CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11572	**Date: August 25, 2022**
	Change Request 12854

SUBJECT: Exceptions to Average Sales Price (ASP) Payment Methodology – Claims Processing Manual Changes

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update language in the Claims Processing Manual (100-04) Chapter 17 Section 20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology and also to include updates to section 20.3. The updates pertain to Wholesale Acquisition Cost (WAC)-based contractor pricing, and payment for infusion drugs furnished through a covered item of durable medical equipment.

EFFECTIVE DATE: October 26, 2022
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 26, 2022

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	17/20.1.3/Exceptions to Average Sales Price (ASP) Payment Methodology
R	17/20.3/Calculation of the Payment Allowance Limit for DME MAC Drugs
R	17/80.3/Billing for Immunosuppressive Drugs

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:
Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 11572	Date: August 25, 2022	Change Request: 12854

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I. GENERAL INFORMATION

A. Background: Payment for most Part B drugs is based on the average sales price (ASP). In limited circumstances, other methodologies, such as Wholesale Acquisition Cost (WAC) and Average Wholesale Price (AWP) are used. This instruction updates language in the Claims Processing Manual (100-04) Chapter 17 Section 20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology, so that the manual aligns with recent changes to the add-on percentage for WAC-based payments for new drugs, as well as other recent legislation that changed the payment for infusion drugs furnished through a covered item of durable medical equipment from AWP to ASP (or another applicable methodology). The manual changes in this CR will primarily affect Part B and DME MACs. Part A MACs are included because they occasionally make payment determinations using the revised manual sections.

B. Policy: For claims with dates of service on or after January 1, 2019, the add-on percentage for WAC-based payments determined by MACs for new drugs before an ASP-based payment limit is available is up to 3 percent. This policy does not apply in OPPS where payment remains at 95 percent of the published AWP.

Payment for infusion drugs furnished through a covered item of durable medical equipment furnished on or after January 1, 2017 is based on ASP (or other applicable methodology in Sections 1847, 1847A, 1847B or 1881(b)(13) of the Social Security Act).

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	
12854.1	Contractors shall be aware of the changes to the internet-only manual.	X	X		X					
12854.2	Contractors shall implement the following change to their payment determinations for new drugs as described in Chapter 17 Section 20.1.3 of the Claims Processing Manual: for claims with dates of service before January 1, 2019, the add-on percentage for these WAC-based payments is 6 percent. For claims	X	X		X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	with dates of service on or after January 1, 2019, the add-on percentage for WAC-based payments determined by MACs for new drugs before an ASP-based payment limit is available is up to 3 percent.									
12854.3	Contractors are not required to search for claims submitted prior to the implementation date or to update payments made for such claims.	X	X		X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12854.4	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	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): Laura Kennedy, 410-786-1000 or Laura.Kennedy@cms.hhs.gov , Rachel Radzyner, 410-786-1000 or Rachel.Radzyner1@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

20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology

(Rev. 11572; Issued: 08-25-22; Effective: 10-26-22; Implementation: 10-26-22)

The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a reasonable charge or prospective payment basis, are determined in the same manner the payment allowance limits were determined on October 1, 2003. Specifically, the payment allowance limits for blood and blood products are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. The payment allowance limits will be updated on a quarterly basis. Blood and blood products furnished in the hospital outpatient department are paid under OPPS at the amount specified for the Ambulatory Payment Classification (APC) to which the product is assigned.

The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment *furnished on or after January 1, 2005, and before January 1, 2017, is* 95 percent of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded or the drug is furnished incident to a professional service. The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment *before January 1, 2017* that were not listed in the published compendia as of October 1, 2003, (i.e., new drugs) are 95 percent of the first published AWP unless the drug is compounded or the drug is furnished incident to a professional service. *Payment for infusion drugs furnished through a covered item of durable medical equipment furnished on or after January 1, 2017 is based on ASP (or other applicable methodology in Sections 1847, 1847A, 1847B or 1881(b)(13) of the Social Security Act).*

The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department. Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost. CMS will supply contractors with the payment allowance limits annually to be effective on August 1 of each year. Contractors will be notified of the availability of payment allowance limits via a Recurring Update Notification.

The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based *either* on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication. 100-04, Chapter 17, *Section 20.4* Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is 106 percent of the lesser of the lowest-priced brand or median generic WAC.

The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration, *that are first sold on or after January 1, 2005*, and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) *Pricing File, are based on either the WAC as determined in the preceding paragraph, or invoice pricing. For claims with dates of service before January 1, 2019, the add-on percentage for these WAC-based payments is 6 percent. For claims with dates of service on or after January 1, 2019, the add-on percentage for WAC-based payments determined by MACs for new drugs before an ASP-based payment limit is available is up to 3 percent. However, in OPPS,* the payment allowance limit *for new drugs and biologicals* is 95 percent of the published AWP.

The payment allowance limits for radiopharmaceuticals are not subject to ASP. A/B MACs (B) should determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. Refer to Chapter 17, §90.2 of the manual regarding radiopharmaceuticals furnished in the hospital outpatient department.

MACs shall develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing files (including the Not Otherwise Classified (NOC) Pricing file). At the contractor's discretion, a contractor should contact CMS to request payment limits for drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors shall substitute CMS-provided payment limits for pricing based on WAC, invoice or other applicable pricing methodology. CMS will provide the payment limits directly to the requesting contractor and/or via posting on the CMS Web site.

20.3 - Calculation of the Payment Allowance Limit for DME MAC Drugs

(Rev. 11572; Issued: 08-25-22; Effective: 10-26-22; Implementation: 10-26-22)

For infusion drugs furnished through a covered item of durable medical equipment furnished on or after January 1, 2017, this section is superseded by updates to section 20.1.3.

Payments for drugs billed to the DME MACs will be based on the implementation of the MPDIMA, beginning January 1, 2004, and will be paid at 85 percent of the AWP for HCPCS payment amounts based on the April 1, 2003 fee schedule. Exceptions to this calculation are as follows:
The payment limits for infusion drugs furnished through an item of durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP.

- The payment limits for new drugs or biologicals will be 95 percent of the AWP. A new drug is defined as an unlisted drug (not currently covered by a HCPCS code) that was FDA approved subsequent to April 1, 2003. A drug would not be considered new if: The brand or manufacturer of the drug changed; a new formulation of the vial size is developed; or the drug received a new indication.

The payment limits for certain drugs studied by the OIG and GAO are based on the percentages of the April 1, 2003 AWPs specified on Table 1 in §20.

Payment limits determined under this instruction shall not be updated during 2004.

80.3 - Billing for Immunosuppressive Drugs

(Rev. 11572; Issued: 08-25-22; Effective: 10-26-22; Implementation: 10-26-22)

Medicare covers a beneficiary's immunosuppressive drugs following a transplant, in accordance with 1861(s)(2)(J) of the Social Security Act, which states that Medicare covers "prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under this title."

Medicare pays for FDA approved immunosuppressive drugs and for drugs used in immunosuppressive therapy with specific restrictions. (See 42 CFR *410.30* and the Medicare Benefit Policy Manual, Chapter 15 for detailed coverage requirements.) Generally, contractors pay for self-administered immunosuppressive drugs that are specifically labeled and approved for marketing as such by the FDA, or identified in FDA-approved labeling for use in conjunction with immunosuppressive drug therapy. This benefit is subject to the Part B deductible and coinsurance provision.

Contractors are expected to keep informed of FDA additions to the list of the immunosuppressive drugs and notify providers. Prescriptions for immunosuppressive drugs generally should be non-refillable and limited to a 30-day supply. The 30-day guideline is necessary because dosage frequently diminishes over a period of time, and further, it is not uncommon for the physician to change the prescription from one drug to another. Also, these drugs are expensive and the coinsurance liability on unused drugs could be a financial burden to the beneficiary. Unless there are special circumstances, contractors will not consider a supply of drugs in excess of 30 days to be reasonable and necessary and should deny payment accordingly. Entities that normally bill the A/B MAC (B) bill the DME MAC.

Entities that normally bill the A/B MAC (A) continue to bill the A/B MAC (A), except for hospitals subject to OPPS, which must bill the DME MAC.

Prior to December 21, 2000 coverage was limited to immunosuppressive drugs received within 36 months of a transplant. In practice, ESRD beneficiaries continue to be limited to 36 months of coverage after a Medicare covered kidney transplant because their Medicare entitlement would end 36 months after a successful organ transplant. See 42 CFR 406.13(f)(2). Effective with immunosuppressive drugs furnished on or after December 21, 2000, there is no time limit, but an organ transplant must have occurred for which immunosuppressive therapy is appropriate. That is, the time limit for immunosuppressive drugs was eliminated for transplant beneficiaries that will continue Medicare coverage after 36 months based on disability or age. The date of transplant is reported to the A/B MAC (A) with occurrence code 36.

CWF will edit claim records to determine if a history of a transplant is on record. If not an error will be returned. See Chapter 27 for edit codes and resolution.

As explained below, there are circumstances in which Medicare cannot locate the Medicare claim for the transplant in the claims databases which would have confirmed that Medicare paid for the transplant. In such cases, where the supplier appropriately submits the KX modifier, Medicare makes the assumption that Medicare paid for the transplant, in accordance with the statute, that the supplier has on file documentation that indicates the date of the transplant, and that the services furnished are medically necessary.

The use of the KX modifier is not required. In the case of immunosuppressive drugs, submission of the KX modifier is intended for adjudicating claims when the supplier attests that it maintains documentation that the beneficiary was eligible for Medicare Part A on the date of his/her transplant, but where Medicare cannot identify a claims record indicating the transplant was paid for by fee-for-service Medicare. The additional information provided by the use of the KX modifier permits Medicare to reasonably assume that a Medicare payment for an organ transplant was made.

For claims received on and after July 1, 2008, DME MACs will accept claims for immunosuppressive drugs without a KX modifier but will deny such claims if CMS cannot identify a record of a claim indicating that the transplant was paid for by fee-for-service Medicare.

For claims filed with the KX modifier on and after July 1, 2008, suppliers that furnish an immunosuppressive drug to a Medicare beneficiary, when such drug has been prescribed due to the beneficiary having undergone an organ transplant, must: 1) secure from the prescriber the date of such organ transplant and retain documentation of such transplant date in its files, 2) attest that it has on file documentation that the beneficiary was eligible to receive Medicare Part A benefits at the particular date of the transplant and retain the documentation in its files, and 3) retain such documentation of the beneficiary's transplant date, Medicare Part A eligibility, and that such transplant date precedes the Date of Service (DOS) for furnishing the drug.

Use of the KX modifier permits Medicare to make a reasonable assumption that Medicare paid for the transplant even when the transplant claim does not appear in the claims database. A claim may not appear in the claims database for reasons such as:

1. At the time of the transplant, the beneficiary was enrolled in a Medicare Advantage plan that paid for the transplant. Medicare Advantage data is not included in the Medicare FFS claims database. Although some encounter data may be available, it may be incomplete or may not contain coding information sufficient to identify a transplant claim.
2. There may be instances where claims related to a transplant are old and may not be identifiable in the claims database despite Medicare's payment for the claim.