpatient Code Editor (OCE) through separate instructions that can be located in chapter 4, section 50 of the Internet Only Manual.

**EFFECTIVE DATE: July 1, 2021**

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

**IMPLEMENTATION DATE: July 6, 2021**

*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: 10836	Date: June 8, 2021	Change Request: 12244
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**EFFECTIVE DATE: July 1, 2021**

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**IMPLEMENTATION DATE: July 6, 2021**

## I. GENERAL INFORMATION

**A. Background:** The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply the contractors with the ASP and Not Otherwise Classified (NOC) drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions that can be located in chapter 4, section 50 of the Internet Only Manual.

**B. Policy:** This recurring update addresses the following pricing files:

File: July 2021 ASP and ASP NOC -- Effective Dates of Services: July 1, 2021 through September 30, 2021

File: April 2021 ASP and ASP NOC -- Effective Dates of Services: April 1, 2021 through June 30, 2021

File: January 2021 ASP and ASP NOC -- Effective Dates of Service: January 1, 2021 through March 31, 2021

File: October 2020 ASP and ASP NOC -- Effective Dates of Service: October 1, 2020, through December 31, 2020

File: July 2020 ASP and ASP NOC -- Effective Dates of Service: July 1, 2020 through September 30, 2020

## Section 405 Implementation

Section 405 of the Consolidated Appropriations Act, 2021 requires the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) to conduct periodic studies on certain self-administered drugs or biologicals that are paid under the statutory payment limit, and permits CMS to apply a “lesser-of” methodology to the ASP calculation, if deemed appropriate. The Medicare payment amount for the drug or biological billing code would be the lesser of (“lesser of” methodology): (1) the payment limit determined using the current ASP+6% methodology, or (2) the ASP+6% amount obtained by excluding the self-administered products identified in an OIG study.

Section 405 also requires that beginning July 1, 2021, the ASP-based payment for billing codes that currently include certain self-administered products identified in a July 2020 OIG report adhere (available at <https://oig.hhs.gov/oei/reports/OEI-BL-20-00100.asp>) to the “lesser of” methodology.

To meet the implementation date of July 1, 2021 required by section 405, CMS will apply the lesser-of methodology to the payment limit calculations for billing and payment codes representing certolizumab pegol and abatacept (J0717 and J0129, respectively). These changes will be incorporated into the July 2021

ASP Drug Pricing Files and a notation of the lesser-of methodology will be included in the July 2021 ASP NDC-HCPCS Crosswalk.

## II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
12244.1	The Virtual Data Center (VDC) shall have available via the CMS Virtual Data Center (CDC) the ASP drug pricing files for Medicare Part B drugs for the July 2021 file and, if released, the revised April 2021, January 2021, October 2020, and July 2020 files.										VDC
12244.1.1	The contractors shall download the July 2021 ASP drug pricing file through the CDC on or after June 16, 2021.	X	X	X	X						VDC
12244.1.1.1	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY21.JUL.E.V0616		X		X						
12244.1.1.2	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY21.JUL.E.V0616.FISS	X		X							
12244.1.1.3	The contractors shall retrieve the July 2021 ASP NOC pricing file from the CMS ASP webpage on or after June 16, 2021.	X	X	X	X						
12244.1.1.4	The contractors shall use the July 2021 ASP and NOC drug pricing files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2021 with dates of service July 1, 2021, through September 30, 2021.	X	X	X	X						
12244.1.1.5	The contractors shall use the July 2021 ASP drug pricing file to update the drug payment limits for claims for infusion drugs furnished through a covered item of Durable Medical Equipment (DME) processed or reprocessed on or after July 1, 2021, with dates of service on or after July 1, 2021.		X		X						
12244.1.2	If released by CMS, the contractors shall download the revised April 2021 ASP drug pricing file through the CDC on or after June 16, 2021.	X	X	X	X						VDC

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
12244.1.2 .1	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY21.APR.E.V0616		X		X						
12244.1.2 .2	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY21.APR.E.V0616.FISS	X		X							
12244.1.2 .3	If released by CMS, the contractors shall overlay or manually update the previous April 2021 file with the new April 2021 ASP drug pricing file.	X	X	X	X						
12244.1.2 .4	If released by CMS, the contractors shall use the revised April 2021 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2021 with dates of service April 1, 2021, through June 30, 2021.	X	X	X	X						
12244.1.2 .5	If released by CMS, the contractors shall retrieve the revised April 2021 ASP NOC pricing file from the CMS ASP webpage on or after June 16, 2021.	X	X	X	X						
12244.1.2 .6	If released by CMS, the contractors shall use the revised April 2021 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2021 with dates of service April 1, 2021, through June 30, 2021.	X	X	X	X						
12244.1.3	If released by CMS, the contractors shall download the revised January 2021 ASP drug pricing file through the CDC on or after June 16, 2021.	X	X	X	X						VDC
12244.1.3 .1	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY21.JAN.E.V0616		X		X						
12244.1.3 .2	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY21.JAN.E.V0616.FISS	X		X							
12244.1.3 .3	If released by CMS, the contractors shall overlay or manually update the previous January 2021 file with the new January 2021 ASP drug pricing file.	X	X	X	X						
12244.1.3 .4	If released by CMS, the contractors shall use the revised January 2021 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2021 with dates of	X	X	X	X						

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
	service January 1, 2021, through March 31, 2021.										
12244.1.3 .5	If released by CMS, the contractors shall retrieve the revised January 2021 ASP NOC pricing file from the CMS ASP webpage on or after June 16, 2021.	X	X	X	X						
12244.1.3 .6	If released by CMS, the contractors shall use the revised January 2021 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2021 with dates of service January 1, 2021, through March 31, 2021.	X	X	X	X						
12244.1.4	If released by CMS, the contractors shall download the revised October 2020 ASP drug pricing file through the CDC on or after June 16, 2021.	X	X	X	X						VDC
12244.1.4 .1	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY20.OCT.E.V0616		X		X						
12244.1.4 .2	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY20.OCT.E.V0616.FISS	X		X							
12244.1.4 .3	If released by CMS, the contractors shall overlay or manually update the previous October 2020 file with the new October 2020 ASP drug pricing file.	X	X	X	X						
12244.1.4 .4	If released by CMS, the contractors shall use the revised October 2020 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2021 with dates of service October 1, 2020, through December 31, 2020.	X	X	X	X						
12244.1.4 .5	If released by CMS, the contractors shall retrieve the revised October 2020 ASP NOC pricing file from the CMS ASP webpage on or after June 16, 2021.	X	X	X	X						
12244.1.4 .6	If released by CMS, the contractors shall use the revised October 2020 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2021 with dates of service October 1, 2020, through December 31, 2020.	X	X	X	X						
12244.1.5	If released by CMS, the contractors shall download the revised July 2020 ASP drug pricing file through	X	X	X	X						VDC

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
	the CDC on or after June 16, 2021.										
12244.1.5 .1	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY20.JUL.E.V0616		X		X						
12244.1.5 .2	The contractors shall retrieve Final File: MU00.@BF12390.ASP.R2.CY20.JUL.E.V0616.FISS	X		X							
12244.1.5 .3	If released by CMS, the contractors shall overlay or manually update the previous July 2020 file with the new July 2020 ASP drug pricing file.	X	X	X	X						
12244.1.5 .4	If released by CMS, the contractors shall use the revised July 2020 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2021 with dates of service July 1, 2020, through September 30, 2020.	X	X	X	X						
12244.1.5 .5	If released by CMS, the contractors shall retrieve the revised July 2020 ASP NOC pricing file from the CMS ASP webpage on or after June 16, 2021.	X	X	X	X						
12244.1.5 .6	If released by CMS, the contractors shall use the revised July 2020 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 1, 2021 with dates of service July 1, 2020, through September 30, 2020.	X	X	X	X						
12244.2	The contractors shall not search and adjust claims that have already been processed unless brought to their attention.	X	X	X	X						
12244.3	The contractors shall notify CMS of successful receipt via email to price_file_receipt@cms.hhs.gov stating the name of the file received, (e.g., Clinical Laboratory Fee Schedule (CLAB), ASP, etc.) and the entity for which it was received (i.e., include states, carrier numbers, quarter, and if Part A, Part B, or both).	X	X	X	X						
12244.4	The ASP and NOC drug pricing files will contain the applicable payment allowance limits (i.e., 106% ASP, 106% Wholesale Acquisition Cost (WAC), or 95% Average Wholesale Price (AWP)); therefore, Medicare contractors shall not make any additional	X	X	X	X						

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
	payment calculations.										
12244.5	For any drug or biological not listed in the ASP or NOC drug pricing files, the contractors shall determine the payment allowance limits in accordance with the policy described in the Medicare Claims Processing Manual, chapter 17, section 20.1.3.	X	X	X	X						
12244.5.1	For any drug or biological not listed in the ASP or NOC drug pricing files that is billed with the KD modifier, the contractors shall determine the payment allowance limits in accordance with instructions for pricing and payment changes for infusion drugs furnished through an item of durable medical equipment on or after January 1, 2017, associated with the passage of the 21st Century Cures Act.	X	X	X	X						
12244.6	The contractors shall use the most current version available of the Medicare Contractor Reporting Template for Part B drugs to report information on Medicare Part B drugs not paid on a cost or prospective payment basis when payment limits are not listed in the quarterly drug pricing ASP and NOC files, or in the OPPS Pricer.	X	X	X	X						
12244.6.1	The contractors shall use the template to report pricing information for: <ul style="list-style-type: none"> <li>NOC drugs not included on the Medicare Part B NOC pricing file</li> <li>any Healthcare Common Procedure Coding System (HCPCS) drug codes not on the ASP file, and</li> <li>OPPS drugs not in the OPPS Pricer.</li> </ul>	X	X	X	X						
12244.6.2	The contractors shall list all drugs that were priced since the last submitted report.	X	X	X	X						
12244.6.3	The contractors shall list each drug priced on the report only once.	X	X	X	X						
12244.6.4	For compounded drugs, the contractors shall report the name of each drug in the compounded product.	X	X	X	X						
12244.6.5	The contractors shall prepare and submit the reports so that each report covers approximately 30 days of	X	X		X						

Number	Requirement	Responsibility										
		A/B MAC			D M E M A C	Shared-System Maintainers				Other		
		A	B	H H H		F I S S	M C S	V M S	C W F			
	pricing activity.											
12244.6.6	The contractors shall report drugs omitted from previous reports in the next report.	X	X	X	X							
12244.6.7	The contractors shall complete the report in its entirety.	X	X	X	X							
12244.6.8	The contractors shall not report radiopharmaceuticals		X									
12244.6.9	A/B MAC Part A shall report pricing information for drugs, biologicals, and radiopharmaceuticals that are billed using C9399.	X		X								
12244.6.10	The contractors shall download the most current version available of the template from the CMS website at <a href="http://www.cms.gov/McrPartBDrugAvgSalesPrice/">http://www.cms.gov/McrPartBDrugAvgSalesPrice/</a> .	X	X	X	X							
12244.6.11	The contractors shall complete the template on a monthly basis.	X	X	X	X							
12244.6.12	The contractors shall ensure that the format of the template is Microsoft Excel.	X	X	X	X							
12244.6.13	The contractors shall send the completed template to <a href="mailto:sec303aspdata@cms.hhs.gov">sec303aspdata@cms.hhs.gov</a> on the first business day of the month.	X	X	X	X							
12244.6.14	If the contractor has not priced any drugs since the last submitted report, in lieu of using the template, the contractor shall send an email to <a href="mailto:Sec303aspdata@cms.hhs.gov">Sec303aspdata@cms.hhs.gov</a> stating that the contractor has no drug pricing to report.	X	X	X	X							

### III. PROVIDER EDUCATION TABLE



Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
12244.7	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	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

**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**