CMS Manual System	Department of Health & Human Services (DHHS)				
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)				
Transmittal 13108	Date: April 11, 2025				
	Change Request 13943				

SUBJECT: Manual Updates to Chapter 17 of the Medicare Claims Processing Manual and Chapter 15 of the Medicare Benefit Policy Manual to Reflect Policies Finalized in the Calendar Year (CY) 2025 Physician Fee Schedule Final Rule

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Chapter 17 of the Medicare Claims Processing Manual (100-04) to reflect policies finalized in the CY 2025 Physician Fee Schedule final rule:

- In Chapter 17 of the Medicare Claims Processing Manual:
 - In section 20.1.3 of the Medicare Claims Processing Manual, we are clarifying policy related to payment limits for pneumococcal, hepatitis B and COVID-19 vaccines.
 - In section 40, we are clarifying JW/JZ Modifier Policy requirements with regard to a billing supplier who does not administer the drug to conform with changes finalized in the CY 2025 PFS final rule.
 - In section 80, we are including reference to COVID-19 vaccines.
 - In section 80.3, we are revising payment policy regarding fills and refills for immunosuppressive drugs to conform to regulatory changes in Subsection (§) 414.1001.
 - In section 80.4.1, we are revising policy to conform with regulatory changes to the conditions in which a clotting factor furnishing fee may be paid in § 410.63.
 - In section 80.7, we are making typographical corrections.

EFFECTIVE DATE: For change in Chapter 17, section 80.7 of the Medicare Claims Processing Manual, no changes to implementation or effective date; January 1, 2025 *Unless otherwise specified, the effective date is the date of service. IMPLEMENTATION DATE: May 12, 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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE			
R	17/20.1.3/Exceptions to Average Sales Price (ASP) Payment Methodology			
R	17/40/Discarded Drugs and Biologicals			
R	17/80/Claims Processing for Special Drug Categories			
R	17/80.3/Billing for Immunosuppressive Drugs			
R	17/80.4.1/Clotting Factor Furnishing Fee			
R	17/80.7/Pharmacy Supplying Fee and Inhalation Drug Dispensing Fee			

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: 13108 Date: April 11, 2025 Change
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SUBJECT: Manual Updates to Chapter 17 of the Medicare Claims Processing Manual and Chapter 15 of the Medicare Benefit Policy Manual to Reflect Policies Finalized in the Calendar Year (CY) 2025 Physician Fee Schedule Final Rule

EFFECTIVE DATE: For change in Chapter 17, section 80.7 of the Medicare Claims Processing Manual, no changes to implementation or effective date; January 1, 2025

*Unless otherwise specified, the effective date is the date of service. IMPLEMENTATION DATE: May 12, 2025

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Chapter 17 of the Medicare Claims Processing Manual (100-04) and Chapter 15 of the Medicare Benefit Policy Manual (100-02) to reflect policies finalized in the CY 2025 Physician Fee Schedule final rule:

- In Chapter 17 of the Medicare Claims Processing Manual:
 - In section 20.1.3 of the Medicare Claims Processing Manual, we are clarifying policy related to payment limits for pneumococcal, hepatitis B and COVID-19 vaccines.
 - In section 40, we are clarifying JW/JZ Modifier Policy requirements with regard to a billing supplier who does not administer the drug to conform with changes finalized in the CY 2025 PFS final rule.
 - \circ In section 80, we are including reference to COVID-19 vaccines.
 - In section 80.3, we are revising payment policy regarding fills and refills for immunosuppressive drugs to conform to regulatory changes in Subsection (§) 414.1001.
 - In section 80.4.1, we are revising policy to conform with regulatory changes to the conditions in which a clotting factor furnishing fee may be paid in § 410.63.
 - In section 80.7, we are making typographical corrections.
- In Chapter 15 of the Medicare Benefit Policy Manual:
 - In section 50.4.4.2, we are clarifying policies with regard to administration of the COVID-19 vaccine and adding new paragraph E. for an additional payment for in-home administration of Part B preventive vaccines.
 - In section 50.5.1, we are clarifying coverage policy for immunosuppressive drugs to conform with regulatory changes in §§ 410.30 and 414.1001.
 - In section 50.5.5, we are revising the text to conform with regulatory changes to the conditions in which a clotting factor furnishing fee may be paid in § 410.63.

II. GENERAL INFORMATION

A. Background: The purpose of this CR is to make revisions to Chapter 17 of the Medicare Claims Processing Manual (Publication 100-04) to reflect policies finalized in the CY 2024 Physician Fee Schedule final rule.

B. Policy: No new policy. The CR updates the manual to more accurately reflect current policy.

III. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC		DME	Shared-System Maintainers			Other		
		Α	В	HHH		FISS	MCS	VMS	CWF	
					MAC					
13943 - 04.1	Contractors shall be aware of the manual updates in Pub. 100-04, Chapter 17, sections 20.1.3, 40, 80, 80.3, 80.4.1, and 80.7.	X	Х		X					

IV. PROVIDER EDUCATION

None

Impacted Contractors: None

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

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):

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

Medicare Claims Processing Manual Chapter 17 - Drugs and Biologicals

Table of Contents (*Rev*.13108; *Issued*: 04-11-25)

Transmittals for Chapter 17

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

(Rev. 13108; Issued: 04-11-25; Effective: 01-01-25; Implementation: 05-12-25)

The payment 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 limits were determined on October 1, 2003. Specifically, the payment limits for blood and blood products are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. The payment 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 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 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 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 limits for influenza, *pneumococcal, hepatitis B and COVID-19 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 A/B MACs with the payment limits *for influenza vaccines* annually to be effective on August 1 of each year. A/B MACs will be notified of the availability of payment limits via a Recurring Update Notification. *Payment limits for pneumococcal and hepatitis B vaccines are updated quarterly and are available on the ASP Drug Pricing File. Payment limits for the COVID-19 vaccines are available on the ASP Drug Pricing File and A/B MACs will be notified of the payment limits. Payment rates for qualifying OPPS products can be found on the OPPS Addendum A and Addendum B.*

The payment limits for drugs and biologicals that are not included in the ASP 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 limit is 95 percent of the published AWP *if the drug or biological is not included in OPPS Addendum B*. In determining the payment limit based on WAC, the A/B MACs 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 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 (1) the WAC as determined in the preceding paragraph, or (2) 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 limit for new drugs and biologicals *that are not included in OPPS Addendum B* is 95 percent of the published AWP. For claims for biosimilars with dates of service on or after July 1, 2024, the payment limit for the biosimilar is the lesser of (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003, or (2) 106 percent of the lesser of the WAC or

ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological.

The payment limits for radiopharmaceuticals are not subject to ASP. A/B MACs (B) should determine payment limits for radiopharmaceuticals based on *any* methodology in place *on or prior to* November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. *Such methodology may include, but is not limited to, the use of invoice-based pricing.* Refer to Chapter 17, §90.2 of the manual regarding radiopharmaceuticals furnished in the hospital outpatient department.

MACs shall develop payment limits for drugs *separately payable under Part B* when CMS does not supply the payment limit on the ASP drug pricing files (including the Not Otherwise Classified (NOC) Pricing file). At the A/B or DME MAC's discretion, a MAC 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, MACs 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 MAC and/or via posting on the CMS Web site.

40 - Discarded Drugs and Biologicals

(Rev. 13108; Issued: 04-11-25; Effective: 01-01-25; Implementation: 05-12-25)

The CMS encourages physicians, hospitals and other providers and suppliers to care for and administer drugs and biologicals to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner.

When a billing provider or supplier must discard the remainder of a single-dose container or single-use package after administering a dose to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.

Effective January 1, 2017, when processing claims for drugs and biologicals A/B MACs shall require the use of the JW modifier to identify unused and discarded amounts (hereafter, discarded amounts) of drugs or biologicals from single-dose containers or single-use packages.

The discarded amount is any amount that is not part of the prescribed dose and not intended to have a therapeutic effect in the patient. Even if certain amounts are extracted from the vial or are required to be in the vial to administer the prescribed dose, we do not consider them to be used if they are not intended for therapeutic effect as part of the prescribed dose. Generally, the discarded amount is the labeled amount on the single-dose container (or containers if more than one is required) minus the dose (the dose being the prescribed amount of drug administered to the patient).

The JW modifier, billed on a separate line, provides payment for the amount of discarded drug or biological. For the administered amount, one claim line shall include the billing and payment code (such as a HCPCS code) describing the given drug, no modifier, and the number of units administered in the unit field. For the discarded amount, a second claim line shall include the same billing and payment code as used for the administered amount, the JW modifier, and the number of units discarded in the unit's field.

For example, if a provider or supplier uses a single-dose container that is labeled to contain 100 units of a drug to administer 95 units to the patient and 5 units are discarded. The 95-unit dose is billed on one line, while the discarded 5 units shall be billed on another line with the JW modifier. Both line items would be processed for payment. Providers must record the discarded amounts of drugs and biologicals in the patient's medical record.

Effective July 1, 2023, A/B MACs and DME MACs shall require the use of the JZ modifier to attest that there are no amounts of drugs or biologicals from single-dose containers or single-use packages were unused and discarded for which the JW modifier would be required if there were discarded amounts. For the administered amount, the claim line should include the billing and payment code (such as HCPCS code) describing the given drug, the JZ modifier (attesting that there were no discarded amounts), and the number of units administered in the unit's field.

The JW modifier is only applied to the amount of drug or biological that is discarded. A situation in which the JW modifier is not permitted is when the actual dose of the drug or biological administered is less than the billing unit. For example, one billing unit for a drug is equal to 10mg of the drug in a single use vial. A 7mg dose is administered to a patient while 3mg of the remaining drug is discarded. The 7mg dose is billed using one billing unit that represents 10mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3mg of drug is not permitted because it would result in overpayment. Therefore, when the billing unit is equal to or greater than the total actual dose and the amount discarded, the use of the JW modifier is not permitted. For dates of service beginning July 1, 2023, the JZ modifier shall be used in this circumstance. The JZ modifier policy does not require that the claim line with the JZ modifier account for only whole vials of the drug and the JW modifier policy does not require that the two claim lines account for only whole vials of the drug.

In general, the JW and JZ modifier policy applies to all drugs separately payable under Medicare Part B that are described as being supplied in a "single-dose" container or "single-use" package based on FDA-approved labeling, including all claims of non-refundable, single-dose container drugs such as multiple source drugs and contrast agents. However, the use of these modifiers is not appropriate for drugs that are from multiple-dose containers. The JW and JZ modifier policy does not apply for drugs that are not separately payable, such as packaged OPPS or ASC drugs, or drugs administered in the FQHC or RHC setting. *The list of billing and payment codes that may require the JW and JZ modifiers is available at:* <u>https://www.cms.gov/files/document/jw-modifier-and-jz-modifier-policy-hcpcs-codes.pdf</u>.

For dates of service in calendar year 2024, a billing supplier who does not administer the drug must bill separately payable drugs under Part B from single-dose containers with the JZ modifier. Beginning January 1, 2025, the JW modifier is required if a billing supplier is not administering a drug, but there are amounts discarded during the preparation process before supplying the drug to the patient. Such a supplier would report the JZ modifier if no amounts were discarded during the preparation process before supplying the preparation process before supplying the drug to the patient.

The JW and JZ modifiers are not required for vaccines described under section 1861(s)(10) of the Act that are furnished from single-dose containers. Since the influenza, pneumococcal, and COVID–19 vaccines specified in section 1861(s)(10) of the Act are often roster billed by mass immunizers, and roster billing cannot accommodate modifiers, it would be impractical to require the JW and JZ modifiers for such vaccines. Such a requirement would likely result in substantial operational issues for mass immunizers and impair patient access to these vaccines.

The JW Modifier and JZ Modifier Policy Frequently Asked Questions (FAQ) document addressing the correct use of these modifiers is available at: <u>https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf</u>.

The JW modifier is not used on claims for CAP drugs. For CAP drugs, see subsection 100.2.9 - Submission of Claims With the Modifier JW, "Drug or Biological Amount Discarded/Not Administered to Any Patient", for additional discussion of the discarded remainder of a vial or other packaged drug or biological in the CAP. Note that the CAP is postponed effective January 1, 2009.

80 - Claims Processing for Special Drug Categories

(Rev. 13108; Issued: 04-11-25; Effective: 01-01-25; Implementation: 05-12-25)

NOTE: Preventive vaccines, *including* influenza, pneumococcal, hepatitis B *and COVID-19 vaccines*, are covered in Chapter 18 of this manual.

NOTE: The definition of Off-Label and its uses are described in the Medicare Benefit Policy Manual, Chapter 15.

80.3 - Billing for Immunosuppressive Drugs

(Rev. 13108; Issued: 04-11-25; Effective: 01-01-25; Implementation: 05-12-25)

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 immunosuppressive drugs *irrespective of whether they can be self-administered* 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 *limited to a supply of up to 90 days. Medicare will allow payment for refills of prescriptions for immunosuppressive drugs.*

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 who will continue Medicare coverage after 36 months based on disability or age. In 2020, section 402 of the Consolidated Appropriations Act (CAA) amended sections 226(a), 1836, 1837, 1838, 1839, 1844, 1860-D-1, 1902, and 1905 of the Act to make an exception for eligibility for enrollment under Medicare Part B solely for the purposes of coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. Effective January 1, 2023, this provision allows individuals whose Medicare entitlement based on ESRD ends 36 months after the month in which they received a successful kidney transplant to continue enrollment under Medicare Part B only for the coverage of immunosuppressive drugs described in section 1861(s)(2)(J) Act without a time limit. This benefit is referred to as the Part B immunosuppressive drug benefit or "Part B-ID" or "PBID". For additional information on PBID eligibility please see section 40.9.1 of IOM publication 100-01, chapter 2.

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.
 - a. Medicare's payment for the claim.

80.4.1 - Clotting Factor Furnishing Fee

(Rev. 13108; Issued: 04-11-25; Effective: 01-01-25; Implementation: 05-12-25)

The Medicare Modernization Act section 303(e)(1) added section 1842(o)(5)(C) of the Social Security Act which requires that, beginning January 1, 2005, a furnishing fee will be paid for items and services associated with clotting factor.

Beginning January 1, 2005, a clotting factor furnishing fee is separately payable to entities that furnish clotting factor unless the costs associated with furnishing the clotting factor is paid through another payment system. Blood clotting factors for which the furnishing fee is paid must be self-administered. Therapies that enable the body to produce clotting factors and do not directly integrate into coagulation cascade are not clotting factors for which the furnishing fee applies.

The clotting factor furnishing fee is updated each calendar year based on the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending with June of the previous year.

The clotting factor furnishing fees applicable for dates of service in each calendar year (CY) are listed below:

CY 2005 - \$0.140 per unit CY 2006 - \$0.146 per unit CY 2007 - \$0.152 per unit CY 2008 - \$0.158 per unit CY 2009 - \$0.164 per unit CY 2010 - \$0.170 per unit CY 2011 - \$0.176 per unit CY 2012 - \$0.181 per unit CY 2013 - \$0.188 per unit CY 2014 - \$0.192 per unit CY 2015 - \$0.197 per unit CY 2016 - \$0.202 per unit CY 2017 - \$0.209 per unit CY 2018 - \$0.215 per unit CY 2019 - \$0.220 per unit CY 2020 - \$0.226 per unit CY 2021 - \$0.238 per unit CY 2022 - \$0.239 per unit CY 2023 - \$0.250 per unit CY 2024 - \$0.250 per unit *CY 2025 - \$0.258 per unit*

Annual updates to the clotting factor furnishing fee are subsequently communicated by a Recurring Update Notification.

CMS includes this clotting factor furnishing fee in the nationally published payment limit for clotting factor billing codes. When the clotting factor is not included on the Average Sales Price (ASP) Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, the contractor must make payment for the clotting factor as well as make payment for the furnishing fee.

80.7 - Pharmacy Supplying Fee and Inhalation Drug Dispensing Fee

(Rev. 13108; Issued: 04-11-25; Effective: 01-01-25; Implementation: 05-12-25)

Section 303(e)(2) of the MMA *establishes* a supplying fee for immunosuppressive drugs, oral anti-cancer chemotherapeutic drugs, and oral anti-emetic drugs used as part of an anti-cancer chemotherapeutic regimen. Effective January 1, 2005, Medicare *pays* a separately billable supplying fee of \$24 to a pharmacy, dialysis facility in the State of Washington or any hospital outpatient department not subject to the OPPS for each supplied prescription of the above-mentioned drugs. Medicare also *pays* a separately billable supplying fee of \$50 for the initial supplied prescription of the immunosuppressive drugs during the first month following the patient's transplant.

Effective January 1, 2006, Medicare *pays* \$24 for the first prescription of the above-mentioned drugs supplied by a pharmacy in a 30-day period and *pays* \$16 for each subsequent prescription, after the first one, supplied in that 30-day period. A pharmacy will be limited to one \$24 fee per 30-day period even if the pharmacy supplies more than one category of the abovementioned drugs (for example, an oral-anticancer drug and an oral anti-emetic drug) to a beneficiary. If two different pharmacies supply the above-mentioned drugs to a beneficiary during a 30-day period, each pharmacy will be eligible for one \$24 supplying fee for the first prescription supplied during that 30-day period, and a supplying fee of \$16 for each subsequent prescription supplied in that 30-day period. For a refill prescription, Medicare will allow payment of a \$24 supplying fee to a particular supplier up to seven days before the end of the 30-day period for which the last \$24 supplying fee was paid to that supplier; however, each supplier will be limited to twelve \$24 supplying fees per beneficiary per year. Medicare will pay a supplying fee for each prescription, including

prescriptions for different strengths of the same drug supplied on the same day (for example, a prescription for 100 mg tablets and 5 mg Tablets). These changes do not alter the one-time \$50 supplying fee *paid by Medicare* for the first immunosuppressive prescription after a transplant.

Effective January 1, 2006, Medicare pays an initial dispensing fee of \$57 to a pharmacy for the initial 30day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This initial 30-day dispensing fee is a one-time fee applicable only to beneficiaries who are using inhalation drugs for the first time as a Medicare beneficiary. Except in those circumstances where an initial 30-day dispensing fee is applicable, Medicare *pays* a dispensing fee of \$33 to a pharmacy/supplier for each 30-day supply of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during the 30 day period. Medicare *pays* a dispensing fee of \$66 to a pharmacy/supplier for each 90-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during the 90 days. Only one 30-day dispensing fee will be payable per 30-day period, and only one 90-day dispensing fee will be payable per 90-day period, regardless of the numbers of suppliers used during the respective periods. A 30-day and 90-day supplying fee cannot be paid for drug supplied for the same month. For a refill prescription, Medicare will allow payment of the dispensing fee no sooner than 7 days before the end of usage for the current 30-day or 90-day period for which a dispensing fee was previously paid. Each inhalation drug supplier will be allowed no more than 12 months of dispensing fees per beneficiary per year. Medicare will not pay separately for compounding drugs. This cost is in the dispensing fees.

Supply fees and dispensing fees must be billed on the same claim as the drug.

HCPCS Codes and Fees:

<u>GO369, G0370, G0371, G0374 -</u> not recognized by Medicare as of 1/1/06.

Q0510 - First immunosuppressive prescription after a transplant, \$50.00 fee

<u>Q0511 - Pharmacy supplying fee for immunosuppressive, oral-anti-cancer, and oral anti-emetic drugs, first</u> prescription in a one month period. Each pharmacy may receive this fee once in a 30-day period. Fee is \$24.00.

<u>Q0512 - Pharmacy supplying fee for immunosuppressive, oral anti-cancer, and oral anti-emetic drugs - each subsequent prescription in a 30-day period</u>. Fee is \$16.00.

Q0513 - Pharmacy dispensing fee for inhalation drug(s); per 30-days.

Effective 1/1/06, Medicare will pay a dispensing fee of \$33 to a pharmacy for a 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that period. Payment will be made on the first claim received.

Q0514 - Pharmacy dispensing fee for inhalation drugs(s); per 90-days.

Effective 1/1/06, Medicare will pay a dispensing fee of \$66 to a pharmacy for a 90-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that period. Payment will be made on the first claim received.

<u>G0333- Pharmacy dispensing fee for initial inhalation drug(s); initial 30 day supply to a beneficiary.</u>

Effective January 1, 2006, Medicare will pay an initial dispensing fee of \$57 to a pharmacy for the initial 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs

dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This initial 30-day dispensing fee is a one-time fee applicable only to beneficiaries who are using inhalation drugs for the first time as a Medicare beneficiary.

Based on the code descriptions above, a supplying fee and a dispensing fee is not appropriate for one drug. The supplying fee is for immunosuppressives, oral anti-cancer drugs and oral anti-emetic drugs. The dispensing fee is for inhalation drugs only. A supplier cannot be paid for more than one of the following -- an initial dispensing fee (G0333), a 30-day dispensing fee (Q0513), or a 90-day dispensing fee (Q0514) - for a beneficiary for the same period.